National HIV Behavioral Surveillance among Transgender Women

Model Surveillance Protocol

Behavioral Surveillance Team
NCHHSTP/DHAP-SE/BCSB

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1 Introduction

1.1 Purpose of National HIV Behavioral Surveillance (NHBS)

Based on a June 1999 review of national HIV prevention programs, CDC's Advisory Committee for HIV and STD Prevention and other external experts called for the development of a national plan for HIV/AIDS prevention. In 2000, CDC, in collaboration with representatives from state and local health departments, academic institutions, and clinical and prevention organizations, initiated a strategic planning process that culminated in the development of CDC's *HIV Prevention Strategic Plan Through 2005*[1]. As part of this plan, four national goals were identified to reduce the annual number of new HIV infections in the United States by half. One of these goals, which remains a national priority[2,3], was to strengthen the national capacity to monitor the HIV epidemic to better direct and evaluate prevention efforts . In 2002, as an initial step toward meeting this goal, CDC awarded supplemental funds to state and local health departments to develop and implement National HIV Behavioral Surveillance (NHBS)[4,5].

NHBS was developed to help state and local health departments establish and maintain a surveillance system to monitor selected behaviors and prevention services among groups at highest risk for HIV infection. Findings from NHBS are used to enhance the understanding of HIV risk and testing behaviors in these groups, and to develop and evaluate HIV prevention programs that provide services to them. Within each participating Metropolitan Statistical Area (MSA), data are collected within the major city or HIV epicenter. Depending on the cycle and sampling method, other areas within the MSA may also be targeted for data collection.

NHBS activities are implemented in rounds composed of three cycles. The first cycle of each round focuses on men who have sex with men (MSM), the second cycle focuses on persons who report injection drug use (IDU), and the third, on heterosexuals at increased risk of HIV infection (HET). These cycles are repeated in rounds so that data are collected from each risk group every three years. Cycles are referred to by the group of interest (NHBS-MSM, NHBS-IDU, and NHBS-HET), and the round of data collection is indicated by a number following the group of interest (e.g., NHBS-MSM1, NHBS-MSM2, etc).

This protocol covers NHBS activities among transgender women, otherwise known as NHBS-Trans. Transgender women (referred to throughout this protocol as trans women) were included as an optional population for data collection in the NHBS funding opportunity announcement 16-1601; NHBS project areas submitted applications to collect additional data among trans women. While individuals have their own conception and understanding of gender, for the purposes of these activities, trans women are defined as individuals who were assigned a male sex at birth and who now consider themselves women, female, or trans women.

1.2 Timeline and Scope of Protocol

To date, NHBS has completed four rounds of data collection for core NHBS populations, and the fifth round began in January 2017 with the NHBS-MSM5 cycle. NHBS-Trans will begin in 2018. The activities described in this protocol are for the NHBS-Trans cycle.

1.3 Collaborating Agencies

NHBS-Trans activities were included as part of the existing NHBS cooperative agreement (RFA-PS16-1601). Funding for NHBS-Trans was provided to CDC through the Secretary Minority Initiative Fund (SMAIF). Of the 22 funded NHBS health departments, 13 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. Funding is recommended for the top 7 scoring applicants (i.e. the grantees) to conduct NHBS-Trans in the following cities:

- Atlanta, GA (grantee: Georgia Department of Public Health)
- Los Angeles, CA (grantee: Los Angeles County Department of Health)
- San Francisco, CA (grantee: San Francisco Department of Public Health)
- New Orleans, LA (grantee: Louisiana Office of Public Health)
- New York City, NY (grantee: New York City Department of Health and Mental Hygiene)
- Seattle, WA (grantee: Washington State Department of Health)
- Philadelphia, PA (grantee: Philadelphia Department of Public Health)

Together, these 7 cities accounted for over 24% of all persons living with HIV at year end 2012 in the U.S.[6]

1.4 Responsibilities

CDC investigators are principally responsible for developing the protocol and supporting appendices, and for providing technical assistance to the project sites. NHBS project site investigators are to 1) contribute to protocol development, 2) successfully implement the project using the methods described, and 3) ensure submission of data to CDC in a timely manner.

1.5 Justification for NHBS-Trans

The ongoing and systematic collection and analysis of data is needed to identify baseline risk behaviors and prevention service utilization, as well as to measure progress toward meeting prevention goals. NHBS-Trans will provide data on the sexual and drug-use behaviors that place trans women at risk for HIV infection, as well as provide data on their use of HIV prevention

services. These data will also provide valuable information for monitoring and evaluating national HIV prevention goals[2,3] and for guiding national and local HIV prevention efforts. Furthermore, NHBS-Trans data may be used by public health officials and researchers to identify HIV prevention needs, allocate prevention resources, and develop and improve prevention programs directed to the populations of interest and their communities.

Although HIV behavioral surveillance data cannot be used to evaluate the efficacy of specific interventions, they are important for monitoring whether HIV prevention efforts are reaching at-risk populations within a community and whether these efforts meet national and local prevention goals. At the individual level, NHBS-Trans participants may benefit directly from HIV prevention counseling, knowledge of their HIV status, and referrals for additional HIV risk information and care. Participants who have preliminary HIV positive or confirmed HIV positive test results will be counseled and referred for treatment and case management services.

Trans women are at high risk for HIV infection. HIV prevalence estimates in this population have varied, ranging from 3% to 60% for self-reported HIV infection; 16% to 68% for laboratory-confirmed HIV infection.[7] Compared with white trans women, HIV prevalence estimates are higher among African American or black (hereafter referred to as black) trans women.[7] Factors contributing to HIV infection among trans women include condomless sex, survival sex, injection drug use, hormone and silicone injection, unstable housing, and depression and anxiety.[7-9] In addition, trans women often face barriers to healthcare, including lack of health insurance and lack of culturally competent healthcare providers, that can increase risk for HIV and hinder HIV treatment.[10]

1.6 NHBS Objectives

NHBS contributes to the nation's program of HIV surveillance by being the only multi-site population-based system that provides estimates on key HIV prevention measures among high-risk HIV-negative individuals, HIV-positive individuals unaware of their infection, and HIV-positive individuals aware of their infection who are in and out of care. Accurate and precise data on the behaviors in these populations are critical for tracking the epidemic, planning effective responses, and monitoring and evaluating those responses.

The objectives of NHBS-Trans are designed to monitor behaviors that place trans women at risk for HIV infection. The objectives are as follows:

Seroprevalence

- Assess the prevalence of HIV infection.
- Assess the prevalence of STI infection (where appropriate, if funding is available)

Risk Behaviors

- Assess the prevalence of risk behaviors and social determinants that increase the risk of HIV acquisition and transmission, including:
  - sexual risk behaviors

– drug-use risk behaviors

HIV Testing and Treatment

- Describe utilization of HIV testing, linkage to care, and antiretroviral therapy

Prevention

- Assess exposure to and use of prevention services.
- Identify gaps in prevention services and missed opportunities for prevention interventions.

1.7 General Approach for NHBS Implementation

NHBS cycles are cross-sectional surveys of persons at increased risk of HIV infection. The survey method used to recruit participants is Respondent Driven Sampling (RDS). RDS has been found effective for recruiting populations that are "hidden". We refer to hidden populations as those for which no sampling frame exists or whose members engage in stigmatized or illegal activities, making them reticent to divulge information that may compromise their privacy. Trans women are an example of a hidden population.

Participants receive tokens of appreciation for participating in NHBS activities. The token of appreciation amounts are determined locally by the NHBS project sites, and are based on previous experience with NHBS cycles or other similar studies. The token of appreciation is for the time required to complete the survey and for providing specimens for HIV testing. The average amount of these tokens of appreciation is $25 for the survey and $25 for HIV testing.

RDS, a chain-referral sampling strategy similar to snowball sampling[11], is used to recruit trans women that are connected by strong social networks and ties. RDS methods have been widely employed by public health officials and researchers to sample persons at increased risk for HIV for purposes of developing and evaluating HIV/AIDS interventions and for conducting behavioral surveillance.[12] RDS was used to recruit minority trans women in a 2009 CDC pilot, and was an effective sampling strategy.[13] RDS implementation begins with a limited number of initial recruits, or "seeds." Seeds can be identified by persons who work with the target populations or through outreach. People who work with these target populations may be able to appropriately identify dynamic individuals and refer them to the NHBS project staff. If outreach is used to identify seeds, the NHBS project staff should have an informal conversation to determine if the person meets the characteristics of a good seed. Seeds complete the surveillance activities, which include the eligibility screener, the survey, and an optional HIV test, and then are asked to recruit a specified number (up to 5) of people they know. These persons, in turn, complete the surveillance activities and are asked to recruit others. This recruitment process continues until the sample size has been reached. Participants receive tokens of appreciation for recruiting others; the average amount of recruiter tokens of appreciation, based on comparable amounts used in similar studies in these cities, is $10 per eligible participant who completes an interview.

By 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, study investigators assemble a final sample that resembles the underlying eligible population living in the project area and is unbiased by the characteristics of the seeds.[11,14]

1.8 Sample Size

Because NHBS is largely descriptive, power calculations, which are done for studies that are primarily designed to test specific hypotheses, were not performed. However, the sample size of 200 eligible respondents per each project site was determined by considering the presumed number of trans women in each city and desired standard error for key indicators of interest (see Chapter 7, section 1), as well as the efficiency of the sampling method used, termed the *design effect*. This approach has been presented by Salganik[15] to calculate sample sizes for RDS. The sample size calculation recommended for estimating the prevalence of a trait with a given precision is:

$$n = deff \cdot \frac{P_A(1-P_A)}{(se(P_A))^2}$$

where *deff* is the design effect and P_A is the prevalence of the trait. Analyses of NHBS-IDU data suggest that a design effect approaching 4 is appropriate for RDS studies[16]. If we assume a maximally-conservative estimated prevalence for any indicator – 0.5 – and a design effect of 4, then a sample size of 200 is adequate to detect such indicators with adequate precision (no greater than 0.1).

The target sample size for each project site, exclusive of "seeds," is 200 completed interviews with participants who meet NHBS-Trans definition inclusion criteria (see Chapter 4, section 2). Across the 7 participating project sites, this would result in a combined sample size of 1,400 trans women.

1.9 Purpose and Use of the NHBS-Trans Protocol

This protocol describes the methods that must be followed to conduct the NHBS project in a standardized manner. It also provides historical information about project development and design. A standardized protocol is essential for a multi-site project like NHBS; it ensures comparability of data across sites, thereby allowing the data to be aggregated and presented as findings at the national level.

This protocol describes the activities that NHBS project sites will conduct for NHBS-Trans. The chapters include formative assessment activities (Chapter 2), data collection procedures and instruments (Chapter 3), sampling and recruitment methods (Chapter 4), HIV testing procedures (Chapter 5), data management (Chapter 6), plans for data analysis and dissemination (Chapter 7), data security and confidentiality guidelines (Chapter 8), and human subjects considerations (Chapter 9).

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2 Formative Assessment Activities

2.1 Definition and Goals of Formative Assessment

Formative assessment is the process by which public health researchers and practitioners define a community of interest, investigate attributes of the community relevant to specific public health issues, and determine ways of accessing the community.[1, 2] The purpose of NHBS formative assessment is to guide local implementation of NHBS activities to ensure successful data collection. Particularly, formative assessment can help ensure that the desired sample size is achieved and that the resulting NHBS sample is reflective of the population of interest (referred to hereafter as the 'NHBS population').

NHBS formative assessment activities are completed over a period of up to 7 months that precede the implementation of surveillance activities. NHBS project sites may wish to hire a local ethnographer or researcher with knowledge of ethnographic methods to guide the collection, analysis, and interpretation of qualitative formative assessment data. Upon completion of their formative assessment activities, project sites are required to submit a series of short reports to their CDC project officer. These reports serve as the basis upon which project sites, in consultation with CDC, tailor the implementation of the project to ensure its local acceptability and success.

The sampling strategy for NHBS-Trans requires formative assessment activities to ensure that the resulting sample will meet the goals of the surveillance project.

2.1a Goals of formative assessment

NHBS-Trans formative assessment goals are to:

- Garner the support of the community and its stakeholders for NHBS
- Define the social and demographic characteristics of the local trans population
- Develop questions of local interest for HIV prevention
- Identify programs, resources and unmet needs for services of the local trans population
- Monitor the on-going implementation of NHBS.
- Obtain information relevant to field logistics (e.g., appropriate locations and hours of operation for field site(s), whether appointment systems are feasible, and ideal attributes of field staff);
- Identify potential "seeds", or initial recruits, for RDS;

- Obtain information on the major networks of the NHBS population in the Division or MSA and identify networks with potentially high "homophily" (i.e. the degree of insularity or in-group preference for recruitment); and
- Identify strategies for reaching the NHBS population for data collection (e.g., areas where the population can be reached, community and neighborhood organizations that serve the population, and individuals that are knowledgeable about and have access to the population).

A key feature of NHBS formative assessment is that it is an iterative process: knowledge about the NHBS population builds as information is collected during each of the formative assessment activities mentioned above. This on-going processing of formative assessment data helps project staff identify gaps in knowledge and determine if there is a need to collect additional information.

A number of methods should be employed in order for sites to meet the formative assessment goals. These methods include review of secondary data and collection of primary data including key informant interviews, community key informant interviews, focus group interviews, and direct observations.

2.2 Review of Secondary Data

The purpose of the secondary data review is two-fold: (1) establish a foundation of information regarding the NHBS population within the designated MSA or Division; and (2) identify gaps in knowledge regarding the population that could affect successful implementation.

Secondary data sources may include published or unpublished surveillance data on HIV/AIDS, hepatitis, and other sexually transmitted diseases; HIV epidemiological profiles; HIV prevention plans; HIV counseling and testing data; data and information from HRSA; and local studies of the population.

Secondary data are reviewed to:

- Describe the demographic characteristics of the local NHBS population's HIV/AIDS epidemic (e.g., age, race/ethnic group, geographic location, risk behaviors);
- Compile a list of community stakeholders and subject matter experts to help garner support for NHBS and/or invite for interviews

2.3 Primary Data Collection

Formative assessment is an iterative process, thus information obtained through primary data collection should be used to validate findings from the secondary data review and to explore new and emerging issues related to the implemention of NHBS.

NHBS formative assessment activities include the collection of data using an array of methods common to qualitative and ethnographic studies of health: key informant interviews and focus groups.[3-10] Each NHBS project site should follow local requirements regarding informed consent for focus groups and key informant interviews. Three model consent forms are provided (Appendices A-C) and should only be modified in order to meet local IRB requirements. To protect the anonymity of those interviewed, consent to participate should only be provided verbally by participants and no data collection activities should be video- or audio-taped.

2.3a Interviews with Key Informants

Key informants are cultural and subject matter experts that provide insight about (1) the NHBS population's HIV-related behavior, (2) study barriers that may be encountered in the field, (3) recruiting potential NHBS participants, and (4) gaps in services among the NHBS population. Key informants can include: community leaders, researchers and persons doing outreach who are familiar with the population, health department staff, and individuals who are members of the population of interest[6].

The interview guide for key informant interviews should be semi-structured allowing for detailed and in-depth discussions. Topics discussed should include the context of the community and NHBS population (e.g., the locations where people in the community meet and socialize and characteristics of the population), gaps in services and community needs, and implementation and logistics-based strategies (e.g., the best days, times, and locations for data collection and barriers to recruitment and participation). Sites should also work with key informants to begin compiling a list of local trans-friendly service providers that they can make available to NHBS participants.

Appendix A contains a model consent form for key informant interviews where providing tokens of appreciation for participation is not appropriate. These include interviews with individuals such as health department officials, police, business and community leaders, and others whose official duties include the dissemination of information about local communities. Appendix B contains a model consent form for members of the local communities who should not be expected to contribute information on community characteristics without receiving tokens of appreciation.

2.3b Focus Groups

Focus groups are conducted with several individuals at one time under the direction of a moderator.[3] Focus group participants should be recruited from within the MSA and may include community stakeholders and leaders, staff from organizations that serve at-risk populations, and community residents.

Similar to key informant interviews, focus group interviews should be semi-structured. Discussions may include such topics as: social, sexual, and drug-using networks in the MSA; venues or geographical areas within the MSA that are significant to the population; gaps in services; strategies for garnering community support for NHBS, marketing NHBS locally, and recruiting the NHBS population for participation; and the identification of key community members.

Appendix C contains a model consent form for focus groups.

2.4 Field Site Logistics

Implementation of NHBS will occur at fixed field sites (storefront, office or van locations) identified through formative assessment. Field site locations should be easily accessible for the NHBS population, safe, culturally welcoming, and designed in a manner that ensures that participant confidentiality will be maintained. It is important to ensure that potential participants have no real or perceived barriers to the location. For example, locating a field site where local business owners or residents resist the presence of the NHBS population would present a barrier to potential participants.

2.5 Garnering Community Support

The support of the local trans community and its stakeholders is key to ensuring the acceptability of NHBS's formative and surveillance activities. Project sites should seek out community members, stakeholders, and organizations representative of or related to the NHBS population. Such individuals and organizations may include:

- Community-based service and social organizations that serve the population
- Health service providers
- Local government and social service providers
- Religious communities
- Not-for-profit and non-governmental organizations
- Local media outlets

Identifying community stakeholders can be achieved by:

1. Requesting names from key informants, focus groups, and state and local health department staff
2. Identifying community leaders and members at public meetings
3. Contacting local cultural and subject matter experts including local researchers and academics

Once identified, project staff should inform community stakeholders about NHBS, engage them in the process of developing local prevention questions, and solicit their input about gaps in

services and potential barriers to NHBS, including logistics, community acceptance, and possible ways to overcome those barriers.

2.6 Ongoing Formative Assessment

Ongoing formative assessment involves gathering additional information to address concerns identified either from reviewing the process monitoring reports or via feedback from the field staff. NHBS project sites will conduct ongoing formative assessment throughout the cycle to ensure successful implementation. Information collected during ongoing formative assessment activities will help project staff better understand participation barriers and potential recruitment schemes so that local procedures can be developed and implemented to improve project activities.

Based upon findings from ongoing formative assessment, project sites may need to make modifications to their field operations, as approved by their CDC Project Officer.

Project sites will use a combination of methods to monitor enrollment rates, effectiveness of seeds, potential concerns about respondents' eligibility, demographic characteristics of the sample, and other relevant indicators of data quality. Ongoing formative assessment will also monitor whether participants are distributing their coupons to people that they do not know (i.e., people who are "strangers"); an important assumption of the RDS method is that participants recruit people that they know, as opposed to strangers who are not a part of their social network.

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3 Data Collection

3.1 Data Collection Instruments

3.1a Network Questions

Information about the size and characteristics of participants' networks, and descriptions of the relationships between the participant and the person who gave them the coupon, will be used to account for sources of bias inherent to the RDS method and to calculate population estimates and sample variances. A "network" for RDS is defined as those persons whom the participant knows and has recently interacted with, and who meet the eligibility criteria for the given study. A participant's personal network size is based on how many people they know who fit the eligibility criteria for the current NHBS-Trans cycle. Questions to obtain necessary network data are included as part of the NHBS-Trans questionnaire, following the eligibility screener (see Appendix E).

Development of the Network Questions

The network questions used during previous NHBS cycles were developed based on consultation with Douglas Heckathorn (the developer of the RDS method), experiences during previous cycles, consultation with NHBS principal investigators, and cognitive testing of the previous questions used in NHBS conducted by the National Center for Health Statistics. The network questions for NHBS-Trans are based on previous NHBS network questions and lessons learned from development, testing, and use of those questions.

3.1b Questionnaire

Questionnaire components

The NHBS-Trans questionnaire consists of two components. First, the core NHBS-Trans questions constitute a standardized main component and are based on the standard questionnaire used for all NHBS populations. Second, participating NHBS-Trans project sites may develop and add questions that address topics of local interest.

Core Questions. The core questions will be used by all project sites participating in NHBS-Trans and will provide data that will be used for comparisons of risk behaviors and HIV testing behaviors of the population of interest between the MSAs. The core questionnaire covers the following areas:

- Demographics
- Sexual behaviors
- Alcohol and drug use history
- HIV testing and prevention experiences
- Health conditions
- Assessment of prevention activities (i.e., exposure to HIV behavioral interventions)

Local Use Questions. Project sites may include additional questions on topics of local interest. The local use questions shall not exceed 10 minutes maximum for administration.

Development of the questionnaire

Development of the NHBS-Trans questionnaire is a collaborative process between participating NHBS-Trans project sites and CDC. Changes were made to the standard NHBS questionnaire to develop the NHBS-Trans Core questionnaire to reflect population-specific needs, concerns, and gaps. The NHBS-Trans questionnaire was developed in collaboration with external partners and a community advisory board of trans individuals. All decisions regarding the development of to the questionnaire for NHBS-Trans were made to optimize data quality, provide consistent measurement for key NHBS-Trans indicators, and reduce respondent burden. All items were reviewed by subject matter experts.

3.2 Translation of Data Collection Instruments

All NHBS-Trans data collection instruments that involve questions asked directly of participants will be available in English and Spanish. Formatting and appearance of these instruments are the same in both languages. CDC is responsible for translating the eligibility screener, core questionnaire, and other standardized or model materials (e.g., model consent script) into Spanish. Translation of the data collection instruments by a single source ensures consistency across all states and populations. Translation into Spanish of the data collection instrument (except local questions) by other sources is prohibited. Local areas are responsible for translating local questions into Spanish. No other languages will be used for NHBS-Trans and the use of translators is prohibited.

