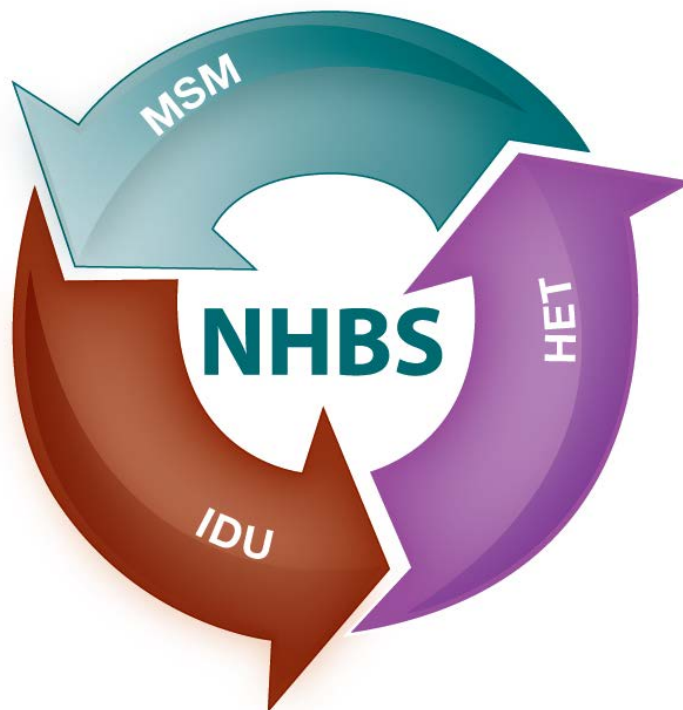


**National HIV Behavioral Surveillance:
Round 5**

Model Surveillance Protocol



**Behavioral Surveillance Team
NCHHSTP/DHAP-SE/BCSB**

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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 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)³.

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).

1.2 Timeline and Scope of Protocol

To date, NHBS has completed four rounds of data collection, and the fifth round began in January 2017 with the NHBS-MSM5 cycle, and NHBS-IDU5 was conducted in 2018. NHBS-HET5 will be conducted in 2019. The table below displays data collection periods for the completed and upcoming NHBS rounds.

NHBS Round	NHBS Cycle		
	MSM	IDU	HET
1	Dec 2003-Dec 2004	Jan-Dec 2005	Jan 2006-Oct 2007
2	Jan-Dec 2008	Jan-Dec 2009	Jan-Dec 2010
3	Jan-Dec 2011	Jan-Dec 2012	Jan-Dec 2013
4	Jan-Dec 2014	Jan-Dec 2015	Jan-Dec 2016
5	<i>Jan-Dec 2017</i>	<i>Jan-Dec 2018</i>	<i>Jan-Dec 2019</i>

The activities described in this protocol are for NHBS-MSM5, NHBS-IDU5, and NHBS-HET5 cycles.

1.3 Collaborating Agencies

The current 5-year funding award, under the program announcement PS-16-1601, began with the NHBS-HET4 cycle in January 2016. NHBS grantees include 6 city health departments independently funded by CDC's Division of HIV/AIDS Prevention and 16 state health departments with jurisdiction over specific MSAs or Divisions within MSAs (For definitions of MSAs and Divisions see <http://www.census.gov/population/www/metroareas/metrodef.html>).

Independently-funded city health departments are: Chicago Division (Chicago MSA); Houston MSA; Los Angeles Division (Los Angeles MSA); New York Division (New York City MSA); Philadelphia Division (Philadelphia MSA); and San Francisco Division (San Francisco MSA). Funded MSAs/Divisions under the jurisdiction of the state health departments listed in brackets include the following: San Diego MSA [California]; Denver MSA [Colorado]; Washington Division, Washington DC MSA [Washington DC]; Miami Division, Miami MSA [Florida]; Atlanta MSA [Georgia]; New Orleans MSA [Louisiana]; Boston Division, Boston MSA [Massachusetts]; Detroit MSA [Michigan]; Nassau Division, New York MSA [New York]; Newark Division, New York MSA [New Jersey]; San Juan MSA [Puerto Rico]; Dallas Division, Dallas MSA [Texas]; Memphis MSA [Tennessee]; Portland MSA [Oregon]; Virginia Beach MSA [Virginia] and Seattle Division, Seattle MSA [Washington]. Here forward, grantees are referred to as project sites.

To ensure that NHBS covers the geographic areas of the United States most affected by the HIV epidemic, NHBS project sites comprise state and local health departments in areas with the highest HIV prevalence. These 22 MSAs/Divisions represent 59% of all persons living with HIV infection in large MSAs (population \geq 500,000) in the United States at the end of 2012⁴. Participating health departments will be funded to conduct activities only within the MSA or Division listed and only within the geographic bounds of the funded entity (where MSAs extend beyond the jurisdiction of the eligible state or city health department). Where it would be impractical to conduct NHBS in the entire MSA or Division, recruitment activities should be limited to the geographic area (e.g., city, county, or health district) within the MSA or Division with the highest HIV/AIDS morbidity. On the other