3.3 General Data Collection Procedures

Data for NHBS-Trans will be collected in a number of steps, described below. The data collection instrument application is developed for use as a computer-assisted personal interview (CAPI) on a portable computer and will be administered in a standardized manner by trained interviewers.

Step 1: Participants present a valid study coupon to NHBS-Trans project staff

At a storefront or mobile van location, potential "seeds" (the initial participants recruited by NHBS-Trans staff) and subsequently, the peers they recruit will present valid coupons to NHBS-Trans project staff. The number on the coupon will be entered into a specialized coupon manager program developed for NHBS-Trans (coupon manager) and its validity will be determined. Coupon manager provides a way to keep track of coupon numbers and tokens of appreciation for participants who agree to recruit others into the study. In order to keep coupons from being duplicated, NHBS-Trans project sites will include non-replicable designs, such as a hologram, on coupons so that project staff can validate them.

Step 2: Eligibility assessment

Eligibility of potential respondents will be assessed using the eligibility screener (Appendix E). The eligibility screener is administered using a portable computer. Eligibility is determined by an algorithm based on both general and cycle-specific questionnaire items, programmed into the portable computer. The interview will automatically end after the eligibility screener is completed if the respondent is not eligible.

Step 3: Obtaining consent

Interviewers will seek informed consent (Appendix F) from the respondents and address any questions. Sites may use a summary form of the consent (Appendix G) and provide the respondent with a copy of the full consent form, provided the full consent is not required by local IRB or other regulatory guidelines. Consent to participate will be obtained orally. Interviewers will check a box in the CAPI program indicating whether consent was obtained. The CAPI program will automatically end if the respondent does not agree to participate in the survey. Respondents may consent to the survey and any of the following: HIV testing, specimen storage (e.g., dry blood spots), and if applicable, other tests (e.g., hepatitis, STD). All NHBS-Trans project sites planning to store blood locally as well as those planning to ship any specimens to another lab for any reason (e.g., incidence, viral load, or other supplementary HIV tests not returned to participants) must obtain consent for storage from participants in order to store or ship specimens provided by those participants. Participants must consent to the survey to be eligible for the other components; however, if participants do not consent to the survey but still wish to receive an HIV test or other tests, project staff in each NHBS-Trans site will provide referrals and information in order for the person to access these resources.

Step 4: Core questionnaire and local questions

Eligible participants who provide consent will be administered the NHBS-Trans core questionnaire (Appendix E). The local questions will be launched automatically at the end of the core survey; these questions are also administered to respondents by the interviewer.

Step 5: HIV and other testing

Testing procedures and the information recorded in the testing logs by staff do not require that additional questions be asked of the participants. See Chapter 5 for more details on testing procedures.

Step 6: Tokens of appreciation for participation

Participants will receive a small token of appreciation for participation in NHBS-Trans activities. The token of appreciation amounts are determined locally by the NHBS-Trans project sites, and are based on investigators' previous experience with NHBS-Trans cycles or other similar studies. The tokens of appreciation are for the participant's time spent completing the survey

(approximately $25) and, if applicable, the HIV test (approximately $25) or other tests. If local regulations prohibit cash tokens of appreciation, equivalent tokens of appreciation may be offered (e.g., gift certificates, fares for public transportation). Cash tokens of appreciation are highly encouraged if not prohibited by local regulations. Participants may be offered a smaller token of appreciation for incomplete surveys, in accordance with local policies.

Local areas may have requirements about documenting distribution of tokens of appreciation. This should be done in accordance with requirements for maintaining anonymity (see Chapter 9).

Step 7: Training participants to recruit others

After the interview is completed, the interviewer will ask participants meeting the recruitment criteria (see Chapter 4) if they would be willing to recruit other participants for a small token of appreciation. In this context, a token of appreciation could mean cash, which is generally highly effective for recruitment, or a non-cash gift of health promotional materials, fares for transportation, or certificates redeemable at health-oriented retailers (e.g. pharmacy convenience stores). Cash or gift cards may be provided in limited cases when local formative research suggests cash tokens of appreciation are necessary to reach certain populations.

After a brief training on the recruitment process, those who agree to recruit will be given up to 5 coded, non-replicable coupons (Appendix H). The participant will be told to give one coupon each to up to five different people they know personally and who live in the project area (Appendix I).

Each coupon will have the local NHBS-Trans project name, location(s) of field sites or vans, phone number(s) where staff can be reached to make appointments, and a Survey ID number printed on it. The Survey ID on the coupon will be linked to the Survey ID of the participant the coupon is issued to (i.e., the recruiter), which will be documented in the coupon manager.

Participants who agree to recruit ("recruiters") will be asked to provide specific information that is used to create a Unique ID (different from their Survey ID) and to provide information about any visible tattoos or physical marks so that their identification can be verified when they return to receive the tokens of appreciation for recruiting other people (Appendix I). This information will be stored in the coupon manager and destroyed following local procedures (Chapter 8).

Participants who successfully recruit new participants will receive their tokens of appreciation by returning to the storefront where they were interviewed and checking in with the coupon manager. Project staff will use the Unique ID and any visible, physical marks to verify the identity of each recruiter returning to claim tokens of appreciation for recruitment. After verification, recruiters will be given a token of appreciation valued at approximately $10 per eligible participant who completed an interview. If a coupon recipient does not complete an interview, their recruiter will not receive a token of appreciation for that coupon. However, project staff have the option of distributing nominal tokens of appreciation to recruiters for returning to the storefront (e.g., bus tokens, HIV prevention materials, etc.).

3.4 Monitoring Data Collection

All interview data are vulnerable to bias from variability in the way respondents are sampled and in the way interviews are conducted. This bias may arise from variability between interviewers or from variability between interviews conducted by a single interviewer. To minimize these biases, and to ensure that proper procedures are followed, monitoring procedures will be implemented to assess the consistency and quality of NHBS-Trans data collection activities.

The NHBS-Trans field supervisor or another project manager will periodically monitor each staff member as he or she conducts the eligibility screener, obtains informed consent, administers the NHBS-Trans questionnaire, and trains participants to recruit their peers. Feedback on performance – areas of proficiency as well as areas for improvement – should be given shortly after observations are conducted. Supervisors are to monitor 10% of interviews administered by each interviewer.

3.5 Training for Personnel

All NHBS-Trans personnel will be appropriately trained to conduct NHBS-Trans project activities. CDC will hold Field Operations Training for Project Coordinators and Field Supervisors covering topics including: proper survey administration; required elements of informed consent; techniques for monitoring interviewers and staff; and instructions for creating a local training for interviewers and other project staff. Representatives from the Data Coordinating Center, or DCC (Chapter 6), will train Data Managers on best practices for organizing, editing and transmitting data via the DCC web portal. CDC will develop a detailed manual describing surveillance operations and procedures and will test knowledge of NHBS-Trans staff periodically. The local NHBS-Trans Principal Investigator has responsibility for ensuring all HIV counselors are trained according to local guidelines and standards with regard to HIV risk-reduction counseling and testing procedures.

4 Sampling and Recruitment Methods

4.1 Overview

There are multiple activities that make up sampling for NHBS. The first activity, formative assessment, is discussed in Chapter 2. This chapter focuses on the remaining activities.

4.2 Eligibility Criteria

Participant inclusion criteria

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

- Present a valid NHBS-Trans coupon
- Have not previously participated in the current NHBS-Trans cycle
- Live in the participating MSA or Division
- Are 18 years of age or older*
- Have a gender identity of woman or trans woman
- Were assigned a male or intersex sex at birth

and

- Are able to complete the interview in English or Spanish

*NHBS is a surveillance system of the HIV risk behaviors of adults in the United States, and the methods are designed to recruit an adult population. 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.[3]

Criteria	**Trans participant** (Eligible to complete interview and recruit; included in analysis; count toward required sample size, N= 200)	**To be a seed**
Presented a valid NHBS-Trans coupon	**X**	Seeds are recruited by NHBS staff
Has not previously participated in the current cycle of NHBS-Trans	**X**	**X**
Lives in the participating MSA or	**X**	**X**

Division		
Is ≥ 18 years of age	**X**	**X**
Has a gender identity of "woman" or "trans woman"	**X**	**X**
Was assigned male or intersex sex at birth	**X**	**X**
Is able to complete the interview in English or Spanish	**X**	**X**
Identifies race/ethnicity as Black or Hispanic/Latina		**X**

4.3 RDS Methods

There are four main activities that make up Respondent-Driven Sampling (RDS): 1) formative assessment to identify networks and inform operating procedures for study implementation (Chapter 2); 2) recruiting, screening and interviewing "seeds", or initial recruits; 3) screening and interviewing persons who present a valid coupon to NHBS project staff; and 4) training eligible NHBS participants to recruit others. This section focuses on the last three activities.

4.3a Initial Recruits -"Seeds"

RDS is a chain-referral strategy similar to snowball sampling. It is based on the theory that if peer recruitment proceeds through a sufficiently large number of waves, the composition of the sample will stabilize, becoming independent of the "seeds" – or initial recruits – from which recruitment began, and thereby overcoming any bias the nonrandom choice of seeds may have introduced.[1, 2]

In RDS, a limited number of seeds are the starting point for the chain-referral process.

Identifying Seeds
Seeds may be identified though a variety of methods described in the formative assessment chapter (Chapter 2). The ideal seeds are dynamic individuals who are knowledgeable about and well connected to the NHBS population and are motivated NHBS participants. Because seeds are the initial recruiters for the project and have a vested interest in the population, they are more likely to encourage others to participate and to provide support for the project in the community. Selecting appropriate seeds accelerates recruitment, promotes longer recruitment chains (successive recruitment waves), and helps reduce bias in the sample. Because NHBS-Trans aims primarily to recruit trans women who belong to minority race/ethnicity groups, all seeds should be Hispanic/Latino or black/African-American.

The following criteria should be considered when assessing whether an individual might be a good candidate for a seed:

- **Seeds should be diverse with respect to factors such as, age, or other factors identified during formative assessment that would create more insular networks.** The goal of RDS is to recruit a sufficiently large number of waves, so that the overall composition of the sample will stabilize and become independent of the seeds from which recruitment began; this stable sample composition is termed "equilibrium." Homophily, or similarity within a group, has an impact on how quickly equilibrium is reached; the more insular a group, the more likely they are to recruit others like themselves and the more waves it takes to reach equilibrium. Having a diverse set of seeds will help ensure diversity of networks with regards to the degree of insularity included in the initial waves.

- **Seed selection should take into account network characteristics.** Network ties determine prevalence and extent of risk behaviors. Seeds should therefore be representative of the major NHBS population networks in an MSA that are affected by the local epidemic. Formative assessment activities will provide information on various networks and may also help in accessing appropriate networks for the population.

- **As a group, seeds should reflect geographic diversity**. As a group, seeds should come from a variety of areas within the MSA, particularly where the NHBS population is spread across different regions of the MSA.

- **Seed selection need not take place only at the beginning of NHBS.** The RDS method does not require that all seeds be selected at the same time. If an important network is under-represented during the course of NHBS sampling, adding seeds from this group can be useful.

In addition, seeds must meet all eligibility criteria for the NHBS-Trans cycle.

Recruitment of Seeds

NHBS project staff will recruit an initial group of approximately 5-10 seeds. The number of initial seeds will depend on the capacity of the project staff as well as the locations and types of target networks across the MSA.

When a potential seed is identified or contacted, NHBS project staff will briefly describe the current NHBS project and ask the potential seed if they would be willing to go to the field site location to complete the NHBS procedures (screening, interviewing, and testing). If the potential seed cannot do so at that time, they will be given a referral card to come to the field site location at a time of their choosing (a recruitment coupon may also serve as a referral card for seeds, see Appendix D). In some cases, seeds may be interviewed at the location where they have been contacted or identified by project staff, for instance, in a neighborhood venue or in a mobile van. When screening, interviewing,

and testing potential seeds, staff will ensure that they do not compromise the confidentiality of the participant; even when conducted on the street, NHBS surveys will be done in such a way as to ensure no one else besides project staff and the participant can hear or observe the proceedings. If confidentiality of interviews cannot be ensured in a street location, project staff will set up an appointment with the potential seed to be interviewed at the field site or office.

Eligibility Screening

Potential seeds will be assessed for eligibility using the eligibility screener (Appendix D). If ineligible, the individual will be thanked for their time and interest in the project. If eligible, they will continue with the consent process.

Consent and Interviewing

After eligibility is determined, the interviewer will obtain informed consent by reading the consent form and obtaining verbal agreement to participate (Appendix F). Interviewers will address any questions that the participant may have prior to starting the survey interview.

No data is collected from participants who does not provide consent. However, participants who do not consent will be asked why they are not interested in participating to assess study barriers.

Interviews will be conducted using the NHBS questionnaire (Appendix D) administered using a portable computer and personal interview program. The interview will take about 30 to 40 minutes. Interviews are conducted in a secure, private area within the field site location to preserve participants' confidentially.

HIV and other testing

Participants will be offered an anonymous HIV test. The testing component of NHBS is voluntary and consent for HIV testing is obtained prior to survey participation. HIV counseling and testing must be conducted in accordance with the NHBS protocol (Chapter 5) and in accordance with local standards established by state and local health departments. Other tests may also be offered if appropriate.

Training to Recruit Others

After the interview and HIV test is completed, the interviewer will ask eligible seeds that complete a valid survey if they would be willing to recruit other participants for a small token of appreciation. After a brief training on the recruitment process, those who agree to recruit will be given up to 5 coded, non-replicable coupons (Appendix H). The participant will be told to give one coupon to each of up to 5 individuals he or she knows who live in the project area and meet certain cycle specific criteria.

Each coupon will have the current NHBS cycle name, location(s) of field site locations, phone number(s) where staff can be reached to make appointments, and a Survey ID number printed on it. The Survey ID on the coupon will be linked to (but not identical to) the Survey ID of the participant the coupon is issued to (i.e., the recruiter), which will be documented in the coupon manager.

4.3b Coupon Redemption and Subsequent Recruitment

All persons who bring a valid coupon to a field site will be assessed for eligibility. Those found to be eligible and who give consent to participate will be interviewed. These steps are the same as described in Section 4.2a above; however, non-seed participants must be interviewed at a field site location. Eligibility criteria for NHBS participation and recruitment are described in Section 4.3 below.

After completion of the interview process, non-seed participants who complete a valid survey and meet the recruiter criteria will be asked if they would be willing to help to recruit other participants for a small token of appreciation.

Those who agree to recruit others will be given a brief training on the recruitment process (Appendix N), and then will be given up to 5 coded, non-replicable coupons. The participant will be told to give one coupon to each of up to 5 individuals they know who live in the project area and meet certain cycle specific criteria. The process of recruitment and interviewing continues until the minimum target sample size is achieved (Chapter 1).

Obtaining Tokens of Appreciation for Recruiting

Participants who agree to recruit other participants ("recruiters") will be asked to provide specific information that is used to create a Unique ID (different from their Survey ID). They will also be asked to provide information about any of their visible physical marks (e.g., tattoos, scars, piercings); this information and the Unique ID will be used to verify the recruiter's identity in providing tokens of appreciation for recruiting other eligible participants. This information will be stored in the coupon manager and destroyed following local procedures (Chapter 8).

When a recruiter returns to claim tokens of appreciation for recruiting, their identity will be verified using the Unique ID and the visible physical marks. After verification, they will be given a token of appreciation valued at approximately $10 per eligible participant who completed an interview.

Pacing and Ending Recruitment

The pace of recruitment must be monitored to ensure that peer-referral chains are dense and have multiple "waves"; yet, the pace must not be so rapid as to overcrowd the field site location and place an undue burden on NHBS staff. Close monitoring of the sample will enable NHBS project sites to adjust the pace of recruitment.

An activation date on the coupon may help control the pace of enrollment, so that potential participants do not overwhelm the project staff. Similarly, an expiration date on the coupons may be useful as a way to encourage participants to schedule an interview within a short time after the date of the recruiter's interview (e.g. approximately 4 weeks).

The field location should have operating days and hours that are well communicated to the NHBS population (via coupons, signs, etc.). Project staff should determine the maximum number of interviews they can conduct each day in order to properly schedule interviews. Project staff should encourage participants to make an appointment to be interviewed, but may need to consider allowing walk-in appointments depending on which strategies allow for best recruitment of the population.

4.4 References

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5 HIV Testing

5.1 Overview

All persons who agree to participate in NHBS will be offered an anonymous HIV test. The testing component of NHBS is voluntary. The purpose of testing is to estimate HIV prevalence among populations participating in NHBS. HIV counseling and testing must be conducted in accordance with the NHBS protocol and in accordance with standards established by state and local health departments.

Persons who agree to participate in the testing component of NHBS will be provided with information about HIV testing. In accordance with local procedures and practices, project sites may offer rapid or laboratory-based HIV testing to participants. Specimens will be collected for long term storage to conduct additional testing, such as evidence of recent HIV infection, HIV viral load, presence of antiretroviral drugs, genome sequencing or drug resistance.

HIV test results will be returned to participants by a trained counselor during a scheduled counseling visit or shortly after the time of testing if a rapid test is used. Additional testing such as HIV viral loads using dried blood spots are done through in-house techniques and investigational assays that are not FDA approved to provide individual test results. Therefore, these results will not be returned to participants.

5.2 Procedures/Methods

5.2a Informed consent

Based on site-specific testing options, consent for NHBS will include: 1) participating in the survey; 2) testing blood specimens for the presence of HIV antibodies, antigens, and/or RNA; 3) other testing (e.g., hepatitis, sexually transmitted disease (STD)) when funds are available; and 4) storing leftover specimens for additional tests, including HIV viral load and any other testing beyond local procedures for HIV diagnostic testing when applicable. The informed consent process should follow local guidelines and standards with regard to HIV risk reduction counseling and testing procedures.

During the consent process, interviewers will explain to participants the purposes, procedures, benefits, and risks of giving a specimen and being tested for HIV. Participants who request an HIV test but do not consent to participating in NHBS will be given referrals and information for HIV testing. For participants that elect to participate in the interview but refuse to provide consent for HIV testing. NHBS staff will confirm the participant's decision to decline the HIV test at the end of the core survey to ensure he or she is given every opportunity to receive an HIV

test. Appendix F contains a model consent form; if required, this form can be slightly modified to meet local requirements.

All tests done for NHBS will be anonymous. NHBS project sites unable to perform anonymous HIV testing will not be allowed to participate in NHBS.

5.2b HIV counseling

After a participant consents to participating in NHBS, survey administration is completed; next, HIV counseling and referrals are provided. No counseling can occur before the survey has been administered. Counseling for rapid and laboratory-based HIV testing should follow standards established by state and local health departments. Appropriate risk-reduction counseling is provided to all participants who elect testing for HIV. Counselors will target prevention messages to specific risks identified during the behavioral surveillance interview. Barriers to risk reduction will be assessed, and methods to reduce or remove those barriers will be explored as appropriate for the participant. Counselors will provide referrals for any additional social support or medical services identified during the counseling session.

5.2c Specimen collection

Tests using blood are more sensitive to detect HIV infection than oral fluid, especially early infections. Blood specimens for HIV testing are strongly recommended based on the improved sensitivity of blood-based testing compared to oral specimens, and the challenges identified with oral specimens in previous NHBS cycles. Blood specimens from finger stick or venipuncture are collected for the purpose of HIV testing. Oral specimens can be collected only under circumstances in which blood specimens cannot be obtained from participants.

NHBS project sites will offer rapid HIV testing to participants with rapid or laboratory-based supplemental or confirmatory testing. Rapid testing is encouraged because it allows staff to provide preliminary results and make appropriate referrals to HIV care even for participants who may not return for lab-based supplemental or confirmatory test results. Standard (non-rapid) HIV testing can be conducted only under circumstances in which rapid HIV testing cannot be administered.

Project sites have the option to implement a rapid testing algorithm using multiple rapid tests. A rapid test algorithm preferably begins with the most sensitive test so that early stage infections are not missed by the first rapid test. Participants may receive a false-negative test result if a rapid test is used that is not sensitive to early infection. This may particularly be an issue in a population with a high proportion of new infections.

Rapid test specimens may be collected prior to survey administration, but only if local requirements allow counseling to be provided after specimen collection. For project sites that will have laboratory-based supplemental or confirmatory testing, persons who test positive for HIV on a rapid test must be asked to provide a blood or oral specimen for laboratory-based supplemental or confirmatory testing at the time that preliminary positive test results are given.

Results of rapid tests and specimen collection for supplemental or confirmatory testing should be available after the survey has been administered.

Specimens are labeled with unique Survey ID numbers that match the participant's laboratory slip, questionnaire, and counseling card. No personally identifiable information is included on any survey, specimen, laboratory slip, or instrument; this includes any tests provided locally (e.g., STD testing). The unique Survey ID is also affixed to the participant's appointment card, and the participant is counseled to keep the card in order to receive his or her results.

The NHBS Project Coordinator and collaborating technician at the laboratory will maintain a log of all samples received for NHBS. This log will contain the participant's Survey ID, the time and date of specimen collection and information regarding the participant's consent for storage. If the participant consents to storage, the log will indicate the date and time the sample was processed for storage and the amount frozen (if applicable). If the participant does not consent to storage, the log will indicate the date and time the sample was destroyed. NHBS Project Coordinators will work closely with the laboratory to ensure the proper storage and disposal of NHBS specimens.

5.2d Counseling/returning HIV test results

Participants who are provided with rapid HIV testing will receive their results during the NHBS encounter. Those participants who do not undergo rapid testing will receive their HIV test results by trained counselors within one to three weeks of the date of the specimen collection. NHBS project sites should develop flexible systems for return of HIV test results and counseling that are easily accessible by participants. During the initial encounter, the counselor will work with the participant to schedule a counseling session for return of results. The participants should be given an appointment card with the name and telephone number of the health department personnel or counselor and the date, time and location of their appointment. The appointment card must have an affixed Survey ID number to link test results to the participant. No personal identifying information will be linked to the participant's HIV test result.

In the event that an in-person counseling session cannot be scheduled, participants may elect to receive HIV test results by telephone but only if local requirements allow the return of results in this manner. NHBS project sites providing HIV results over the telephone must provide appropriate training to all telephone counselors.

All participants who test positive for HIV should be referred for appropriate medical care and HIV case management services at the time they receive their test results. NHBS project areas should make a referral to care for participants with preliminary positive results at the time of the NHBS encounter during the counseling session and after a confirmatory specimen has been collected. The HIV test result can only be used for NHBS analysis purposes, participants may not be reported to the state or local health department for HIV/AIDS surveillance purposes.

5.2e Other testing

NHBS sites must collect blood via finger sticks (dry blood spots) or venipuncture for additional testing at the CDC laboratory from participants who consent to specimen storage. The additional tests could include: genome sequencing, drug resistance tests, HIV viral load tests, other tests such as HIV antigen detection tests that are capable of detecting acute/ recent HIV infection, and tests to detect the presence of antiretroviral drugs.

To standardize the specimens used for recency testing, sites conducting phlebotomy that are providing specimens for recency testing will be asked to prepare dry blood spots from the blood tubes. Additional laboratory tests can only be done provided that participants consent to specimen storage.

The goal of conducting resistance testing on dry blood spots will be to detect minority drug resistance mutations. The goal of the antigen testing would be to measure HIV antigen in the absence of antibody to detect recent or acute infections, and to measure HIV community viral loads. These tests will be conducted at the CDC laboratory in Atlanta, after all specimens have been batched and data collection in the field is complete. The goal of testing for the presence of antiretroviral drugs will be to monitor the use of pre-exposure prophylaxis among HIV-negative individuals and HIV treatment among antibody-positive individuals. These tests will be conducted at the CDC laboratory in Atlanta after all specimens have been batched and data collection in the field is complete. Testing is done through in-house techniques and investigational assays that have not been FDA approved to provide individual test results. Therefore, results will not be returned to participants. All HIV-positive participants are referred to facilities offering HIV care and treatment. HIV viral loads will be conducted at these facilities as part of the clinical evaluation of HIV-positive persons.

5.2f Additional tests

During NHBS-Trans, as funding permits, sites will collect rectal swabs, pharyngeal swabs, and urine to perform anonymous STI testing for gonorrhea and chlamydia at CDC or a local lab. STI testing is required by this protocol if funding for testing is available. Decisions about funding for STI testing may differ by type of specimen and testing. Project sites with local regulations prohibiting such testing (e.g. laws prohibiting anonymous STI testing) or whose formative assessment identified STI testing as significantly detrimental to NHBS-Trans goals or operations may request an exemption from STI testing through their CDC project officer. Exemption requests will be evaluated on a case-by-case basis.

NHBS project sites can conduct other tests in addition to an HIV test provided funds are available. For example, some NHBS sites may conduct testing for hepatitis B virus (HBV) and hepatitis C virus (HCV) using blood collected via venipuncture.

Results of STI and additional tests will be available to participants within one to three weeks of collection. Participants may be given the option to provide NHBS study staff with their phone number to receive test results or contact NHBS staff. If necessary, NHBS staff will provide

referrals to participants with positive test results. Model hepatitis and STI testing logs are provided in Appendix J and Appendix K.

5.2g Token of Appreciation

HIV testing will be provided at no cost to participants. After specimens have been collected, participants may be given a token of appreciation valued at approximately $25 for their time and effort. Similar tokens of appreciation may be provided for additional testing, provided funding is available to support it.

5.2h Data collection

HIV testing data should be collected on logs maintained by NHBS project staff. HIV testing data (specimen information and results of all testing including tests for recent infection) will be linked to interview data via the unique survey ID. All logs or laboratory slips containing HIV testing data should be stored in a secure and locked file cabinet. Access to the logs should be limited to designated NHBS project staff.

HIV test results

Results of HIV tests will be recorded on a data collection form completed by the laboratory personnel or by NHBS project staff from a copy of the HIV test results. HIV test result logs will contain but are not limited to:

- survey ID
- laboratory ID
- rapid test(s) performed (if applicable)
- rapid test(s) results (if applicable)
- rapid test result returned
- specimen type
- laboratory-based test(s) performed
- laboratory-based test results
- self-report of HIV+ status
- final test result returned

A model HIV testing log is found in Appendix L. This log will be modified by project sites depending on testing methods implemented.

Specimen information for laboratory-based testing

The NHBS laboratory coordinator will maintain a log of all specimens received. The log will contain:

- unique Survey ID;
- time and date of specimen collection;
- time and date the specimen was processed;

If consent for storage is obtained:

- time and date the sample was frozen;
- amount of sample frozen; and
- date and amount of frozen sample sent to CDC or a designated laboratory.

5.3 Data Management

Test results will be entered into the Test Results Logs in the Data Coordinating Center (DCC; see chapter 6) Data Portal's online database. These data will be entered at least weekly so that reports generated by the DCC will reflect project sites' current numbers.

5.4 References

1. CDC. Interpretation and use of the western blot assay for serodiagnosis of human immunodeficiency virus type 1 infections. MMWR Morb Mortal Wkly Rep, 1989. 38(Suppl 7): 1-7.
2. CDC. Update: HIV counseling and testing using rapid tests--United States, 1995. MMWR Morb Mortal Wkly Rep, 1998. 47(11): 211-5.
3. CDC. Notice to readers: Protocols for confirmation of reactive rapid HIV tests. MMWR Morb Mortal Wkly Rep, 2004. 53(10): 221-222.
4. Schneider, E., Whitmore, S., Glynn, K.M., Dominguez, K., Mitsch, A., and McKenna, M.T. Revised surveillance case definitions for HIV infection among adults, adolescents, and children aged <18 months and for HIV infection and AIDS among children aged 18 months to <13 years--United States, 2008. MMWR Recomm Rep, 2008. 57(RR-10): 1-12.
5. Parekh, B.S., Pau, C.P., Kennedy, M.S., Dobbs, T.L., and McDougal, J.S. Assessment of antibody assays for identifying and distinguishing recent from long-term HIV type 1 infection. AIDS Res Hum Retroviruses, 2001. 17(2): 137-46.
6. Masciotra, S., Dobbs, T.L., Candal, D., Hanson, D., Delaney, K., Rudolph, D., Charurat, M., Harrigan, R., McDougal, S., and Owen, M., Antibody Avidity-based Assay for Identifying Recent HIV-1 Infections Based on Genetic Systems TM ½ plus O EIA, in 17th Conference on Retroviruses and Opportunistic Infections (CROI). Feb 16-19, 2010: San Francisco, CA.

6 Data Management

6.1 Overview

The purpose of this chapter is to describe basic data management procedures. The format for specific databases and directions for submitting data will be developed in collaboration with CDC and participating sites.

6.2 Data Configuration

6.2a Data Files

Each NHBS project site will maintain the following databases:

1. Database of NHBS questionnaire records
2. Database of local questionnaire records
3. Coupon manager database
4. HIV testing database
5. STD databases (if applicable).

To ensure consistency in database layouts across the NHBS project sites, CDC will design and program the NHBS questionnaire and HIV testing database, including the questions or variable text, variable names, field limits, skip logic, consistency checks, response values, and formats.

QDS (Questionnaire Development System) software will be used to program the electronic version of the NHBS questionnaire, collect data, and manage data collection.

6.2b Data Submissions to CDC

All data submissions to CDC are made through the Data Coordinating Center (DCC). The DCC collects and processes data for delivery to the CDC as well as sites. Data management procedures performed by the DCC use standard data processing tools such as SQL and SAS. Basic procedures include: managing incoming data, merging data from different databases, generating data management and monitoring reports, and incorporating any data changes into datasets. Data are transmitted to the DCC either by file upload (e.g., database of NHBS questionnaire records) or direct data entry (e.g., Data Error Log, HIV testing data, etc.) using secure data entry screens within the web-based data portal system. In addition to sending data to DCC, the portal can also be used by sites to revise submitted data, view reports, track field site activities (e.g. recruitment and interview performance) and retrieve processed datasets.

After the NHBS data are sent through the DCC web portal, they will be processed by the

DCC data manager. The DCC will then produce a report, on a monthly basis, for each NHBS project site that lists any data inconsistencies; the project sites will respond to the DCC's report and the edits will be incorporated into subsequent data sets.

During the course of the NHBS cycles, project sites should communicate data collection and management problems to both their Project Officer and to DCC representatives in order to resolve these issues in a timely manner.

Representatives from the DCC will train Data Managers on best practices for organizing, editing and transmitting data on the DCC web portal. Data Managers will also receive a detailed manual that will list all requirements for maintaining NHBS data sets; this manual shall be the primary resource for conducting NHBS data management activities.

6.3 NHBS Analysis File

After the conclusion of NHBS-Trans, the DCC will create a reconciled dataset for each project site. NHBS project sites will only receive their own site's data. The purpose of the standardized datasets is to ensure that reports of NHBS data are consistent at both the local and national levels.

7 Data Analysis and Dissemination

7.1 Data Analysis and Dissemination

CDC will have principal responsibility for analyzing and disseminating multi-site survey data. CDC will also have principal responsibility for analyzing multi-site data on HIV prevalence. The CDC analyses will focus primarily on questions related to the objectives of this project described in Chapter 1. To examine the key behavioral outcomes, data will be weighted when possible to account for the complex sampling design.

NHBS project sites are required for to produce at least one report (fact sheets, epidemiologic profiles, surveillance reports, peer-reviewed manuscripts or other formats as appropriate) and conduct at least one presentation to community partners and stakeholders. Project sites are encouraged to establish Community Advisory Boards (CABs) or other organizations to transmit project findings to the community and stakeholders within the community.

7.1a Outcomes and minimum meaningful differences

Anticipated outcomes for this project vary by population of interest and include:

- Prevalence of HIV risk behaviors;
- Prevalence and frequency of HIV testing, early linkage to care, and receiving antiretroviral therapy
- Receipt of HIV prevention services; and
- Prevalence of HIV infection, including awareness of HIV infection.

7.1b Anticipated products

Each NHBS cycle will result in national and local products and publications. CDC will disseminate national reports, usually via *CDC HIV Surveillance Reports* and other CDC reports, the *Morbidity and Mortality Weekly Report* (*MMWR*), and peer-reviewed journals. CDC will also present results at national conferences and meetings. Local NHBS-Trans project sites are expected to disseminate local results to health department officials and the public by presenting results from NHBS-Trans at conferences, preparing reports for community planning groups, or publishing the results in peer-reviewed journals. NHBS-Trans project sites and CDC may collaborate on articles and reports when appropriate.

7.2 Limitations and Potential Biases

7.2a Respondent-Driven Sampling

There are several sources of bias in RDS:

- Groups that are more insular (i.e., more likely to recruit only within their own group) are more likely to be over-represented (if recruitment chains become trapped inside the

group) or under-represented (if recruitment chains cannot access the group) in the sample than less insular groups.
- Groups with larger networks may be overrepresented in the sample because more recruitment paths lead to their members.
- Some groups may be less willing or able to participate in the survey and would be underrepresented in the sample.

There are several ways to assess this bias and compensate for it. Some of the potential sources of bias are controlled by project staff; for instance, staff are encouraged to ensure that their initial peer-recruits, or seeds, are diverse by age, geographic location and other important factors that would have the effect of increasing the insularity of recruitment and of homophily (i.e., groups that recruit only within their own group). It is also important for project sites to conduct adequate formative assessment to help determine the proper placement of field sites to minimize participants' barriers to taking a survey.[1,2]

Other sources of bias are taken into account during data analysis using information obtained during the survey. To calculate the population estimates and sample variances derived from RDS, participants' network size and information on who recruited whom (made possible through the coupon tracking system) are factored in to arrive at population estimates that reflect the underlying population. If these sources of bias cannot be satisfactorily controlled and measured, or if there are unknown barriers to peer-recruitment, some assumptions on which RDS is based may not be met and the resulting estimates may not reflect the true population parameters of the NHBS population. Formative assessment and monitoring the sample throughout data collection is critical to minimize the effect of these sources of bias.

7.2b HIV testing data

Biases in enrollment and agreement to HIV testing may result in over- or under-estimation of HIV prevalence or incidence. If those who agree to be tested differ from those who decline in terms of age, race, or sex, findings may be less generalizable.

7.3 References

1. Magnani R, Sabin K, Saidel T, Heckathorn D. Review of sampling hard-to-reach and hidden populations for HIV surveillance. *AIDS.* May 2005;19 Suppl 2:S67-72.

2. McKnight C, Des Jarlais D, Bramson H, et al. Respondent-driven sampling in a study of drug users in New York City: notes from the field. *J Urban Health.* Nov 2006;83(6 Suppl):i54-59.

3. MacKellar DA, Gallagher KM, Finlayson T, Sanchez T, Lansky A, Sullivan PS. Surveillance of HIV risk and prevention behaviors of men who have sex with men--a national application of venue-based, time-space sampling. *Public Health Rep.* 2007;122 Suppl 1:39-47.

4. Iachan R, Finlayson T, Kyle T, Le B, Wejnert C, Paz-Bailey G. Weighting for venue-based sampling: the MSM3 study. Paper presented at: Joint Statistical Meetings 2013; Montreal, CA.

8 Data Security and Confidentiality

8.1 HIV/AIDS Surveillance Assurance of Confidentiality

As a component of HIV/AIDS surveillance, NHBS data are protected by the Assurance of Confidentiality (Section 308(d) of the Public Health Service Act, 42 U.S.C. 242 m(d)). This assurance prohibits the disclosure of any information that could be used to directly or indirectly identify individuals. A copy of the *Assurance of Confidentiality for HIV/AIDS Surveillance Data* is provided in Appendix M.

8.2 Written Data Security Policy

In accordance with the Assurance of Confidentiality requirements, each funded health department will write a data security policy covering the NHBS data and incorporate it into their existing policy for HIV/AIDS surveillance data. The written data security policy should be approved by the Overall Responsible Party (ORP) at the funded health department prior to implementing data collection. Until this is done, NHBS project sites must apply their existing standards for HIV/AIDS surveillance, which are approved by the ORP, to the NHBS data. For guidance on developing data security policies for HIV surveillance data, consult the *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action* (available online at http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf). This document establishes the minimum data security standards for protecting HIV/AIDS surveillance data.

The written policy will describe:

- The standard operating procedures and policies for maintaining the security of NHBS data.
- A data release policy describing the provisions for protecting against access to raw data or data tables containing small-denominator populations that could be indirectly identifying and how data can be accessed and released.
- An evaluation of the data security measures outlined in the document.

8.3 Security and Confidentiality Requirements

The following are the most applicable requirements for protecting the security of NHBS data. They are not inclusive of all the requirements listed in the *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action.*

Therefore, while drafting the local data security policy, NHBS project staff should not rely solely on the requirements provided in this document, but also review in full the *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action*.

8.3a Maintain anonymity of the participants

- Participant names should not be included in any NHBS data collection instruments or systems, including QDS programs, coupon manager database, and lab slips or test results. The only number used to label and identify data from the same participant is the Survey ID.
- If written consent forms are used and local policy requires participants to sign their real names to the forms, the consent forms should not be labeled with the Survey ID and are to be maintained in a separate file from other NHBS instruments. NOTE: Consent for all NHBS participants will be documented using the portable computer and will be a part of each participant's survey record.
- If an appointment system is used for interviews, the appointment form will identify a prospective participant by the Survey ID.
- In the event that a local policy requires participants to indicate they received a token of appreciation, it is recommended that the Survey ID be used to identify the participant and NOT the participant's name or signature. If policy will not allow the use of the Survey ID in lieu of the name or signature, special care should be taken to ensure that the Survey ID is not included on the form and that the form is stored separately from NHBS instruments. In either case, any receipts should not describe the project or contain the name of the NHBS project.
- Specimens, laboratory slips, and questionnaires are to be linked using the Survey ID number and the interview date. No personal identifiers should be written or affixed to the test results or laboratory slips. All HIV tests, including confirmatory and supplemental tests, must be conducted anonymously. Any additional tests must also be anonymous.
- If permitted by local regulations, project sites may offer to call the participant and provide test results by phone. Project sites must receive CDC project officer approval before implementing call backs. Contact information (phone number) will not be linked to any document including the study name or data and will be maintained in a separate file from any data collection instruments. Contact information will be destroyed after the test results are returned.
- Unique IDs, information used to create the Unique ID, and any information about visible tattoos or physical marks collected as part of the recruitment process must be destroyed within 8 months of the Data Coordinating Center finalizing the NHBS data. Each funded NHBS site must have in place a policy requiring the destruction of such information which includes the destruction process and confirmation to the CDC Project Officer.

8.3b Protect the electronic security of surveillance databases

- Computers that can access electronic NHBS data should be physically secured and should be protected by coded passwords.
- Electronic databases containing NHBS data should be protected using coded passwords.
- Only authorized persons are to have access to electronic NHBS databases. Only individuals within the health department (and the authorized contractors) should be authorized to access NHBS data. Access to NHBS data must be defined in a formal, written data release policy.
- Access to data by personnel outside the surveillance unit must (1) be limited to those authorized on the basis of an expressed and justifiable public health need, (2) not compromise or impede surveillance activities, (3) not affect the acceptability of the surveillance system, and (4) be approved by the State ORP.
- Portable computers used for CAPI
    - Portable computers must be kept in the possession of the field staff at all times when in the field. Although the data management module of QDS is the only module that allows viewing of completed and entered interviews in the QDS files, the CAPI module of QDS (used to launch the NHBS questionnaire on the portable computers) can view incomplete interviews. Portable computers incorporate the use of encryption software. NHBS data must be encrypted when stored on a portable computer. The key for de-encryption must not be written on the computer. Since NHBS interviews are encrypted by QDS and the de-encryption key is in the QDS warehouse module, the QDS warehouse should not be loaded on the computer. Portable computers must be protected by using a coded password known only to authorized NHBS project staff. Portable computers must be collected and secured by the field supervisor after the last interview of the day. When not in use in the field, the portable computers are to be locked in a drawer or office at the health department or the contracted agency conducting the surveillance. If this is not feasible, then a plan should be developed and incorporated into the data security policy that will ensure the security of the portable computers.
    - Portable computers must be purged of NHBS data after the last interview of the day by uploading the collected interviews to the main database (e.g. QDS warehouse). This is important to minimize the amount of data carried on the portable computer. It will also minimize the number of records lost or compromised if the portable computer is lost or stolen.
- The ORP, NHBS Principal Investigator, and the CDC project officer must be notified in the event that a computer (including portable computers) containing NHBS data is lost or stolen.
- When a computer used for NHBS is taken out of service, any hard drives that may have once contained NHBS data should be reformatted before being used for another purpose.
- Other removable storage media (e.g., flash drives used to store data backups) that are no longer needed for NHBS should be destroyed and not used for another purpose.

8.3c Protect the transmission of electronic data

NHBS data will be transmitted to DCC using the DCC portal, a secure internet-based system hosted by DCC. Data submitted through the DCC portal should be encrypted before being uploaded.

Surveillance data may not be transmitted through email because copies of the data will be maintained on various servers. A secure method for transmitting data files between local computer systems must be identified. Transfer files containing the NHBS data must be encrypted using commercially available software with at least 128-bit encryption capability. Encrypted databases may be transferred to a diskette or compact disk (CD) that can then be delivered by a courier service with package tracking capability (e.g., Federal Express or UPS) to an authorized individual who can upload the data to the other computer system.

The use of modems for data transfers must be approved by the ORP and incorporate the use of access controls. In addition, the NHBS data must be encrypted prior to electronic transfer.

8.3d Protect the physical security of paper copies of NHBS forms

- Paper copies of consent forms and other NHBS forms must be stored in locked filing cabinets that are inside locked offices.
- Only authorized persons should have access to paper copies of NHBS forms.
- Paper copies of completed consent forms and NHBS forms should be kept secured while interviews are being conducted in the field. Interviewers should use a clipboard or other device to gather these files during office hours and maintain possession of them throughout the field event. Field supervisors must gather all paper copies of completed consent forms and NHBS forms at the end of each field event and store them in a locked cabinet at the health department or within the field office.

8.3e Require project staff to take individual responsibility in protecting data

- All authorized NHBS project staff must sign a confidentiality statement (see Standard 1.7 in *Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs*). Newly hired staff must sign a confidentiality statement before access to NHBS data is authorized. This statement must indicate that NHBS data will not be released to unauthorized individuals. The original statement must be held in the employee's personnel file and a copy given to the employee. Staff must sign the confidentiality statement on an established periodic basis (at least annually).
- All authorized NHBS project staff with access to data must be knowledgeable about the data security policies and procedures. The written data security policy should be readily available and data security awareness trainings should be provided at regular intervals (at least annually).
- NHBS project staff should not discuss the participants or the information shared during the questionnaire interviews with any unauthorized individual. Interviewers may share information with field supervisors or other project managers who have authorized access to NHBS data for problem-solving issues that arise in the field.

- Each NHBS project staff member will be responsible for protecting their workstation, laptop or portable computer that contains NHBS data. This responsibility includes protecting the keys to the physical space (e.g., offices), passwords, and other codes that would allow access to sensitive data. In addition, NHBS project staff must take care not to infect the computers with viruses or damage the equipment through exposure to the elements or misuse.
- NHBS project staff must not install software on the portable computers or laptops containing NHBS data without prior approval of the CDC project officer.
- NHBS project staff should keep completed NHBS forms secured while interviewing in the field; use of clipboards or other devices that are in the possession of the interviewer at all times during field operations is recommended for this purpose.
- NHBS project staff must shred documents containing sensitive information before disposing of them.

8.4 Breaches in Data Security Procedures

Breaches in the data security procedures should be investigated promptly by NHBS staff to assess the causes and implement remedies. Confirmed breaches resulting in the release of sensitive information should be reported to the ORP, the NHBS Principal Investigator, the local IRB (if applicable), and the CDC Project Officer within 48 hours of the adverse event.

9 Human Subjects Considerations

9.1 Institutional Review Board Approval

CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Associate Director for Science Office determined NHBS-Trans to be a routine disease surveillance activity (Appendix E). Because CDC has classified NHBS-Trans as surveillance and not research, CDC does not require project sites to submit NHBS-Trans to their local IRB(s) for review and approval. Nevertheless, sites must still adhere to their local policies for human subjects protection. These policies may require sites to submit NHBS-Trans to their local IRB(s) for a research determination or for an expedited or full review. Even if a local IRB determines that NHBS-Trans is not research, CDC still recommends that the project site obtain local IRB approval for NHBS-Trans due to the human subjects requirements of many scientific journals.

Participation in formative activities involves the completion of an anonymous interviewer-administered interview or facilitator-led focus group. Consent will be obtained for interviewer-administered key informant interviews (Appendices A and B) and facilitator-led focus groups (Appendix C). Participation in surveillance activities involves the completion of an anonymous interviewer-administered risk behavior survey and voluntary HIV counseling and testing; these activities are described to the participant during the informed consent process (Appendix F). The interviewer will document consent in the portable computers used for interviewing by indicating whether consent was obtained for the survey, for HIV testing and, where applicable, other tests (e.g., STI) or specimen storage.

9.1a Justification of waiver of documentation of informed consent

For this protocol, a waiver of documentation of informed consent is recommended. The only record linking the subject and NHBS activities would be the consent document, and the principal risk is the potential harm resulting from a breach of confidentiality. This protocol presents no more than minimal risk of harm to subjects. If necessary, NHBS Principal Investigators should request a waiver of documentation of informed consent to allow the use of oral consent (Appendix N) on the basis that NHBS presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of a research context.

9.2 Potential Risks and Anticipated Benefits

Participation in NHBS presents no more risks to respondents than that which might occur outside of the context of surveillance. These non-surveillance contexts include participation in individual or group HIV prevention activities and interactions with HIV prevention and health-care providers in public or clinical settings. Similar to these contexts, participating in NHBS might cause discomfort to those participants who do not recognize their risks for HIV/STI infection.

Although privacy will be protected to the greatest extent possible, some acquaintances may recognize those respondents who enter field site locations, and who choose to participate.

9.2a Risks and benefits of the survey

Participants may benefit from participating in the NHBS survey by better recognizing their own risks for HIV infection, speaking to trained staff about how to reduce those risks, learning more about local HIV prevention efforts, and obtaining prevention materials and referrals for health care, drug treatment, or HIV/STI testing and prevention services. Participating in NHBS also benefits communities by helping prevention planners to better direct state and local HIV prevention efforts.

Participants may feel uncomfortable about some of the questions in the survey, particularly those that are about sex and drug use.

9.2b Risks and benefits of testing

The risks of participating in the testing component of NHBS are minimal and include those associated with loss of anonymity, drawing blood, and returning test results. Drawing blood may cause temporary discomfort such as bruising and rarely, infection. Some persons may pass out, and some have become injured while having their blood drawn; both of these circumstances are rare. There is minimal risk of secondary infection associated with phlebotomy. Disclosure of confirmed reactive or preliminary positive HIV test result may cause substantial psychological trauma. The risks of participating in additional testing for STIs are minor and include gagging and temporary discomfort from collecting pharyngeal swabs and temporary irritation, discomfort, and mild bleeding from collecting a rectal swab.

Individuals who agree to participate in HIV testing will receive counseling about how to prevent acquiring or transmitting HIV infection and, if appropriate, referral to local programs, support groups and health care providers. For sites conducting other testing, participants with positive results will be referred to treatment services. Participants will receive information or referrals to other available services as appropriate.

9.3 Voluntary Participation

Participation in NHBS is completely voluntary. Participants can refuse to participate in the NHBS survey or in the testing component(s) without penalty. Participants are not required to take an HIV or STI test to participate in the survey. However, participants will not be able to receive an HIV or STI test without first completing the NHBS survey. Once participants have started the survey, they can refuse to answer any question or end the survey at any time without penalty. Participants whom NHBS project staff deem mentally incompetent to give informed consent, including those who are inebriated with alcohol or drugs, will not be allowed to participate in the interview.

All consent forms, questionnaires, and other survey instruments will be professionally translated into Spanish and certified. All consent forms, questionnaires, and survey instruments in Spanish will be administered by Spanish-speaking NHBS project staff.

9.4 Vulnerable Populations

Persons under the age of 18 years of age will not be included in NHBS. Prisoners and pregnant women are not specifically targeted in sampling procedures for this project, but may be recruited for NHBS if they meet eligibility criteria. No special procedures are required for the participation of pregnant women. Persons with mental disabilities may also be included; however any person who cannot provide informed consent will be excluded from participation in the project. Interviewers will be trained to identify participants who cannot provide informed consent; these persons will be given the opportunity to reschedule their appointment as appropriate. All participants will be afforded the same protections.

9.5 Informed Consent Process

Participants will take part in an informed consent process prior to beginning the survey. A model statement of informed consent is provided in Appendix F. Because participants may have difficulty reading and comprehending a written consent form, consent information should be read to each participant. Sites may use a summary consent if their local policies and regulations allow (Appendix G) and should provide participants with a copy of the full consent form.

Documentation of obtaining consent will be entered into the personal interview program after the eligibility screener is administered. The personal interview program will automatically end the NHBS survey questionnaire if the respondent does not agree to participate. Respondents have the option of participating in the survey but declining the HIV test or other tests that are being offered. Sometimes, participants may change their mind about taking the HIV test during survey implementation; therefore, participants who initially decline the HIV test will be offered another opportunity at the end of the survey to receive the HIV test as part of the study. NHBS respondents are not required to agree to receive the results of their HIV test in order to participate in the study.

Participants will be offered a copy of the consent forms to read along with the interviewer; they may keep the form if they wish. Consent scripts or forms developed by NHBS project sites must contain all required elements of informed consent (Appendix O). Each NHBS project site's consent script or form must be reviewed and approved by the respective CDC project officer. CDC approval must be obtained before submission to the local IRB.

9.6 Age of Participants

NHBS is a surveillance system of adults in the United States, and the methods used in NHBS are designed to recruit an adult population. Previous NHBS cycles have used the same age criteria as proposed here and successfully recruited participants aged 18 and older.[1-6]

Persons younger than 18 years of age are excluded from NHBS because a separate, age-specific study of persons less than 18 years old is warranted and preferable. Sufficient numbers of subjects less than 18 years of age would be needed for age-specific analyses to be meaningful.

9.7 Anonymity and Privacy Protections

NHBS is covered under the *Assurance of Confidentiality for HIV/AIDS Data* (Appendix M).

9.7a Anonymity protections

Participation in NHBS is anonymous. Participants will not be required to provide their names or other personal identifiers as a condition for participation. In order to prevent inadvertent linkage, consent forms that must be signed (due to local IRB requirement) are not labeled with a Survey ID number and are maintained separately from other documents. Blood specimens, lab slips, coupons and questionnaires are linked by Survey ID numbers only. No personal identifiers are on any of these forms. If participants voluntarily disclose their names or personal identifiers, these will not be maintained by NHBS- project staff nor linked with any survey instrument.

Project sites may offer to call the participant with their test results or to provide reminders for appointments. If contact information (phone number) are collected, this information will only be available to local staff and will not be submitted to CDC. Participants' contact information will be destroyed after they receive their test results. Contact information will not be linked to any data and will be maintained in a separate file from any data collection instruments.

Participants who agree to become peer-recruiters will be asked to provide certain information, such as physical characteristics, in order for NHBS project staff to provide tokens of appreciation to participants who return to collect them. This information will be kept in the coupon manager database for the purposes of accurate accounting of tokens of appreciation and will be destroyed after the completion of recruitment and data closeout. The coupon manager database is password-protected.

9.7b Privacy protections

NHBS project staff will always conduct surveillance activities in ways that adhere to the ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality, and autonomy of participants.

Paper copies of NHBS consent forms, test results or other forms will be stored in locked filing cabinets that are maintained in secure office environments with limited and controlled access.

Equipment used to administer the CDC-developed personal interview program (including portable computers) will be password protected. Computers and networks where data will be downloaded and stored will also be password protected. Only authorized project staff will have access to completed survey data and study files. All project staff that will have access to the NHBS data must undergo local security and confidentiality training and must sign a statement of confidentiality.

The NHBS project sites will send data to CDC using the Data Coordinating Center (DCC), managed by ICF Macro. The DCC must use the secure data transfer algorithm, FIPS 140-2 (Federal Information Processing Standards Publication). Information about the algorithm can be found at this web-site (http://www.csrc.nist.gov/publications/fips/fips140-2/fips1402.pdf). The secure data transfer methodology is compliant and meets the guidelines set forth in OMB memorandum M-0404 (E-Authentication Guidance for Federal Agencies) (http://www.whitehouse.gov/omb/memoranda/fy04/m04-04.pdf) and NIST Special Publication 800-63 (E-Authentication Guideline: Recommendation of the National Institute of Standards and Technology) (http://csrc.nist.gov/publications/nistpubs/800-63/SP800-63V1_0_2.pdf). The DCC data management systems must be in compliance with OMB, HHS, and CDC Certification and Accreditation Guidelines outlined in NIST SP 800-37 (Guide for Applying the Risk Management Framework to Federal Information Systems) (http://csrc.nist.gov/publications/nistpubs/800-37-rev1/sp800-37-rev1-final.pdf). In addition to the technical requirements listed above, data management processes must be in compliance with The Guidelines for HIV/AIDS Surveillance – Security and Confidentiality. (http://www.cdc.gov/hiv/topics/surveillance/resources/guidelines/guidance)

9.8 Tokens of Appreciation

Activities that are part of NHBS include the survey (which is the only activity required for participation) and taking a voluntary HIV and (where applicable) STI test. Participants will receive a small token of appreciation for participation in NHBS activities. The type and approximate value of tokens of appreciation are determined locally by the NHBS project sites; included in this document are examples of tokens of appreciation used in previous NHBS cycles or other similar studies.

Respondents will receive a token of appreciation of approximately $25 in cash for their participation in the NHBS survey. If local regulations prohibit cash disbursement, equivalent non-cash tokens of appreciation may be offered in the form of gift certificates; however, all non-cash tokens of appreciation should have appropriate value to the population. The formative assessment process can help verify what types of non-cash tokens of appreciation are appropriate. All participants will be offered referrals to and materials with appropriate prevention information, testing resources, medical services, and other support services.

HIV antibody and STI tests will be provided at no cost to participants. In addition, participants will receive a token of appreciation of approximately $25 for their time and inconvenience. Appropriate risk-reduction counseling will be provided to all participants who elect testing for

HIV. Interviewers will target prevention messages to specific risks identified from the during the interview. Barriers to risk reduction will be assessed, and methods to reduce or remove those barriers will be explored as appropriate for the participant.

Participants will receive their tokens of appreciation after the survey has been administered and the specimen collected for HIV testing (if participant agrees to the HIV test). Project sites may choose to have either the coupon manager provide and document receipt of tokens of appreciation.

In RDS, voluntary recruitment of peers constitutes an additional, voluntary, NHBS activity. Participants who agree to recruit their peers receive a small token of appreciation for each eligible person they recruit into the project; the average amount of these is $10 for each eligible person recruited into the project, and the number of peer-recruits is limited to up to 5 persons.

9.9 Adverse Events

9.9a Definition of an adverse event

In NHBS, adverse events are defined as events leading to serious psychological, social, or physical harm to a participant that result from his or her participation in the study, including responding to the survey, and that are reported to or observed by any project staff. Adverse events should be distinguished from the mild, transient, and normal discomfort or awkwardness that some participants may experience during risk behavior interviewing (such as fidgeting in the seat, seeming apprehensive when speaking, not looking at the interviewer or looking down, blushing).

9.9b Examples of adverse events

- **Violations of confidentiality or privacy.** Having information about their participation disclosed by a member of NHBS project staff.
- **Hazing, harassment, or violence.** Examples are emotional trauma, physical violence or verbal abuse directed at a participant or project staff as a result of taking part in an interview.
- **Negative reactions from the community.** An example is a participant losing housing or other services because of participation in the study.
- Complaints about **inappropriate behavior on the part of NHBS project staff.**
- **Psychological or physical trauma** as a result of HIV testing.
- **Violations of the NHBS protocol**.

9.9c Response to adverse events

Adverse events must be taken seriously and handled in a consistent manner by all NHBS project staff. The field supervisor must be notified of the event within 24 hours. The field supervisor will determine whether the reported event was related to NHBS and will document and report the

event and its outcome. Adverse events determined to be related to NHBS must be reported to CDC and all local IRBs that reviewed and approved the protocol within 2 business days or earlier as mandated by local IRB and local health department guidelines; the CDC NHBS staff will report adverse events to the Associate Director for Science in the Division of HIV/AIDS Prevention for review and follow-up.

NHBS project staff are trained to respond to emergency situations involving NHBS participants, such as if a participant expresses suicidal feelings upon receiving a positive HIV test result. NHBS personnel are locally trained to respond to questions and concerns from participants who consent to HIV testing. They are also trained in de-escalation techniques, and how to respond to emergencies (e.g., fire/police/hospital contact numbers).

9.10 References

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2. Lansky A, Sullivan PS, Gallagher KM, Fleming PL. HIV behavioral surveillance in the U.S.: a conceptual framework. *Public Health Rep.* 2007;122 Suppl 1:16-23.

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4. CDC. Characteristics associated with HIV infection among heterosexuals in urban areas with high AIDS prevalence - 24 cities, United States, 2006-2007. *MMWR Morb Mortal Wkly Rep.* 2011;60(31):1045-1052.

5. CDC. HIV testing among men who have sex with men--21 cities, United States, 2008. *MMWR Morb Mortal Wkly Rep.* Jun 3 2011;60(21):694-699.

6. CDC. HIV Infection and HIV-Associated Behaviors Among Injecting Drug Users - 20 Cities, United States, 2009. *MMWR Morb Mortal Wkly Rep.* Mar 2 2012;61:133-138.

Appendix A Model Key Informant Interview Consent Form

English Version; Grade Reading Level by Flesch-Kincaid Method: 7.9

National HIV Behavioral Surveillance
Key Informant Consent Form

A. Purpose

The [**Agency Name**] and the Centers for Disease Control and Prevention (CDC) are doing a study of persons who may be at risk for HIV infection, and who will be asked to take an HIV test. The reason for this interview is to learn about the best way to do this future study. We are asking you to participate in this interview because you may be able to provide us with ideas about the future study.

B. Procedures

If you agree to be interviewed, this is what will happen.

1. During the interview, a staff member will ask you questions about the following issues:
    a. Ways to encourage participants to take the survey;
    b. Reasons people might not want to take an HIV test, and ways to encourage them to do so;
    c. Appropriate incentive levels for survey participation and HIV testing;
    d. Descriptions of local neighborhoods and communities of persons at-risk of HIV.

2. Notes from the interview will be recorded on paper.

3. You can refuse to answer a question at any time. If you do not answer a question or want to end the interview, there will not be any penalty to you. No one except the study staff at [**Agency Name**] will have access to the information you provide to us.

The interview is anonymous. Your name will not be attached to your responses.

C. Discomforts and Risks

There are no physical risks to you by participating in this interview. No one will ask about your own behaviors, and you should not share this information during your interview.

D. Benefits

There are no direct benefits by being in this interview. The information you give us may help us have a better future study.

E. Compensation

You will not be paid for the time you spend taking part in the interview.

F. Persons to Contact

This study is run by: [*name of principal investigator and phone number*]. You may call them with any questions about being interviewed.

If you have questions about your rights as a participant or if you feel that you have been harmed, contact [*IRB committee or contact name and phone number*].

G. Confidentiality Statement

What you tell us is confidential. No one except the study staff at [**Agency Name**] and CDC will have access to your comments, except as otherwise required by law. Any comments made by you will not be attributed to you as an individual but to the collective group of individuals we interview as a whole. This interview will not be audio- or video-taped.

H. Right to Refuse or Withdraw

Doing this interview is VOLUNTARY. You have the right to refuse to answer any questions. You can end the interview at any time you want.

I. Agreement

Do you have any questions?

Interviewer: Answer the participant's questions about the interview before proceeding to the next question.

You have read or had read to you the explanation of this study, you have been given a copy of this form, the opportunity to discuss any questions that you might have and the right to refuse participation. I am going to ask for your consent to participate in this interview. By saying yes, you agree to participate in the interview. Do you agree to take part in the interview?

Date: _____ Interviewer initials in box confirm affirmative consent
I have fully explained to the participant the nature and purpose of the procedures described above and the risks involved in its performance. I have asked if any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

Date: _____ Signature of interviewer: _____

Apéndice A Modelo de hoja de consentimiento para la entrevista con un informante clave

Sistema nacional de vigilancia del comportamiento relacionado con el VIH
Hoja de consentimiento para la entrevista con un informante clave

A. Propósito

El/la [**nombre de la agencia**] y los Centros para el Control y la Prevención de Enfermedades (CDC) están haciendo un estudio sobre personas que pueden estar en riesgo de infectarse por el VIH, y a quienes se les pedirá que se hagan la prueba del VIH. El propósito de esta entrevista es conocer la mejor manera de hacer este estudio futuro. Le pedimos que participe en esta entrevista porque usted podría darnos ideas para el estudio futuro.

B. Procedimientos

Si usted acepta participar en la entrevista, esto es lo que sucederá.

1. Durante la entrevista, un miembro del personal le hará preguntas sobre los siguientes temas:
    a. Maneras de animar a las personas para que participen en la encuesta.
    b. Razones por las que las personas no quieren hacerse la prueba del VIH y maneras de animarlas a hacérsela.
    c. Incentivos adecuados por participar en la encuesta y hacerse la prueba del VIH.
    d. Descripción de los vecindarios y grupos locales de personas en riesgo de contraer el VIH.

2. Se tomarán notas en papel sobre lo que se diga en la entrevista.

3. Usted puede negarse a contestar alguna pregunta en cualquier momento. Si no contesta alguna de las preguntas o quiere terminar la entrevista, no se le penalizará de ninguna manera. Nadie, a excepción del personal del estudio de [**nombre de la agencia**] tendrá acceso a la información que usted nos brinde.

La entrevista es anónima. Su nombre no se asociará a sus respuestas.

C. Molestias y riesgos

No hay ningún riesgo físico por participar en esta entrevista. No se le preguntará sobre sus propios comportamientos y usted no deberá compartir esta información durante la entrevista.

D. Beneficios

No hay beneficios directos por participar en esta entrevista. La información que nos brinde nos podría ayudar a mejorar el estudio futuro.

E. Compensación

No se le pagará por el tiempo que dedique a participar en esta entrevista.

F. Personas para contactar

Este estudio está dirigido por: [*nombre y número de teléfono del investigador principal*]. Puede llamarle para hacer cualquier pregunta que tenga sobre la participación en la entrevista.

Si tiene preguntas sobre sus derechos como participante o si considera que ha sido afectado, comuníquese con [*Comité de Revisión Independiente (Independent Review Board o IRB), o nombre y número de teléfono del contacto*].

G. Declaración de confidencialidad

Lo que usted nos diga es confidencial. Nadie tendrá acceso a sus comentarios, con excepción del personal del estudio de [**nombre de la agencia**] y de los CDC, a menos que la ley lo requiera. Cualquier comentario que usted haga no se asociará a usted individualmente, sino que se atribuirá al grupo de personas entrevistadas. Esta entrevista no se grabará ni en audio ni en video.

H. Derecho a negarse o a retirarse

La participación en esta entrevista es VOLUNTARIA. Usted tiene derecho a negarse a responder cualquier pregunta. Puede terminar la entrevista en cualquier momento que lo desee.

I. Acuerdo

¿Tiene alguna pregunta?

Entrevistador: Responda a las preguntas del participante sobre la entrevista antes de pasar a la pregunta siguiente.

Usted ha leído o le han leído la explicación de este estudio, ha recibido una copia de esta hoja, ha tenido la oportunidad de hacer las preguntas que pudo tener y tiene el derecho de negarse a participar. Ahora le voy a pedir su consentimiento para participar en esta entrevista. Si responde que sí, significa que está de acuerdo en participar en esta entrevista. ¿Acepta participar en esta entrevista?

Fecha: _____ Las iniciales del entrevistador en la casilla confirman el consentimiento obtenido

He explicado en detalle al participante la naturaleza y el propósito de los procedimientos descritos anteriormente y los riesgos que implica su participación. Le he preguntado si tiene dudas sobre los procedimientos y le he respondido a mi mejor saber y entender.

Fecha: _____ Firma del entrevistador: _____

Appendix B Model Community Key Informant Interview Consent Form

English Version; Grade Reading Level by Flesch-Kincaid Method: 7.9

National HIV Behavioral Surveillance
Community Key Informant Consent Form

A. Purpose

The [**Agency Name**] and the Centers for Disease Control and Prevention (CDC) are doing a study of persons who may be at risk for HIV infection, and who will be asked to take an HIV test. The reason for this interview is to learn about the best way to do this future study. We are asking you to participate in this interview because you may be able to provide us with ideas about the future study.

B. Procedures

If you agree to be interviewed, this is what will happen.

1. During the interview, a staff member will ask you questions about the following issues:
    a. Ways to encourage participants to take the survey;
    b. Reasons people might not want to take an HIV test, and ways to encourage them to do so;
    c. Appropriate incentive levels for survey participation and HIV testing;
    d. Opinions that people in this neighborhood have about HIV and HIV prevention.
    e. Descriptions of local neighborhoods and communities of persons at-risk of HIV.

2. Notes from the interview will be recorded on paper.

3. You can refuse to answer a question at any time. If you do not answer a question or want to end the interview, there will not be any penalty to you. No one except the study staff at [**Agency Name**] will have access to the information you provide to us.

4. The interview is anonymous. Your name will not be attached to your responses.

5. You will receive $25.00 for the time you spend taking part in the interview.

C. Discomforts and Risks

There are no physical risks to you by participating in this interview. No one will ask about your own behaviors, and you should not share this information during your interview.

D. Benefits

There are no direct benefits by being in this interview. The information you give us may help us have a better future study.

E. Compensation

You will be paid $[XX] for the time you spend taking part in the interview.

F. Persons to Contact

This study is run by: [*name of principal investigator and phone number*]. You may call them with any questions about being interviewed.

If you have questions about your rights as a participant or if you feel that you have been harmed, contact [*IRB committee or contact name and phone number*].

G. Confidentiality Statement

What you tell us is confidential. No one except the study staff at [**Agency Name**] and CDC will have access to your comments, except as otherwise required by law. Any comments made by you will not be attributed to you as an individual but to the collective group of individuals we interview as a whole. This interview will not be audio or video-taped.

H. Right to Refuse or Withdraw

Doing this interview is VOLUNTARY. You have the right to refuse to answer any questions. You can end the interview at any time you want.

I. Agreement

Do you have any questions?

Interviewer: Answer the participant's questions about the interview before proceeding to the next question.

You have read or had read to you the explanation of this study, you have been given a copy of this form, the opportunity to discuss any questions that you might have and the right to refuse participation. I am going to ask for your consent to participate in this interview. By saying yes, you agree to participate in the interview. Do you agree to take part in the interview?

Date: _____ Interviewer initials in box confirm affirmative consent
I have fully explained to the participant the nature and purpose of the procedures described above and the risks involved in its performance. I have asked if any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

Date: _____ Signature of interviewer: _____

Apéndice B Modelo de hoja de consentimiento para la entrevista con un informante clave de la comunidad

Sistema nacional de vigilancia del comportamiento relacionado con el VIH
Hoja de consentimiento para la entrevista con un informante clave de la comunidad

A. Propósito

El/la [**nombre de la agencia**] y los Centros para el Control y la Prevención de Enfermedades (CDC) están haciendo un estudio sobre personas que pueden estar en riesgo de infectarse por el VIH, y a quienes se les pedirá que se hagan la prueba del VIH. El propósito de esta entrevista es conocer la mejor manera de hacer este estudio futuro. Le pedimos que participe en esta entrevista porque usted podría darnos ideas para el estudio futuro.

B. Procedimientos

Si usted acepta participar en la entrevista, esto es lo que sucederá.

1. Durante la entrevista, un miembro del personal le hará preguntas sobre los siguientes temas:
    a. Maneras de animar a las personas para que participen en la encuesta.
    b. Razones por las que las personas no quieren hacerse la prueba del VIH y maneras de animarlas a hacérsela.
    c. Incentivos adecuados por participar en la encuesta y hacerse la prueba del VIH.
    d. Opiniones que las personas de su vecindario pueden tener sobre el VIH y su prevención.
    e. Descripción de los vecindarios y grupos locales de personas en riesgo de contraer el VIH.

2. Se tomarán notas en papel sobre lo que se diga en la entrevista.

3. Usted puede negarse a contestar alguna pregunta en cualquier momento. Si no contesta alguna de las preguntas o quiere terminar la entrevista, no se le penalizará de ninguna manera. Nadie, a excepción del personal del estudio de [**nombre de la agencia**] tendrá acceso a la información que usted nos brinde.

4. La entrevista es anónima. Su nombre no se asociará a sus respuestas.

5. Usted recibirá un pago de $25.00 por el tiempo que dedique a participar en esta entrevista.

C. Molestias y riesgos

No hay ningún riesgo físico por participar en esta entrevista. No se le preguntará sobre sus propios comportamientos y usted no deberá compartir esta información durante la entrevista.

D. Beneficios

No hay beneficios directos por participar en esta entrevista. La información que nos brinde nos podría ayudar a mejorar el estudio futuro.

E. Compensación

Usted recibirá $25 por el tiempo dedicado a participar en esta entrevista.

F. Personas para contactar

Este estudio está dirigido por: [*nombre y número de teléfono del investigador principal*]. Puede llamarle para hacer cualquier pregunta que tenga sobre la participación en la entrevista.

Si tiene preguntas sobre sus derechos como participante o si considera que ha sido afectado, comuníquese con [*Comité de Revisión Independiente (Independent Review Board o IRB), o nombre y número de teléfono del contacto*].

G. Declaración de confidencialidad

Lo que usted nos diga es confidencial. Nadie tendrá acceso a sus comentarios, con excepción del personal del estudio de [**nombre de la agencia**] y de los CDC, a menos que la ley lo requiera. Cualquier comentario que usted haga no se asociará a usted individualmente, sino que se atribuirá al grupo de personas entrevistadas. Esta entrevista no se grabará ni en audio ni en video.

H. Derecho a negarse o a retirarse

La participación en esta entrevista es VOLUNTARIA. Usted tiene derecho a negarse a responder cualquier pregunta. Puede terminar la entrevista en cualquier momento que lo desee.

I. Acuerdo

¿Tiene alguna pregunta?

Entrevistador: Responda a las preguntas del participante sobre la entrevista antes de pasar a la pregunta siguiente.

Usted ha leído o le han leído la explicación de este estudio, ha recibido una copia de esta hoja, ha tenido la oportunidad de hacer las preguntas que pudo tener y tiene el derecho de negarse a participar. Ahora le voy a pedir su consentimiento para participar en esta entrevista. Si responde que sí, significa que está de acuerdo en participar en esta entrevista. ¿Acepta participar en esta entrevista?

Fecha: _____ Las iniciales del entrevistador en la casilla confirman el consentimiento obtenido

He explicado en detalle al participante la naturaleza y el propósito de los procedimientos descritos anteriormente y los riesgos que implica su participación. Le he preguntado si tiene dudas sobre los procedimientos y le he respondido a mi mejor saber y entender.

Fecha: _____ Firma del entrevistador: _____

Appendix C Model Focus Group Consent Form

English Version; Grade Reading Level by Flesch-Kincaid Method: 7.4

National HIV Behavioral Surveillance
Focus Group Consent Form

A. Purpose

The [**Agency Name**] and the Centers for Disease Control and Prevention (CDC) will be doing a survey of persons who may be at risk for HIV infection and who will be asked to take an HIV test. The reason for the focus group is to learn about the best way to do this future study. We are asking you to be in the group because you may be able to provide us with ideas about the future study.

B. Procedures

1. If you agree to be in the focus group, you will take part in a focus group with up to 10 other people that will last between 1½ and 2 hours.

2. During the session, people will be asked questions about the following issues:
   a. Ways to encourage participants to take the survey;
   b. Reasons people might not want to take an HIV test, and ways to encourage them to do so;
   c. Payment for the survey.

3. Notes from the focus groups will be recorded on paper.

4. The focus group is anonymous. We will not record your name or any other characteristics that might identify you at any time during the interview. No one except the study staff at [**Agency Name**] will have access to the information you provide to us.

5. You will be given $[XX] for being in the focus group.

6. You can refuse to answer a question at any time. If you do not answer a question or want to leave the focus group, there will not be any penalty to you.

C. Discomforts and Risks

There are no physical risks to you by participating in this focus group. No one will ask about your own behaviors and you should not share this information during your session.

Other focus group members may say things that may make you feel uncomfortable. If this happens, the staff will help to resolve the problem.

D. Benefits

The information you give us may help us have a better future survey.

E. Compensation

You will be paid $[XX] for the time you spend taking part in the focus group.

F. Persons to Contact

This focus group is run by: [*name of principal investigator and phone number*]. You may call them with any questions about being in the focus group.

If you have questions about your rights as a participant or if you feel that you have been harmed, contact [*IRB committee or contact name and phone number*].

G. Confidentiality Statement

What you tell us is confidential. Your responses will be labeled with a study number only. No one except the study staff at [**Agency Name**] and CDC will have access to the focus group's comments, except as otherwise required by law. Any comments made by persons in this group will not be attributed to individual members but to the group as a whole. This focus group will not be audio- or video-taped.

H. Right to Refuse or Withdraw

Being in this focus group is VOLUNTARY. You have the right to refuse to answer any questions. You can leave the focus group at any time.

I. Agreement

Do you have any questions?

Moderator: Answer the participant's questions about the focus group before proceeding to the next question.

You have read or had read to you the explanation of this study, you have been given a copy of this form, the opportunity to discuss any questions that you might have and the right to refuse participation. I am going to ask for your consent to participate in this focus group. By saying yes, you agree to participate in the focus group. Do you agree to take part in the focus group?

Date: _____ Moderator initials in box confirm affirmative consent
I have fully explained to the participant the nature and purpose of the procedures described above and the risks involved in its performance. I have asked if any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

Date: _____ Signature of moderator: _____

Apéndice C Modelo de hoja de consentimiento para el grupo focal

Sistema nacional de vigilancia del comportamiento relacionado con el VIH
Modelo de hoja de consentimiento para el grupo focal

A. Propósito

El/la [**nombre de la agencia**] y los Centros para el Control y la Prevención de Enfermedades (CDC) harán una encuesta sobre personas que pueden estar en riesgo de infectarse por el VIH, y a quienes se les pedirá que se hagan la prueba del VIH. El propósito de este grupo focal es conocer la mejor manera de hacer este estudio futuro. Le pedimos que participe en el grupo porque usted podría darnos ideas para el estudio futuro.

B. Procedimientos

1. Si acepta formar parte del grupo focal, se reunirá con un grupo de hasta 10 personas durante una hora y media o dos.

2. Durante la reunión, se harán preguntas sobre los siguientes temas:
   a. Maneras de animar a las personas para que participen en la encuesta.
   b. Razones por las que las personas no quieren hacerse la prueba del VIH y maneras de animarles a hacérsela.
   c. Pago por participar en la encuesta.

3. Se tomarán notas en papel sobre los comentarios del grupo focal.

4. El grupo focal es anónimo. No mantendremos ningún registro de su nombre ni de ninguna otra característica que pueda identificarlo a usted durante la entrevista. Nadie, a excepción del personal del estudio de [**nombre de la agencia**] tendrá acceso a la información que usted nos brinde.

5. Usted recibirá [XX] dólares por participar en el grupo focal.

6. Usted puede negarse a contestar alguna pregunta en cualquier momento. Si no contesta alguna pregunta o quiere salirse del grupo focal, no se le penalizará.

C. Molestias y riesgos

No hay ningún riesgo físico al participar en este grupo focal. Nadie le preguntará sobre sus propios comportamientos y usted no deberá compartir esta información durante la reunión.

Puede ser que otros miembros del grupo focal digan algo que a usted le haga sentir incómodo. Si esto sucede, el personal ayudará a solucionar el problema.

D. Beneficios

La información que nos brinde nos podría ayudar a mejorar el estudio futuro.

E. Compensación

Usted recibirá [XX] dólares por el tiempo dedicado a participar en este grupo focal.

F. Personas para contactar

Este grupo focal está dirigido por: [*nombre y número de teléfono del investigador principal*]. Puede llamarle para hacerle cualquier pregunta que tenga sobre su participación en el grupo focal.

Si tiene preguntas sobre sus derechos como participante o si considera que ha sido afectado, comuníquese con [*Comité de Revisión Independiente (Independent Review Board o IRB), o nombre y número de teléfono del contacto*].

G. Declaración de confidencialidad

Lo que usted nos diga es confidencial. Sus respuestas serán identificadas únicamente con un número de estudio. Nadie tendrá acceso a los comentarios del grupo focal, con excepción del personal del estudio de [**nombre de la agencia**] y de los CDC, a menos que la ley lo requiera. Cualquier comentario que hagan las personas en este grupo será atribuido al grupo, y no a algún miembro individual. Este grupo de enfoque no se grabará ni en audio ni en video.

H. Derecho a negarse o a retirarse

La participación en este grupo focal es VOLUNTARIA. Usted tiene derecho a negarse a responder cualquier pregunta. Puede retirarse del grupo focal en cualquier momento.

I. Acuerdo

¿Tiene alguna pregunta?

Moderador: Responda a las preguntas del participante sobre el grupo focal antes de pasar a la pregunta siguiente.

Usted ha leído o le han leído la explicación de este estudio, ha recibido una copia de esta hoja, ha tenido la oportunidad de hacer las preguntas que pudo tener y tiene el derecho de negarse a participar. Ahora le voy a pedir su consentimiento para participar en este grupo focal. Si responde que Sí, significa que está de acuerdo en participar en este grupo focal. ¿Acepta participar en este grupo focal?

Fecha: _____ Las iniciales del moderador en la casilla confirman el consentimiento obtenido.

He explicado en detalle al participante la naturaleza y el propósito de los procedimientos descritos anteriormente y los riesgos que implica su participación. Le he preguntado si tiene dudas sobre los procedimientos y le he respondido a mi mejor saber y entender.

Fecha: _____ Firma del moderador: _____

Appendix D Data Collection Instrument

D.1 Summary of Appendix D Contents

Appendix D – Data Collection Instrument is composed of the following files:

1) English version of the NHBS-Trans CAPI Reference Questionnaire (CRQ). Filename: NHBS_Trans_CRQ_2017-10-25

2) Spanish version of the NHBS-Trans NHBS CRQ. Filename: NHBS_Trans_CRQ_2017-10-23_SP

Due to document size, the two NHBS CRQ files are often maintained as separate files from the NHBS Protocol.

REQUEST FOR NCHHSTP PROJECT DETERMINATION & APPROVAL

NCHHSTP ADS/ADLS Office on behalf of CDC (New, Continuation, or Amendment)

This form should be used to request NCHHSTP/OD/ADS or ADLS office review and approval on behalf of CDC of a new, continued, or amended project for those projects for which NCHHSTP staff/employees, branches, divisions, and center/OD/ADS or ADLS office are responsible.

Any NCHHSTP activity that meets the definition of a project (see the following section) and represents one of the four project categories must be approved by the respective NCHHSTP branch and division and by the NCHHSTP/OD/ADS or ADLS office. Approval by the NCHHSTP ADS or ADLS office (nchstphs@cdc.gov) of these projects indicates approval by CDC. This review and approval process complies with obligations for adherence of projects to federal regulations, state laws, ethics guidelines, CDC policies, and publication requirements.

For research that involves identifiable human subjects in which CDC/NCHHSTP is engaged, use CDC Human Research Protection Office forms and submit them to CDC Human Research Protection Office through the NCHHSTP ADS human subjects email box after approval at the branch and division levels.

RELEVANT INFORMATION

What is a project?

A project is defined as a time-limited activity that is funded for a specific period of time, an activity with specified funds for a limited time, or as a limited time responsibility by specific CDC employees or staff, including projects that might be ongoing or continuous for an extended period. A project has defined objectives, tasks (e.g., essential public health services), dedicated resources, and is funded for a specified time. NCHHSTP reviews and approves projects for the four project categories listed on this form. Every project officer, project team and staff, NCHHSTP branch, and NCHHSTP division or office is responsible for submitting this form for each project and for obtaining NCHHSTP OD/ADS or ADLS approval on behalf of CDC before project initiation, continuation, or amendment. Such programs as surveillance are approved and funded as specific projects for certain periods.

What is research?

The federal regulations and CDC/OD/ADS office define ***research*** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research, regardless if these activities are conducted or supported under a program that is not considered research for other purposes. For example, demonstration and service programs sometimes include research activities.

What is a human subject?

A ***human subject*** is a living individual about whom an investigator (whether professional or student) conducting research obtains

1. data through intervention or interaction with the individual or
2. identifiable private information.

What is an intervention?

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

What is private information?

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is occurring and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Private information identifies individuals (i.e., the identity of the person is or might be readily ascertained by the investigator or associated with the information) for the information to constitute research involving human subjects.

What does being "engaged" mean?

An institution becomes ***"engaged"*** in human subjects research when its employees or agents intervene or interact with living individuals for research purposes, or obtains individually identifiable private information for research purposes. An institution is automatically considered to be engaged in human subjects research whenever it receives funding or resources (e.g., a direct award) to support such research. In such cases, the awardee institution has the ultimate responsibility for protecting human subjects under the award.

What is surveillance?

CDC defines ***surveillance*** as "the ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link of the surveillance chain is the application of these data to prevention and control. A surveillance system includes a functional capacity for data collection, analysis, and dissemination linked to public health programs."

What is program evaluation?

Program evaluation is the systematic collection of information about the activities, characteristics, and outcomes of programs to make judgments about the program, improve program effectiveness, or inform or guide decisions about future program development. Program evaluation should not be confused with *treatment efficacy*, which measures how well a treatment achieves its goals and that can be considered research.

Sources (links)

- http://intranet.cdc.gov/od/oads/osi/hrpo/
- http://www.hhs.gov/ohrp/index.html

PROJECT REQUEST

Project Stage

Choose one by selecting a checkbox:

- **New:** Fill out entire form, even if a protocol is attached (approval is for work by CDC/NCHHSTP employees).

  Continuation: For projects expected to continue beyond NCHHSTP approved date; include brief description of changes and attach clean and marked copies of approved determination (approval is for continued work by CDC/NCHHSTP employees).

  Amendment: Include brief description of changes and attach relevant documentation and a copy of approved project (approval is for continued work by CDC/NCHHSTP employees).

Project Information:

Project Title: National HIV Behavioral Surveillance among Transgender Women (NHBS-Trans)

NCHHSTP Project Number: 7048

Division: Division of HIV/AIDS Prevention

Project Location/Country(ies):
United States - Atlanta, GA, Los Angeles, CA, San F

Telephone: (404) 639-6055

CDC Project Officer or CDC Co-Leads:
Cyprian Wejnert, PhD

Project Dates:
Start 09/01/2017
End 12/31/2019

Laboratory Branch Submission:
If applicable, select the checkbox:

Project Categories

Select the corresponding checkbox to choose the category and subcategory.

- **I. Activity is not human subject research.** The primary intent of the project is public health practice or a disease control activity.

  A. Epidemic or endemic disease control activity; collected data directly relate to disease control. If this project is an Epi-AID; provide the Epi-AID number and documentation of the request for assistance, per division policy. Epi-AID no.

  - **B.** Routine disease surveillance activity; data will be used for disease control program or policy purposes.

  C. Program evaluation activity; data will be used primarily for that purpose.

  D. Post-marketing surveillance of effectiveness or adverse effects of a new regimen, drug, vaccine, or device.

  E. Laboratory proficiency testing.

II. Activity is not human subjects research. The primary intent is public health program activities.

A. Public health program activity (e.g., service delivery; health education programs; social marketing campaigns; program monitoring; electronic database construction or support; development of patient registries; needs assessments; and demonstration projects to assess organizational needs, management, and human resource requirements for implementation).

B. Activity is purely administrative (e.g., purchase orders or contracts for services or equipment).

III. Activity is research but does NOT involve identifiable human subjects.

A. Activity is research involving collection or analysis of data about health facilities or other organizations or units (i.e., not individual persons.)

B. Activity is research involving data or specimens from deceased persons.

C. Activity is research using unlinked or anonymous data or specimens: **ALL** (1–4) below are required:

1. No one has contact with human subjects in this project; **and**
2. Data or specimens are or were collected for another purpose; **and**
3. No extra data or specimens are or were collected for this project; **and**
4. Identifying information was (one of the following boxes must be checked)
    a. not obtained;
    b. removed before this submission, or before CDC receipt, so that data cannot be linked or re-linked with identifiable human subjects; or
    c. protected through an agreement (i.e., CDC investigators and the holder of the key linking the data to identifiable human subjects enter into an agreement prohibiting the release of the key to the investigators under any circumstances. A copy of the agreement must be attached.)

IV. Activity is research involving human subjects, but CDC involvement does not constitute "engagement in human subject research." Select only one option by checking the box: A indicates the project has current funding; B or C indicates no current funding is applicable.

A. This project is funded under a grant, cooperative agreement, or contract award mechanism. **ALL** of the following 3 elements are required:

1. CDC staff will not intervene or interact with living individuals for research purposes.
2. CDC staff will not obtain individually identifiable private information.
3. Supported institution(s) must have a Federalwide Assurance (FWA), and the project must be reviewed and approved by a registered IRB or an institutional office linked to the supported institution's FWA.*

    Supported institution of primary investigator or co-Investigators/entity name:*

Supported institution/entity FWA Number:*
FWA expiration date:*
Expiration date of IRB approval:*
***Attach copy of IRB approval letter(s) supporting project review and approval.**

B. CDC staff provide technical support that does not involve possession or analysis of data or interaction with participants from whom data are being collected (no current CDC funding).

C. CDC staff are involved only in manuscript writing for a project that has closed. For the project, CDC staff did not interact with participants and were not involved with data collection (no current CDC funding).

Project Description

Participating project staff must complete all 18 elements of this section.

This is a required description from CDC employees or staff for review and approval of a project plan or proposal (or for changes) for projects conducted by CDC or in which CDC is involved. All 18 elements are required to standardize the review and approval process across NCHHSTP, document that all 18 elements have been addressed, expedite review and approval by the NCHHSTP ADS or ADLS office, and minimize CDC/OD/ADS office audit requests for additional information. A protocol may be attached to this form, but it does not eliminate the requirement to complete all 18 elements.

PROJECT TITLE: National HIV Behavioral Surveillance among Transgender Women (NHBS-Trans)

Instructions: Use the following boxes to complete the 18 items. Each box will expand as you type, and you are not limited in the length of your answers. Formatting features and symbols also may be used.

1. CDC Principal Investigator(s) or Project Directors and branch/division/office affiliations:

Cyprian Wejnert, PhD - DHAP/BCSB/BST

2. CDC Project Officer(s) and each person's role and responsibilities and affiliations:

Project Officers: Kathryn Lee (Atlanta, GA site), Amanda Smith (Los Angeles, CA site), Janet Burnett (San Francisco, CA and Seattle, WA sites), Monica Adams (New Orleans, LA site), Dita Broz (New York City, NY site) and Katherine Doyle (Philadelphia, PA site).

Activity Leads: Dita Broz (Implementation Lead), Cyprian Wejnert (Reporting Lead), Teresa Finlayson (Data Analysis and Management Lead), Kathryn Lee (NHBS-TRANS Project Lead)

Project Officers are responsible for providing technical assistance to grantees for implementation of NHBS and monitoring cooperative agreements in collaboration with the Public Health Advisor, ensuring adherence to NHBS protocols, and conducting site visits to grantees on at least an annual basis. Activity Leads are responsible for national level NHBS operations, including implementation of NHBS methods, development of protocols and other guidance documents, data management and analysis, and reporting and dissemination of NHBS outcomes.

3. Other CDC project members, branches, divisions, and other participating institutions, partners, and staff:

This cooperative agreement has eligibility limited to the directly funded city health departments containing the following Divisions of Metropolitan Statistical Areas (MSAs): Los Angeles, CA (Los Angeles Division); San Francisco, CA (San Francisco Division); New York City, NY (New York Division); Philadelphia, PA (Philadelphia Division); and the State health departments containing the following MSAs or Divisions: Atlanta, GA; New Orleans, LA; Seattle, WA (Seattle Division).

4. Institution(s) or other entity(ies) funding the project:

This project is funded by CDC and SMAIF (the Secretary's Minority AIDS Initiative Fund)

5. Project goals:

NHBS-Trans is a combined qualitative and quantitative project wherein sites conduct formative assessment activities before implementing a version of the NHBS survey for Transgender Women, with qualitative data collection activities including key informant and key community informant interviews, focus groups, and quantitative data collection activities including a behavioral assessment survey and optional HIV testing made available to those who consent to the survey and testing.

The goal of this project is to pilot quantitative data collection methods and existing NHBS infrastructure to conduct HIV surveillance among transgender women (NHBS-Trans) at national and local levels by documenting HIV prevalence, awareness of infection, risk behaviors, HIV testing, receipt of prevention services, and barriers to HIV prevention and care. Data from the behavioral surveillance system will be used for HIV prevention program planning and evaluation at the national and local levels. The purpose of NHBS formative assessment is to guide local implementation of NHBS activities to ensure successful data collection. Particularly, formative assessment can help ensure that the desired sample size is achieved and that the resulting NHBS sample is reflective of the population of interest (referred to hereafter as the 'NHBS population').

6. Project objectives:

The overall strategy for NHBS-Trans is to conduct surveillance among TG women who may be at high risk for HIV acquisition. Surveillance activities include formative assessment, behavioral assessment surveys, and HIV testing. Each of CDC's 7 collaborating organizations will conduct both qualitative and quantitative data collection activities in pursuit of the following goals: 1) conduct formative assessment activities including interviews with key informants, key community informants, and focus groups composed of members of the target communities; 2) recruit and interview at least 200 eligible transgender (TG) women using respondent driven sampling (RDS) methods; 3) conduct anonymous HIV testing on at least 80% of NHBS-Trans participants; 4) refer participants to HIV treatment and health and social services as needed.

Specific objectives of the formative assessment include the following:
1) Garner the support of the community and its stakeholders for NHBS;
2) Define the social and demographic characteristics of the local trans population;
3) Develop questions of local interest for HIV prevention;
4) Obtain information relevant to field logistics (e.g., appropriate locations and hours of operation for field site(s), whether appointment systems are feasible, and ideal attributes of field staff);
5) Identify potential "seeds", or initial recruits, for RDS;
6) Obtain information on the major networks of the NHBS-Trans population in the Division or MSA and identify networks with potentially high "homophily" (i.e. the degree of insularity or in-group preference for recruitment); and
7) Identify strategies for reaching the NHBS-Trans population for data collection (e.g., areas where the population can be reached, community and neighborhood organizations that serve the population, and individuals that are knowledgeable about and have access to the population).

Specific objectives of Behavioral Assessment Survey include the following:
1) To estimate the prevalence of HIV risk behaviors and HIV testing behaviors in TG women who may be at increased risk for acquiring HIV infection in MSAs with high AIDS prevalence.
2) To assess the exposure to and use of HIV prevention services among TG women who may be at increased risk for acquiring HIV infection.
3) To use the data collected to target local HIV prevention activities and evaluate HIV prevention programs for TG women.

7. Public health (program or research) needs to be addressed:

The primary intent of NHBS is to collect data in an ongoing and systematic manner on HIV risk behaviors, HIV testing, exposure and access to HIV prevention programs, and HIV seroprevalence and incidence.

While in high demand, such data on TG women in the US are limited for a number of reasons: 1) TG make up an estimated 0.6% of the general population. As a result, TG participants are not numerous enough in most data sets focusing on broader populations for meaningful analysis. 2) Many of the social, economic, and biological circumstances of TG persons are unique to the TG community. As a result, data systems designed for broader populations may omit information critical to addressing TG-specific needs. 3) The cultural sensitivities surrounding the TG community are complex and require culturally appropriate questions, staff, and environments to build trust among TG participants. 4) Many standard data collection forms lack appropriate ways to distinguish TG from males and females.

8. Population(s) or groups to be included:

Transgender women, ages 18 and older, living in Atlanta, GA, Los Angeles, CA, San Francisco, CA, New Orleans, LA, Seattle, WA, New York City, NY and Philadelphia, PA.

9. Project methods:

The overall strategy for NHBS-Trans is to conduct surveillance among TG women who may be at high risk for HIV acquisition. Surveillance activities include formative assessment, surveys, and HIV testing.

Formative Assessment (Qualitative)
Grantee agencies will work with ethnographers and community-based organizations in their jurisdiction to conduct formative assessment. Within the context of NHBS-Trans, formative assessment allows grantees to gain insight into the context of HIV risk behavior within certain settings and among sub-populations of the specific groups at risk in their community. Formative assessment activities include a review of existing data on the population of interest specific to the MSA, qualitative data collection, garnering the support of community stakeholders, and development of questions that measure local prevention activities.

NHBS formative assessment activities include the collection of data using methods common to qualitative and ethnographic studies of health: key informant interviews and focus groups. Each NHBS project site should follow local requirements regarding informed consent for focus groups and key informant interviews. Three model consent forms are provided (Appendices B1, B2, and B3) and should only be modified in order to meet local IRB requirements. To protect the anonymity of those interviewed, consent to participate should only be provided verbally by participants and no data collection activities should be video- or audio-taped.

Key informant interviews include interviews with individuals such as health department officials, police, business and community leaders, and others whose official duties include the dissemination of information about local communities, and for whom tokens of appreciation are not needed. Community key informants are members of the local communities who should not be expected to contribute information on community characteristics without receiving tokens of appreciation, including: community leaders, researchers and persons doing outreach who are familiar with the population, health department staff, and individuals who are members of the population of interest. Focus group participants should be recruited from within the MSA and may include community stakeholders and leaders, staff from organizations that serve at-risk populations, and community residents.

Behavioral Assessment Survey (Quantitative)

10. Selection, inclusion, or sampling of participants (persons or entities):

The project's target population is TG women within racial and ethnic minority populations, with a special emphasis on black and Latina TG women. Eligibility for NHBS-Trans will be limited to transgender women as assessed by the "two-step" approach measure of gender identity recommended by GenIUSS Group report: "Best Practices for Asking Questions to Identify Transgender and Other Gender Minority Respondents on Population-Based Surveys" (http://williamsinstitute.law.ucla.edu/wp-content/uploads/geniuss-report-sep-2014.pdf). To be eligible for the NHBS-Trans behavioral assessment survey, participants must report male sex at birth AND either female gender or male-to-female transgender identity. Additionally, eligibility will be limited using the standard NHBS eligibility criteria (age ≥18 years, resident of participating city, and able to complete interview in English or Spanish).

We will recruit 200 minority TG women in each city (total n=1,400) using respondent-driven sampling (RDS), which has a proven track record of sampling hard-to-reach populations (Malekinejad M, et al. Using RDS methodology for HIV biological and behavioral surveillance in international settings: a systematic review. AIDS & Behav. 2008; 12:105-130), including TG women (Santos GM, et al. HIV treatment cascade among TG women in a San Francisco RDS study. Sex Transm Infect. 2014; 90: 430-433). RDS is an innovative, peer-referral based sampling method which begins with a small (5-10) convenience sample of initial participants, called "seeds"; Grantees will identify seeds using community partnerships. Upon interview completion the seeds are asked to recruit up to five of their TG women peers to form the next wave of participants, who then recruit their peers, and so on until sample size is reached. In order to focus on TG women in racial and ethnic minority populations, NHBS-Trans seeds will be composed of 100% black or Latina TG women.

Key informant interviews include interviews with individuals such as health department officials, police, business and community leaders, and others whose official duties include the dissemination of information about local communities. Community key informants are members of the local communities including: community leaders, researchers and persons doing outreach who are familiar with the population, health department staff, and individuals who are members of the population of interest. Focus group participants should be recruited from within the MSA and may include community stakeholders and leaders, staff from organizations that serve at-risk populations, and community residents.

11. Incentives to be provided to participants:

Participants will be given approximately $25 in cash for participation in the behavioral assessment and $25 for taking a voluntary HIV test as a token of appreciation for participation; the specific amount will be determined by grantees based on local standards. If regulations prohibit cash tokens of appreciation, equivalent tokens may be offered in the form of gift certificates, cash cards, or bus or subway tokens.

In the RDS methodology, participants receive a token of appreciation for participating as a respondent and a reward for successfully recruiting one or more of their peers. Recruiter rewards are approximately $10 for each of up to five peer referrals, which is standard for RDS studies (Heckathorn et al., 2002; Ramirez-Valles et al., 2005; Wang et al., 2004). As with the behavioral assessment and testing incentives, if local regulations prohibit providing cash, an equivalent token of appreciation may be offered in the form of gift certificates or cash cards.

Key community informants will be given approximately $25 in cash as a token of appreciation for their participation, while key informants who are not members of the target population will not receive a token of appreciation. Focus group participants will be given a token of appreciation whose value is to be determined by site policies regarding tokens of appreciation for focus group participation.

12. Plans for data collection and analysis:

CDC will provide support to NHBS-Trans grantee sites as they recruit, interview, and conduct HIV testing for 200 TG women in each of 7 cities, for a total sample size of 1400 TG women. The entire study will be conducted anonymously, without the collection or storage of participant PII. CDC's support for these activities will include training and training materials to site-based staff, technical assistance using the suite of data collection tools provided by NHBS, guidance through implementation, assistance with ongoing formative evaluation and other forms of appropriate assistance. Sites will document HIV prevalence, awareness of infection, risk behaviors, HIV testing, receipt of prevention services, and barriers to HIV prevention and care among trans women at national and local levels. Data will be processed using established NHBS data process by the existing NHBS Data Coordinating Center.

Implementation of NHBS-Trans will occur at fixed field sites (storefront, office or van locations) identified through formative assessment. Field site locations should be easily accessible for the NHBS-Trans population, safe, culturally welcoming, and designed in a manner that ensures that participant confidentiality will be maintained. It is important to ensure that potential participants have no real or perceived barriers to the location. For example, locating a field site where local business owners or residents resist the presence of the NHBS-Trans population would present a barrier to potential participants.

Respondents may consent to the survey and any/or HIV testing. Participants must consent to the survey to be eligible for HIV testing; however, if participants do not consent to the survey but still wish to receive an HIV test, project staff in each NHBS-Trans site will provide referrals and information in order for the person to access these resources.

NHBS-Trans project sites will offer rapid HIV testing to participants with rapid or laboratory-based supplemental or confirmatory testing. Rapid testing is encouraged because it allows staff to provide preliminary results and make appropriate referrals to HIV care even for participants who may not return for lab-based supplemental or confirmatory test results. Persons who test positive for HIV on a rapid test must be asked to provide a blood or oral specimen for laboratory-based supplemental or confirmatory testing at the time that preliminary positive test results are given. Participants who are provided with rapid HIV testing will receive their results during the NHBS-Trans encounter. These participants who do not undergo rapid testing will receive their HIV test results by trained counselors within one to three weeks of the date of the specimen collection. NHBS-Trans project sites should develop flexible systems for return of HIV test results and counseling that are easily accessible by participants. During the initial encounter, the counselor will work with the participant to schedule a counseling session for return of results. The participants should be given an appointment card with the name and telephone number of the health department personnel or counselor and the date, time and location of their appointment. The appointment card must have an affixed Survey ID number to link test results to the participant. No

13. Confidentiality protections:

NHBS-Trans is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data. The Assurance provides the highest level of legal confidentiality protection to the individual persons who are the subjects of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death. NHBS-Trans is an anonymous, cross-sectional survey. All participants will be explicitly assured during the recruitment process of the anonymous nature of the survey and HIV testing. No personal identifiers are collected during enrollment, interview, or testing. All participants will provide their informed consent to take part in the interview and to be tested for HIV. Because data collection will be anonymous, participant names or other personal identifiers will not be linked to any NHBS-Trans instruments. Consent forms, questionnaires, lab forms, and other NHBS-Trans data collection forms will be maintained in confidential environments and stored in locked filing cabinets. Only authorized persons will have access to NHBS files.

14. Other ethics concerns (e.g., incentives, risks, privacy, or security):

This surveillance activity is funded through cooperative agreements with participating health departments. All data will be collected locally by grantee staff. No individually identifiable private information (i.e., the identity of the subject will be or may readily be ascertained by the investigator or associated with the information) is provided to CDC.

Participation in NHBS presents no more risks to respondents than those that might occur outside the context of surveillance. Non-surveillance contexts include participation in individual or group HIV prevention activities and interactions with HIV prevention and health care providers in public or clinical settings. Respondents may benefit from participating in NHBS-Trans by better recognizing their own risks for acquiring HIV or other sexually transmitted infections, talking with trained staff about how to reduce those risks, learning more about local HIV prevention efforts, and obtaining prevention materials and referrals for health care, social, and prevention services. NHBS-Trans participation will benefit communities by helping HIV prevention and care planners more appropriately allocate state and local HIV prevention resources and federal, state, and local HIV care services.

Neither persons under the age of 18 years nor prisoners will be included in NHBS-Trans. Pregnant women may be included. Persons with mental disabilities may be included in the sample; however, any person who cannot provide informed consent will be excluded from participation in the project. All participants will be afforded the same human rights protections.

BCSB will monitor local review of the NHBS-Trans surveillance protocol on an annual basis; grantees are encouraged to use the model consent form for NHBS (see Appendix A, below, for the current model consent form) which conforms to CDC's IRB requirements for informed consent. Sites may choose to use a summary version of the consent form (see Appendix B, below, for the model consent talking points) and provide participants with a copy of the full consent form. Waivers of documentation of informed consent will be requested by the grantees because the only record linking the subject and the project would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. The NHBS-Trans protocol presents no more than minimal risk of harm to subjects. Participation involves the completion of an anonymous interviewer-administered risk behavior questionnaire and voluntary HIV counseling and testing. Based on available funding, some sites may also conduct testing for other sexually transmitted and bloodborne infections (e.g., HBV, HCV) or store remnant blood samples for up to 10 years after collection. At the same time consent is obtained for the survey and HIV test, consent will be obtained to perform any other tests and to store blood specimens for future testing. Blood will be drawn for the other tests at the time of the survey. Consent will be documented by the interviewer, who will record in the computers used for conducting interviews that consent was obtained for the survey and for testing.

Because CDC has classified NHBS as surveillance and not research, CDC does not require project sites to submit NHBS to their local IRB(s) for review and approval. Nevertheless, sites must still adhere to their local policies for human subjects protection. These policies may require sites to submit NHBS to their local IRB(s) for a research determination or for an expedited or full review. Even if a local IRB determines that NHBS is not research, CDC still recommends that the project site obtain local IRB approval for NHBS due to the human subjects requirements of many

15. Projected time frame for the project:

9/1/2017 - 12/31/2019

16. Plans for publication and dissemination of the project findings:

CDC will disseminate the information through: 1) DHAP surveillance reports, presentations, and publications and 2) providing assistance to grantees for their local dissemination efforts.

NHBS-Trans collaborators will disseminate findings from project activities through presentations, reports, and publications to community, public health, and scientific partners at local and national levels.

17. Appendices — including informed consent documents, scripts, data collection instruments, focus group guides, fact sheets, or brochures:

Att_A_ NHBS Questionnaire CoverPage_Trans.doc

Att_B1_KeyInformant Consent_Trans.doc
Att_B1_SPAN KeyInformantConsent_Trans.doc
Att_B2_CommunityKeyInformantConsent_Trans.doc
Att_B2_SPAN Community KI Consent_Trans.doc
Att_B3_Focus Group Consent_Trans.doc
Att_B3_SPAN FocusGroupConsent_Trans.doc

Att_C1_Model Consent Form_Trans.doc
Att_C1_SPAN Model Consent Form_Trans.doc

Att_D_Model Coupon_Trans.doc
Att_E_ModelRecTalkingPts_Trans.doc

Att_F_HIV Testing Log_Trans.doc

Att_G_AssuranceConfidentiality_Trans.doc
Att_H_WaiverInformed Consent_Trans.doc
Att_I_ElementsofInformedConsent_Trans.doc

Informed consent for the survey participation must be obtained if required by state and local IRBs for participating project areas, but may be waived with site IRB approval. A model consent form that can be modified for local area use is included in Attachment C1.

18. References (to indicate need and rationale for project):

Arnett JJ. Emerging adulthood. A theory of development from the late teens through the twenties. Am Psychol 2000;55:469-480.
Centers for Disease Control and Prevention. Sexual identity, sex of sexual contacts, and health-risk behaviors among students in grades 9-12 —youth risk behavior surveillance, selected sites, United States, 2001-2009. MMWR Early Release 2011;60(June 6).
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Draus P, Siegal H, Carlson R, Falck R, Wang J. Cracking the cornfields: Recruiting illicit stimulant drug users in rural Ohio. The Sociological Quarterly 2005; 46:165-189.
Dudley M, Rostosky S, Korfhage B, Zimmerman R. Correlates of high-risk sexual behavior among young men who have sex with men. Aids Education and Prevention 2004;16:328-340.
Elford J, Bolding G, Davis M, Sherr L, Hart G. The Internet and HIV study: design and methods. Bmc Public Health 2004;4.
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PROJECT APPROVAL

Choose one of the following options (Division or Center/OD Project)

- **DIVISION PROJECT**

NCHHSTP BRANCH AND DIVISION ADS REVIEW AND APPROVAL (Sign electronically by clicking next to the X and following the prompts)

X Heather M. Bradley -S — Digitally signed by Heather M. Bradley -S Date: 2017.08.25 15:05:35 -04'00'

Branch Chief or Branch Science Officer

X Laura J. Fehrs -S — Digitally signed by Laura J. Fehrs -S Date: 2017.09.06 15:40:49 -04'00'

Division ADS, Acting ADS, or Deputy ADS

CENTER/OD PROJECT

NCHHSTP OD OFFICE REVIEWS AND APPROVALS (Sign electronically by clicking next to the X and following the prompts)

X

Office Associate Director or Designee

X

NCHHSTP ADS or Designee

NCHHSTP ADS/DEPUTY ADS OR ADLS REVIEW AND APPROVAL

Project Title: National HIV Behavioral Surveillance among Transgender Women (NHBS-Trans)

Date received in NCHHSTP ADS or ADLS office:

Date received by NCHHSTP Deputy ADS or ADLS:

Select the checkbox for each applicable comment for Nos. 1–5 or select the checkbox for No. 6 if all of the comments apply. Additional applicable comments may be added to No. 7. If additional information is required before approval can be granted, select No. 8.

1. This project is approved by NCHHSTP/CDC and CDC (per CDC policies and federal regulations) for CDC staff participation.
2. Participating partners and sites must obtain project review and approval, according to their institutional policies and procedures and according to local, national, and international regulations and laws, including 45 CFR 46 regulations and state laws. CDC project officers must maintain a current copy of local sites' approvals in project records.
3. CDC investigators and project officers need to adhere to the highest ethics standards of conduct and to respect and protect the privacy, confidentiality, autonomy, data, welfare, and rights of participants and integrity of the project. All applicable country, state, and federal laws and regulations must be followed.
4. Informed consent or script is needed as required by laws and regulations. Information conveyed in an informed consent or script process needs to address all applicable required elements of informed consent. Consent of employees in related projects about their institutions needs to include a statement that their voluntary participation or withdrawal would not affect their employment status or opportunities.
5. OMB Paperwork Reduction Act determination by the NCHHSTP OMB/PRA Coordinator might be needed for this project.

■ 6. **All** previous comments apply.

7. **Other applicable comments:** Type your comment in the box. The space will expand as you type.

8. **More information is required before approval is granted:** Explain what additional information is requested by typing in the box. The space will expand as you type.

Date Information was requested:

Date Information was received:

Approval must be granted by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Associate Director for Science (ADS), Acting ADS, or Deputy ADS, or for laboratory-associated projects, by the Associate Director for Laboratory Science (ADLS) or Acting ADLS.

Project Title: National HIV Behavioral Surveillance among Transgender Women (NHBS-Trans)

X Alcia A. Williams -S6 Digitally signed by Alcia A. Williams -S6 Date: 2017.09.29 12:33:53 -04'00'

NCHHSTP ADS, Acting ADS, or Deputy ADS

Or

X

NCHHSTP ADLS or Designee

Appendix F Model Consent Form

English Version; Grade Reading Level by Flesch-Kincaid Method: 7.3

National HIV Behavioral Surveillance
Model Consent Form

The [**Agency Name**] and the Centers for Disease Control and Prevention (CDC) invite you to be part of a study about HIV in your community The information I will give you can help you make a good choice about joining the study.

A. Why we are doing this project

The purpose of this study is to learn about risk for HIV. We will use this information to plan better HIV prevention and treatment programs for people in your community. This study is anonymous which means that no one will know your name or be able to identify you. Being in this study is voluntary.

B. What will happen

If you agree to be in this study, this is what will happen.

1. You will do a survey with a trained staff member.

The survey has questions about your health, drug use, sex practices, and HIV prevention services. It will take about 40 minutes. At the end of the survey, I may offer you a chance to recruit up to 5 other people for this study.

2. If you agree to the survey, we will offer you a free HIV test. If you already know that you are HIV-infected, we would still like to offer you an HIV test today so that we can link today's HIV test result with your survey results.

3. *[For sites doing HIV tests on blood only]* If you agree to an HIV test, you will also be asked to have your blood sample stored

4. *[For sites doing hepatitis testing]* We will also offer you free hepatitis B and C testing.

5. *[For sites doing STI testing]* We will also offer you free gonorrhea and chlamydia testing.

If you agree to the HIV test, you will have a 10- to 15-minute HIV prevention counseling session with a trained staff member. The session will cover the meaning of results from the HIV test. You will also learn about how to reduce your chances of being infected with HIV and other infectious diseases.

The HIV test will be done by a *[For sites doing the Standard Test:* standard] *[For sites doing the Rapid Test:* rapid] test as discussed below.

[For sites doing the Standard Test]
Standard Test
We will [draw less than 1 tablespoon of your blood using a needle/ stick the tip of one of your fingers to obtain a few drops of blood/take a swab from your mouth] and test it for HIV. Your test results will be ready within one week. We will set up a day and time for you to get your results. You will get counseling about what the test results mean and referrals to services, if needed. [*For sites that allow HIV test phone results:* If you cannot return for your HIV test results, you can arrange to receive your counseling and test results by telephone.]

[For sites doing the Rapid Test]
Rapid Test
We will [stick the tip of one of your fingers to obtain a few drops of blood/take a swab from your mouth]. You will get counseling about what the test result means. You can get the result of your HIV test within [1 hour/*maximum time for the specific test used*]. You will get referrals to services, if needed. If the rapid test result is reactive, or if you know you are already HIV-infected, we will [draw less than 1 tablespoon of your blood by needle/stick the tip of one of your fingers to obtain a few drops of blood] for a second test to confirm your rapid test result. The result of the confirmatory test will be ready within one week. We will set up a day and time for you to get your results.

[For sites doing the Rapid Test Algorithm]
Rapid Test Algorithm
We will [draw less than 1 tablespoon of blood/stick the tip of one of your fingers to obtain a few drops of blood]. You can get the result of your HIV test within [1 hour/*maximum time for the specific test used*]. You will get counseling about what the test result means. If the first rapid test is reactive, we will do a second rapid test to confirm your results. For the additional rapid test, we will [use the blood we drew for the first test/stick the tip of one of your fingers to obtain a few drops of blood]. If you know you are already HIV- infected, we may only do one rapid test. *[For sites required/choosing to do laboratory confirmation]* Finally, we will use the [blood/oral fluid] to confirm your rapid test result in a laboratory. The result of the confirmatory test will be ready within one week. We will set up a day and time for you to get your results.

[For sites doing Hepatitis B and C tests]
Hepatitis B and C Tests
We will offer you free screening for hepatitis B and C infection. We will collect a blood sample (about 2 teaspoons) with a needle from your arm. You will get counseling about what the test results mean. You will get referrals to services, if needed. The result of the hepatitis B and C tests will be ready within two weeks. We will set up a day and time for you to get your results. You will get counseling about what the test results mean and referrals to services, if needed. *[For sites that allow hepatitis test phone results:* If you cannot return for your hepatitis test results, you can arrange to receive your counseling and test results by telephone.]

[For sites doing STI tests]
Gonorrhea and chlamydia tests
We will offer you free screening for gonorrhea and chlamydia. We will ask you to swab the back of your throat and gently insert a swab in your rectum (butt) to collect samples. We will also ask you urinate into a cup. The results of the gonorrhea and chlamydia tests will be ready within two weeks. We will set up a day and time for you to get your results. You will get counseling about what the test results mean and referrals to services, if needed. *[For sites that allow gonorrhea and chlamydia test phone results:* If you cannot return for your test results, you can arrange to receive your results by telephone.]

[Include any additional test to be offered].

Linkage
We will link your test results with your survey so we can learn about sexual and drug-use risk behaviors known to be connected with HIV infection. We will link your test results using the same ID assigned to the survey. Your name will not be on the test results or the survey. No one besides you will be told your test results, and neither the survey nor the test will be placed in any medical record.

[For sites doing Storage for Additional Tests]
Storage for Additional Tests
We would like to store any blood [*for sites offering STI testing*: and other body fluids] that is left over after we do your test. We plan to use this sample for studies we will do in the future. We will store your sample with some data about you, such as your age, race, and gender. We will not put your name on the sample and there will be no way to know it is yours: thus, we will not be able to report back any test results to you. We will not use your blood for cloning. You can decline to let us store your blood and still be in this study. If you do not wish to have us store your blood, your blood sample will be destroyed after this testing is completed. If you agree to have us store your blood, we will destroy your blood sample within 10 years.

C. Things to consider

There are minimal risks from being in this study:

1. Some of the questions in the survey are about sex and drugs and may make you feel uncomfortable.

2. [*If doing blood testing:* Drawing blood may cause temporary discomfort from the needle/finger stick, bruising, bleeding, light-headedness, and local infection.]

3. [*For sites offering STI testing*] Collecting pharyngeal (throat) samples may cause gagging and temporary discomfort. Collecting rectal (butt) samples may cause temporary irritation, discomfort, and mild bleeding. Collecting a urine sample does not pose a physical risk.

4. You may feel uncomfortable finding out you might have been infected with HIV [*or diseases tested for*].

5. If your HIV test result [*for sites offering STI testing*: or STD test results] is/are negative, there is a slight chance that the results are wrong and that you could still be infected.

D. Benefits

Benefits you may get from being in this study include:

1. You will receive condoms and information on HIV/AIDS and STDs.

2. You will receive free referrals to other local programs, as needed.

3. If your HIV *[or additional tests offered]* results are positive, you will be counseled about ways to prevent the spread of infection and you will be able to talk about your concerns, if you wish. You will also be referred for medical care.

4. If your test results are negative, you will receive counseling on how to prevent future infections.

E. Alternatives

If you choose not to take part in the study but would like to take an HIV test *[or additional tests offered]*, we will inform you of agencies or organizations that provide testing. You will get no medical treatment in this study.

F. Compensation

For completion of the survey, you will get *[survey incentive]*. If you take part in the HIV test, you will get an additional *[HIV test incentive]*. *[For IDU & HET only]* You may also get *[recruitment incentive]* each for up to 5 people whom you send to us for the study. *[If you take part in other tests offered, you will get (incentives for additional tests offered if applicable)]*.

G. Persons to Contact

This study is run by: [*name of principal investigator and phone number*]. You may call them with any questions about being in the study.

If you have questions about your rights as a participant or if you feel that you have been harmed, contact [*IRB committee or contact name and phone number*].

If you want one, you will get a copy of this form to keep.

H. Confidentiality Statement

This survey is anonymous. Your responses and test results will be labeled with a study number only. The study staff at **[Agency name]** and CDC will have access to the survey. Other collaborators will have access to the survey, but will not be allowed to see any information that could identify you. Your responses will be grouped with survey answers from other persons.

If you know me, you may ask for another staff member so that your answers will be fully anonymous.

I. Costs

You will not be charged for counseling, the HIV test *[any additional tests offered]*, safer sex and HIV prevention materials, referrals to appropriate agencies, or any other services provided by this study.

J. Right to Refuse or Withdraw

This study is completely VOLUNTARY. You are not giving up any legal claims or rights for being a part of this study. If you agree to participate, you are free to quit at any time. You may refuse to answer any question. You can choose to only do the survey and not to have an HIV test *[or any additional tests offered]*. You can also choose not to recruit others.

K. Agreement

Do you have any questions?

Interviewer: Answer the participant's questions before proceeding to the next question.

You have read or had read to you the explanation of this study, you have been given a copy of this form, the opportunity to discuss any questions that you might have and the right to refuse participation. I am going to ask for your consent to participate in this study.

(Consent will be documented by the interviewer in the portable computer as follows:)

Do you agree to take part in the survey?

- ☐ Yes
- ☐ No

If yes:

Do you agree to HIV counseling and testing?

- ☐ Yes
- ☐ No

Do you agree to hepatitis testing (if offered)?

- ☐ Yes
- ☐ No

Do you agree to STD testing (if offered)?

- ☐ Yes
- ☐ No

Do you agree to let us store some of your blood/STD test sample/blood and STD test sample for future testing?

- ☐ Yes
- ☐ No

If survey declined:

We're interested in knowing why people do not want to do this study. Would you mind telling me which of the following best describes the reason you do not want to do this study?

You don't have time…..……..……....	☐ 1
You don't want to talk about these topics……	☐ 2
Some other reason……..…….……....	☐ 3
You'd rather not say why…..…….……....	☐ 9

Apéndice F Modelo de hoja de consentimiento

Grade Reading Level by Flesch-Kincaid Method: 7.3

Sistema Nacional de Vigilancia del Comportamiento Relacionado con el VIH
Modelo de hoja de consentimiento

El/la [**nombre de la agencia**] y los Centros para el Control y la Prevención de Enfermedades (CDC, por sus siglas en inglés) le invitan a formar parte de un estudio sobre el VIH en su comunidad. La información que le daré puede ayudarle a tomar una buena decisión sobre participar en el estudio.

A. Por qué estamos realizando este proyecto

El propósito de este estudio es conocer los riesgos de infectarse por el VIH. Utilizaremos esta información para planificar mejor los programas de prevención y tratamiento del VIH para personas de su comunidad. Este estudio es anónimo, lo que significa que nadie sabrá su nombre ni podrá identificarlo. La participación en este estudio es voluntaria.

B. Qué sucederá

Si usted acepta participar en este estudio, esto es lo que sucederá.

1. Responderá una encuesta que le hará un miembro capacitado del personal.

La encuesta contiene preguntas sobre su salud, uso de drogas, prácticas sexuales y servicios de prevención del VIH. Para responderla, le tomará aproximadamente 40 minutos. Al final de la encuesta, le podría dar la opción de reclutar hasta 5 personas para que participen en este estudio.

2. Si acepta realizar la encuesta, le ofreceremos una prueba del VIH gratis. Si usted ya sabe que tiene el VIH, de todos modos nos gustaría ofrecerle hoy una prueba del VIH para enlazar el resultado de la prueba del VIH que le haremos hoy con los resultados de su encuesta.

3. *[Para los sitios que realizan pruebas del VIH solamente en sangre]* Si está de acuerdo en hacerse la prueba del VIH, le pediremos autorización para almacenar su muestra de sangre.

4. *[Para los sitios que realizan pruebas de la hepatitis]* También le ofreceremos pruebas gratis de la hepatitis B y C.

5. *[Para los sitios que realizan pruebas de las ITS]* También le ofreceremos pruebas gratis de gonorrea y clamidia.

Si usted acepta hacerse la prueba del VIH, tendrá una sesión de consejería sobre la prevención del VIH con un miembro capacitado del personal, la cual durará entre 10 y 15 minutos. En la sesión se explicarán

los resultados de la prueba del VIH. También recibirá información sobre cómo reducir sus posibilidades de infectarse por el VIH y otras enfermedades infecciosas.

La prueba del VIH se hará por medio de un método [*Para los sitios que realizan la prueba con método estándar:* estándar] [*Para los sitios que realizan la prueba con método rápido:* rápido] que se explica a continuación.

[Para sitios que realizan la prueba estándar]
Prueba estándar
Le [extraeremos menos de 1 cucharada de sangre con una aguja/pincharemos la punta de un dedo para sacar unas gotas de sangre/tomaremos con un palillo de algodón una muestra de saliva de su boca] y la analizaremos para detectar el VIH. Los resultados de su prueba estarán listos en una semana. Le diremos el día y la hora en que podrá obtenerlos. Recibirá consejería acerca de los resultados de la prueba y se le referirá a servicios, si son necesarios. [*Para los sitios que permiten dar los resultados de la prueba del VIH por teléfono:* Si usted no puede recoger en persona los resultados de la prueba del VIH, puede solicitar que le den los resultados y la consejería por teléfono.]

[Para sitios que realizan la prueba rápida]
Prueba rápida
Le [pincharemos la punta de un dedo para sacar unas gotas de sangre/tomaremos con un palillo de algodón una muestra de su boca]. Recibirá consejería acerca del resultado de la prueba. Usted podrá obtener el resultado de su prueba del VIH en [una hora/*el tiempo máximo para la prueba específica que se usa*]. Se le referirá a los servicios si son necesarios. Si el resultado de la prueba rápida es reactivo o si usted ya sabe que tiene el VIH, le [extraeremos menos de una cucharada de sangre con una aguja/pincharemos la punta de un dedo para sacar unas gotas de sangre] para una segunda prueba para confirmar el resultado de la prueba rápida. El resultado de la prueba de confirmación estará listo en una semana. Le diremos el día y la hora en que podrá obtenerlo.

[Para sitios que realizan el algoritmo de la prueba rápida]
Algoritmo de la prueba rápida
Le [extraeremos menos de una cucharada de sangre con una aguja/pincharemos la punta de un dedo para sacar unas gotas de sangre]. Usted podrá obtener el resultado de su prueba del VIH en [una hora/*el tiempo máximo para la prueba específica que se usa*]. Recibirá consejería acerca del resultado de la prueba. Si la primera prueba rápida es reactiva, haremos una segunda prueba rápida para confirmar los resultados. Para hacer la prueba rápida adicional, [utilizaremos la misma muestra de sangre que extrajimos para la primera prueba/le pincharemos la punta de un dedo para sacar unas gotas de sangre]. Si usted ya sabe que tiene el VIH, es posible que hagamos solo una prueba rápida. *[Para los sitios que deben/deciden realizar una prueba confirmatoria en un laboratorio]* Finalmente, utilizaremos la muestra de [sangre/saliva] para confirmar en un laboratorio el resultado de la prueba rápida. El resultado de la prueba de confirmación estará listo en una semana. Le diremos el día y la hora en que podrá obtenerlos.

[Para los sitios que realizan pruebas de hepatitis B y C]
Pruebas de hepatitis B y C
Le ofreceremos pruebas de detección de la hepatitis B y C. Le sacaremos con una aguja una muestra de sangre (unas 2 cucharaditas) de su brazo. Recibirá consejería acerca del resultado de la prueba. Se le referirá a los servicios si son necesarios. Los resultados de las pruebas de la hepatitis B y C estarán listos en 2 semanas. Le diremos el día y la hora en que podrá obtenerlos. Recibirá consejería acerca de los resultados de la prueba y se le referirá a servicios, si son necesarios. *[Para los sitios que permiten dar los*

resultados de la prueba de la hepatitis por teléfono: Si usted no puede recoger en persona los resultados de su prueba de la hepatitis, puede solicitar que le den los resultados y la consejería por teléfono.]

[Para los sitios que realizan pruebas de ITS]
Pruebas de gonorrea y clamidia
Le ofreceremos pruebas gratis de gonorrea y clamidia. Le pediremos que se toque con un hisopo la parte posterior de la garganta y que cuidadosamente se inserte un hisopo en el recto (trasero) para recolectar muestras. También le pediremos que orine en un recipiente. Los resultados de las pruebas de gonorrea y clamidia estarán listos en dos semanas. Le diremos el día y la hora en que podrá obtenerlos. Recibirá consejería acerca de los resultados de las pruebas y se le referirá a servicios, si son necesarios. *[Para los sitios que permitan dar los resultados de estas pruebas por teléfono:* Si usted no puede recoger en persona los resultados de sus pruebas, puede solicitar que le den los resultados por teléfono.]

[Incluya las pruebas adicionales que vayan a ofrecerse.]

Enlaces
Enlazaremos los resultados de su prueba con su encuesta para poder conocer sobre el uso de las drogas y las conductas sexuales de riesgo que están asociados con la infección por el VIH. Enlazaremos los resultados de su prueba utilizando el mismo número (ID) asignado a la encuesta. Su nombre no aparecerá en los resultados de la prueba ni en la encuesta. Los resultados de su prueba se le informarán solamente a usted. Además, la encuesta y los resultados de la prueba no se archivarán en ningún registro médico.

[Para los sitios que van a almacenar muestras para pruebas adicionales]
Almacenamiento de muestras para pruebas adicionales
Después de hacer la prueba, quisiéramos almacenar la sangre restante [*para los sitios que ofrecen pruebas de ITS*: y otros líquidos corporales restantes] de la muestra. Planeamos utilizar esta muestra para los estudios que realizaremos en el futuro. Almacenaremos su muestra junto con algunos datos sobre usted, como su edad, raza y género. No escribiremos su nombre en la muestra y no habrá forma de saber que le pertenece a usted: por lo tanto, no podremos darle información sobre los resultados de las pruebas posteriores. No utilizaremos su sangre para clonaciones. Usted puede negarse a permitirnos almacenar su sangre y de todos modos participar en este estudio. Si no quiere que almacenemos su muestra de sangre, la destruiremos después de realizar las pruebas. Si está de acuerdo en que almacenemos su muestra de sangre, la podremos destruir en un plazo de 10 años.

C. <u>Puntos a considerar</u>

Existen riesgos mínimos derivados de la participación en este estudio:

1. Algunas de las preguntas de la encuesta son sobre el sexo y las drogas, y es posible que le hagan sentirse incómodo.

2. [*Si le hacen una prueba de sangre:* La extracción de sangre puede causar molestias temporales debido al pinchazo de la aguja, moretones, sangrado, mareos o una infección local.]

3. [*Para los sitios que ofrecen pruebas de ITS*: La recolección de muestras faríngeas (de la garganta) puede causar sensación de vómito y molestias temporales. La recolección de muestras rectales

puede causar irritación temporal, malestar y sangrado leve. La recolección de una muestra de orina no debe causar un riesgo físico.

4. Es posible que se sienta incómodo al saber que puede estar infectado con el VIH [u otras enfermedades de las que se hizo pruebas].

5 Si el resultado de su prueba del VIH [*para los sitios que ofrecen pruebas de ITS*: o los resultados de las pruebas de ETS] es/son negativo/s, existe una mínima posibilidad de que los resultados sean incorrectos y de que usted sí esté infectado.

D. Beneficios

Los beneficios que usted puede obtener por participar en este estudio son:

1. Recibirá condones e información sobre el VIH/SIDA y las enfermedades de transmisión sexual (ETS).

2. Se le podrá referir en forma gratuita a otros programas locales, según sea necesario.

3. Si los resultados de su prueba del VIH *[o de pruebas complementarias que le hayan realizado]* son positivos, recibirá consejería sobre cómo prevenir la transmisión de la infección y podrá preguntar sobre sus inquietudes, si lo desea. También se le referirá para que reciba atención médica.

4. Si los resultados de su prueba son negativos, recibirá consejería sobre cómo prevenir infectarse en el futuro.

E. Alternativas

Si usted decide no formar parte de este estudio pero desea hacerse una prueba del VIH [u otras pruebas que le ofrezcan], le informaremos sobre las agencias u organizaciones que ofrecen este servicio. Usted no recibirá ningún tratamiento médico en este estudio.

F. Compensación

Por completar la encuesta, recibirá *[incentivo para la encuesta]*. Si se hace la prueba del VIH, recibirá otros *[incentivo para la prueba del VIH]*. También podrá recibir *[incentivo de reclutamiento]* por cada una de hasta 5 personas que nos envíe para participar en el estudio. *[Si se hace otras pruebas que le ofrezcamos, recibirá (incentivo por hacerse otras pruebas, si se aplica)]*.

G. Personas para contactar

Este estudio está dirigido por: [*nombre y número de teléfono del investigador principal*]. Usted puede llamarle para hacerle cualquier pregunta que tenga sobre su participación en el estudio.

Si tiene preguntas sobre sus derechos como participante o si considera que ha sido perjudicado, comuníquese con [*Comité de Revisión Independiente (Independent Review Board o IRB), o nombre y número de teléfono del contacto*].

Si lo desea, le entregaremos una copia de esta hoja para que la conserve.

H. Declaración de confidencialidad

Esta es una encuesta anónima. Sus respuestas y los resultados de sus pruebas serán identificados únicamente con un número de estudio. El personal del estudio de [**nombre de la agencia**] y de los CDC tendrán acceso a la encuesta. Otros colaboradores tendrán acceso a la encuesta, pero no se les permitirá ver ninguna información que lo pueda identificar a usted. Sus respuestas serán agrupadas con las respuestas a la encuesta de otras personas.

Si usted me conoce, puede solicitar que lo entreviste otro miembro del personal, para que sus respuestas sean totalmente anónimas.

I. Costos

No se le cobrará nada por la consejería, la prueba del VIH *[cualquier prueba complementaria que se le haya ofrecido]*, materiales sobre la prevención del VIH y la práctica de relaciones sexuales más seguras, remisiones a las agencias apropiadas ni por ningún otro servicio proporcionado por este estudio.

J. Derecho a negarse o a retirarse

Este estudio es totalmente VOLUNTARIO. Usted no renuncia a ninguna reclamación o derecho legal por participar en este estudio. Si acepta participar, tiene la libertad de retirarse en cualquier momento. Usted puede negarse a contestar cualquier pregunta. Puede optar por responder solamente la encuesta y no hacerse una prueba del VIH *[o las pruebas adicionales ofrecidas]*. También puede decidir no reclutar a otros participantes.

K. Acuerdo

¿Tiene alguna pregunta?

Entrevistador: Responda a las preguntas del participante antes de pasar a la pregunta siguiente.

Usted ha leído o le han leído la explicación de este estudio, ha recibido una copia de esta hoja, ha tenido la oportunidad de hacer las preguntas que pudo tener y tiene el derecho de negarse a participar. Ahora le voy a pedir su consentimiento para participar en este estudio.

(El entrevistador documentará el consentimiento en la computadora portátil de la siguiente manera):

¿Acepta participar en esta encuesta?

☐ Sí
☐ No

Si respondió sí:

¿Acepta hacerse la prueba del VIH y recibir consejería?

☐ Sí
☐ No

¿Acepta hacerse las pruebas de hepatitis (si se las ofrecen)?

☐ Sí
☐ No

¿Acepta hacerse las pruebas de enfermedades de transmisión sexual (si se las ofrecen)?

☐ Sí
☐ No

Si respondió sí a cualquiera de las pruebas:

¿Acepta que almacenemos su muestra de sangre/sus muestras para las pruebas de ETS/sus muestras de sangre y para las pruebas de ETS para realizar pruebas futuras?

☐ Sí
☐ No

Si se negó a participar en la encuesta:
Estamos interesados en saber por qué las personas no desean participar en este estudio. ¿Le importaría decirme cuál de las siguientes situaciones es la que mejor describe la razón por la que no desea participar en este estudio?

No tiene tiempo…..…….…….....	☐ 1
No quiere hablar sobre estos temas……	☐ 2
Otra razón……..…….....	☐ 3
Prefiere no decir el motivo…..…….…….....	☐ 9

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Appendix G Model Consent Talking Points

English Version; Grade Reading Level by Flesch-Kincaid Method: 7.8

All participants will be provided a copy of the full consent form

1. This is a study conducted by [*name of local agency/organization*] to collect information on HIV in your community. We will use this information to plan better HIV prevention and treatment programs for people in your community.
2. Taking part in this project is your decision. Your choice will not affect your right to health care or other services. We will send information from this study to the CDC, but we will not send any information that could identify you.
3. If you agree to participate, you will do a survey with me. I'll ask you questions about your sex practices, drug use, and other health topics. You can refuse to answer any questions. You can stop the survey at any time. The survey will take about 40 minutes.
4. I'll offer you an HIV test. This will involve [drawing a small amount of blood using a needle/swabbing your mouth for oral fluid]. Your results will be ready within [1hour/1 week]. *[Explain how participant will receive results of any non-rapid (standard or confirmatory) tests]*. If you agree, we'd like to store any blood left over for future studies. *[If conducting hepatitis testing]*: We will also offer you free hepatitis B and C tests. This will involve drawing an additional small amount of blood. *[If conducting STD testing]*: We will also offer you free testing for gonorrhea and chlamydia. This will involve *[Explain pharyngeal and rectal swab and urine collection processes for gonorrhea and chlamydia testing]*. If you agree, we'd also like to store any specimen left over from these tests for future studies.
5. I may give you the option to invite up to 5 people to participate in the study.
6. There are minimal risks from being in this study. Some survey questions may make you feel uncomfortable and knowing your HIV test result may be upsetting, but I am here to discuss any concerns you have.
7. You may benefit from this study by learning about HIV/AIDS and other STIs and how to prevent them. You will also learn your HIV status *[or results of any additional tests offered]* and we will refer you for any specialized treatment you may need.
8. If you take the survey we'll pay you *[insert survey incentive amount]*. If you take the HIV test, we'll pay you an additional *[insert HIV test incentive amount]*. [*If you take part in other tests offered, you will get (insert incentives for additional tests offered if*

applicable)]. After the survey, I may ask you to invite a small number of people you know to participate in this study. If you agree, you may receive *[insert recruitment incentive amount]* for each person you refer. *[Insert any additional incentives offered]*.

9. If you decide not to participate, there will be no penalty to you.
10. If you have any questions about this study, you can contact these people **[refer participant to contact information on full consent form]**.
11. Everything you tell us will be kept private—it will only be available to people working on this study—and the entire process is anonymous. I will not ask your name.
12. Do you agree to take part in the survey?
13. Do you agree to HIV counseling and testing?
14. *[if applicable]* Do you agree to hepatitis testing?
15. *[if applicable]* Do you agree to the STD testing?
16. Do you agree to have your blood [STD sample/blood and STD sample] stored?

Apéndice G: Puntos para tratar sobre el modelo de consentimiento

Todos los participantes recibirán una copia del formulario de consentimiento completo.

1. Este es un estudio realizado por [*nombre de la agencia u organización local*] para recoger información sobre el VIH en su comunidad. Utilizaremos esta información para planificar mejor los programas de prevención y tratamiento del VIH para personas de su comunidad.
2. Usted decide si quiere participar o no en este proyecto. Su decisión no afectará su derecho a recibir atención médica ni otros servicios. Enviaremos la información que obtengamos de este estudio a los CDC, pero no enviaremos ninguna información que pueda identificarlo a usted.
3. Si está de acuerdo en participar, le haré una encuesta con preguntas sobre sus prácticas sexuales, consumo de drogas y otros temas de salud. Usted puede negarse a responder cualquiera de las preguntas. Usted puede dejar de responder a la encuesta en cualquier momento. La encuesta tomará aproximadamente 40 minutos.
4. Le ofreceré hacerse una prueba del VIH. Esto incluye [sacarle una pequeña cantidad de sangre con una aguja o pasarle un palillo de algodón en la boca para tomar muestras de saliva]. Los resultados estarán listos en [1 hora/1 semana]. *[Explicar cómo recibirá el participante los resultados de las pruebas no rápidas (estándar o confirmatorias)]*. Si usted lo acepta, guardaremos lo que sobró de la muestra de sangre para estudios futuros. *[Si se van a realizar pruebas para detectar la hepatitis]*: También le ofreceremos pruebas gratis de hepatitis B y C. Esto requerirá sacarle otra pequeña muestra de sangre. *[Si se van a realizar pruebas de ETS]*: También le ofreceremos pruebas gratis de gonorrea y clamidia. Este proceso involucra: *[Explique el proceso de hacer la colección de muestras de la garganta y el recto con los hisopos y de orina para las pruebas de gonorrea y clamidia]*. Si usted lo acepta, también guardaremos los especímenes restantes de estas pruebas para futuros estudios.
5. Le puedo dar la opción de invitar hasta 5 personas para participar en el estudio.
6. Existen riesgos mínimos por participar en este estudio. Algunas preguntas de la encuesta le pueden hacer sentir incómodo, y saber su resultado de la prueba del VIH puede angustiarlo, pero estoy aquí para hablar sobre cualquier inquietud que tenga.

7. Usted podría beneficiarse de este estudio al aprender sobre el VIH/SIDA y otras infecciones de transmisión sexual (ITS) y cómo se previenen. También sabrá si tiene o no el VIH *[o los resultados de otras pruebas que se le ofrezcan]* y le referiremos al tratamiento especializado que pueda necesitar.
8. Si acepta hacer la encuesta le pagaremos *[indique la cantidad de incentivo por la encuesta]*. Si se hace la prueba del VIH, le pagaremos *[indique la cantidad de incentivo por hacerse la prueba del VIH]* adicionales. [*Si se hace otras pruebas que le ofrezcamos, le pagaremos (indique el incentivo por hacerse otras pruebas, si se aplica)]*. Después de la encuesta, puede ser que le pida que invite a unas cuántas personas a participar en este estudio. Si usted acepta, puede recibir *[indique el incentivo por reclutar participantes]* por cada persona que refiera *[indique todos los incentivos adicionales que se ofrezcan]*.
9. Si decide no participar, no se le penalizará.
10. Si tiene preguntas sobre este estudio, puede comunicarse con estas personas **[refiera al participante a la información de contacto en el formulario de consentimiento completo]**.
11. Todo lo que nos diga se mantendrá en forma confidencial, solo estará disponible para las personas que trabajan en este estudio, y el proceso completo será anónimo. No le pediré su nombre.
12. ¿Está de acuerdo en responder la encuesta?
13. ¿Acepta hacerse la prueba del VIH?
14. *[Si se aplica]* ¿Acepta hacerse la prueba de hepatitis?
15. *[Si se aplica]* ¿Acepta hacerse las pruebas de enfermedades de transmisión sexual?
16. *[Si se aplica]* ¿Está de acuerdo en que guardemos su muestra de sangre u otros especímenes?

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Appendix H Model Coupon

FRONT

‹#› **Project ASK** ‹#›

If you are selected, you can earn up to **$100.00!**

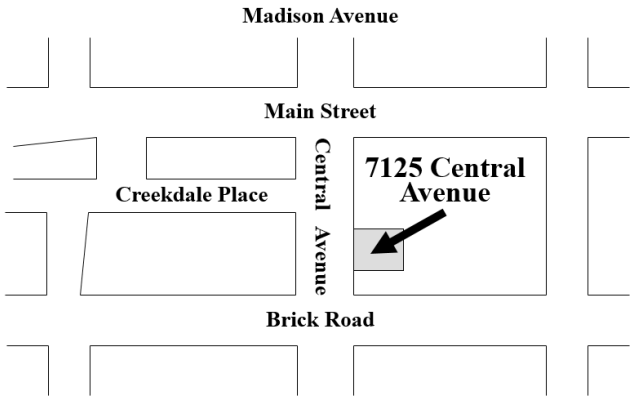
≪ Call 1-888-865-4327 for an appointment or more information ≫

When: Tuesdays and Wednesdays 1 PM - 9 PM
Fridays and Saturdays 10 AM - 6 PM

Where: 7125 Central Avenue, 2nd Floor
(Directions are on back of coupon.)

Coupon is not active before: / / **Coupon expires on: / /**

BACK



Project ASK

is located at 7125 Central Avenue
between Main Street and Brick Road
across from the Salvation Army

1-888-865-4327

PLEASE CALL FOR AN APPOINTMENT

(IT'S A FREE CALL FROM ANY PAYPHONE)

Appendix I Model Recruiter Training Talking Points

Who to Recruit

- We're going to give you ***[insert #]*** coupons to give to other trans women who you associate with so that they can be in the study too.
- Give the coupons to people you know who also know you.
- Do NOT give the coupons to **strangers**.
- Give the coupons to people who live in ***[insert project area]***.
- Give the coupons to people who have not already participated in the study.

Coupons

- Everyone has to have a coupon to be in the study.
- Tell people you recruit to have the coupon with them when they come in or when they call to make an appointment.

Process

- The whole process for the survey takes about 1 hour.
- Children aren't allowed to sit in on the interview, so ask the people you recruit to have someone watch their children if they have any.
- Everyone who completes an interview will get *[survey incentive]*. Everyone who also does an HIV test will get an additional *[HIV test incentive]*.
- People who aren't capable of completing the interview won't be allowed to participate in the study.

Reward

- You will get paid *[recruiter incentive]* for each person you recruit who is selected for the study and who completes the interview; the *[recruiter incentive]* is not guaranteed just for recruiting someone.
- You will not be paid for someone who is not selected for the study.
- You will not be paid for someone who has already participated.
- You will not be paid for someone who does not complete an interview.

- The computer determines who gets to recruit other people for the study and how many coupons they will get.
- Coupons will expire and the study will end at some point.

Recruiter Information

- We ask questions so that we can identify you again when you come to get your rewards.
- We link the numbers on the coupons we give you to the coupon you brought in, so we know who to pay.
- Call the office to find out if you are owed a reward.
- We can't tell you who came in with a coupon from you.
- We will only pay you. Don't send someone else in to get paid.

Do you have any questions? Thanks for helping us, and remember, give the coupons to people you know.

Appendix J Model Hepatitis Testing Log

Hepatitis B:

SURID	*Specimen collected for hepatitis testing?*	*Lab ID# (if different from HIV test ID)*	*Hep B Core total AB (anti-HBc)*	*Hep B surface antibody (anti-HBs)*	*HBsAb Titer*	*Hep B Surface AG (HBsAg)*	*Hepatitis B Result Interpretation*	*Received Hep B test result?*	*Comments*

Hepatitis C:

SURID	*Specimen collected for hepatitis testing?*	*Lab ID# (if different from HIV test ID)*	*Hep C Rapid Test Result*	*Hep C Ab EIA/CIA Result*	*Hep C RNA result*	*Hepatitis C Result Interpretation*	*Received Hep C test result?*	*Comments*

Note: Shaded columns are redundant in each log. Logs can be combined into a single row with only 1 column each for ***SURID***, ***Specimen collected for hepatitis testing, Lab ID#,*** and ***Comments*** fields.

Appendix K Model STD Testing Log

Log for STD Testing:

Survey ID	Collection date	Pharyngeal (throat)				Rectal				…
		Lab ID / barcode	Testing not done	Gonorrhea test result	Chlamydia test result	Lab ID / barcode	Testing not done	Gonorrhea test result	Chlamydia test result	

…	Urine				Consent for storage (Y/N)	Comments**
	Lab ID / barcode	Testing not done	Gonorrhea test result	Chlamydia test result		

*** If unable to collect a pharyngeal/rectal specimen, please check the box "Testing not done" and provide a reason in the comments section.*

Appendix L Model HIV Testing Log

Log for Rapid HIV Testing:

Survey ID	Lab ID	Rapid Test Method *	Self-reported HIV+ during interview? (Y/N)	Rapid Test Result*	Returned Rapid Test Result (Y/N)	*For preliminary HIV+:* Collected Confirmatory Specimen (Y/N)	*For preliminary HIV+:* Type of Confirmatory Specimen	*For preliminary HIV+ if did not self-report HIV+ during interview:* Self-reported HIV+ during counseling session? (Y/N)	Comments**

** Project sites performing a multiple rapid test algorithm should modify the log accordingly.*
*** If unable to collect a confirmatory specimen, provide reason in comments section.*

Log for Laboratory-based HIV Testing:

Survey ID	Lab ID	Collected Lab Specimen (Y/N)	Specimen Type	Self-reported HIV+ during interview? (Y/N)	*If did not self-report HIV+ during interview:* Self-reported HIV+ during counseling session? (Y/N)	Test Type*	Test Result*	Final Test Result Returned (Y/N)	Comments**

**The log will contain a column for each type of test (EIA, Western Blot, NAAT, etc) performed*
*** If unable to collect a confirmatory specimen, provide reason in comments section.*

Appendix M Assurance of Confidentiality for HIV/AIDS Surveillance Data

ASSURANCE OF CONFIDENTIALITY FOR SURVEILLANCE OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) AND INFECTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV) AND SURVEILLANCE-RELATED DATA (INCLUDING SURVEILLANCE INFORMATION, CASE INVESTIGATIONS AND SUPPLEMENTAL SURVEILLANCE PROJECTS, RESEARCH ACTIVITIES, AND EVALUATIONS)

The national surveillance program for HIV/AIDS is being coordinated by the Surveillance Branch of the Division of HIV/AIDS Prevention - Surveillance and Epidemiology (DHAP - SE), the National Center for HIV/STD/TB Prevention, a component of the Centers for Disease Control and Prevention (CDC), an agency of the United States Department of Health and Human Services. The surveillance information requested by CDC consists of reports of persons with suspected or confirmed AIDS or HIV infection, including children born to mothers infected with HIV, and reports of persons enrolled in studies designed to evaluate the surveillance program. The information collected by CDC is abstracted from laboratory, clinical, and other medical or public health records of suspected or confirmed HIV/AIDS cases; and from surveys that interview persons in recognized HIV risk groups or known to have a diagnosis of HIV/AIDS.

Surveillance data collection is conducted by State and Territorial health departments which forward information to CDC after deleting patient and physician names and other identifying or locating information. Records maintained by CDC are identified by computer-generated codes, patient date of birth, and a state/city assigned patient identification number. The data are used for statistical summaries and research by CDC scientists and cooperating state and local health officials to understand and control the spread of HIV/AIDS. In rare instances, expert CDC staff, at the invitation of state or local health departments, may participate in research or case investigations of unusual transmission circumstances or cases of potential threat to the public health. In these instances, CDC staff may collect and maintain information that could directly identify individuals.

Information collected by CDC under Section 306 of the Public Health Service Act (42 U.S.C. 242k) as part of the HIV/AIDS surveillance system that would permit direct or indirect identification of any individual or institution on whom a record is maintained, and any identifiable information collected during the course of an investigation on either persons supplying the information or persons described in it, is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in this Assurance, and will not otherwise be disclosed or released without the consent of the

individual or institution in accordance with Section 308 (d) of the Public Health Service Act (42 U.S.C. 242m(d)). This protection lasts forever, even after death.

Information that could be used to identify any individual or institution on whom a record is maintained by CDC will be kept confidential. Full names, addresses, social security numbers, and telephone numbers will not be reported to this national HIV/AIDS surveillance system. Medical, personal, and lifestyle information about the individual, and a computer-generated patient code will be collected.

Surveillance information reported to CDC will be used without identifiers primarily for statistical and analytic summaries and for evaluations of the surveillance program in which no individual or institution on whom a record is maintained can be identified, and secondarily, for special research investigations of the characteristics of populations suspected or confirmed to be at increased risk for infection with HIV and of the natural history and epidemiology of HIV/AIDS. When necessary for confirming surveillance information or in the interest of public health and disease prevention, CDC may confirm information contained in case reports or may notify other medical personnel or health officials of such information; in each instance, only the minimum information necessary will be disclosed.

No CDC HIV/AIDS surveillance or research information that could be used to identify any individual or institution on whom a record is maintained, either directly or indirectly, will be made available to anyone for non-public health purposes. In particular, such information will not be disclosed to the public; to family members; to parties involved in civil, criminal, or administrative litigation, or for commercial purposes; to agencies of the federal, state, or local government. Data will only be released to the public, to other components of CDC, or to agencies of the federal, state, or local government for public health purposes in accordance with the policies for data release established by the Council of State and Territorial Epidemiologists.

Information in this surveillance system will be kept confidential. Only authorized employees of DHAP - SE in the Surveillance Branch and Statistics and Data Management Branch, their contractors, guest researchers, fellows, visiting scientists, research interns and graduate students who participate in activities jointly approved by CDC and the sponsoring academic institution, and the like, will have access to the information. Authorized individuals are required to handle the information in accordance with procedures outlined in the Confidentiality Security Statement for Surveillance of Acquired Immunodeficiency Syndrome (AIDS) and Infection with Human Immunodeficiency Virus (HIV) and Surveillance-Related Data (Including Surveillance Information, Case Investigations and Supplemental Surveillance Projects, Research Activities, and Evaluations.

Appendix N Model Waiver of Informed Consent

MEMORANDUM

Date:

From: (Principal Investigators)

Subject: Request of Waiver of Documentation of Informed Consent, Protocol (#)

To: Human Subjects Committee

We submit for your review a request to waive documentation of informed consent for protocol (#) entitled "National HIV Behavioral Surveillance among [insert current NHBS cycle]." We request a waiver of documentation of informed consent as provided in the second criterion (below) under Federal Regulations Title 46, Section 117, Documentation of Informed Consent, paragraph (c):

An IRB may waive the requirement for the investigator to obtain a signed informed consent for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. Each subject would be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) *That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.*

Protocol (#) presents no more than minimal risk of harm to subjects. Participation involves the completion of an anonymous interviewer-administered risk behavior questionnaire and a voluntary HIV counseling and testing component.

Appendix O Required Elements of Informed Consent

The Code of Federal Regulations for the Protection of Human Subjects, Section §46.116, describes eight elements required in each consent process/document. Element number six is only required if the project is determined to be greater than minimal risk.

Element	45 CFR 46.116(a)
1.	A. a statement that the study involves research
	B. an explanation of the purposes of the research
	C. the expected duration of the subject's participation
	D. a description of the procedures to be followed
	E. identification of any procedures which are experimental
2.	a description of any reasonably foreseeable risks or discomforts to the subject
3.	a description of any benefits to the subject or to others which may reasonably be expected from the research
4.	a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
5.	a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
6.	A. an explanation as to whether any compensation is available if injury occurs
	B. an explanation as to whether any medical treatments are available if injury occurs, and, if so
	C. what they consist of or where further information may be obtained
7.	A. an explanation of whom to contact for answers to pertinent questions about the research
	B. an explanation of whom to contact for answers to pertinent questions about the research subjects' rights
	C. whom to contact in the event of a research-related injury to the subject
8.	A. a statement that participation is voluntary
	B. refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
	C. the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled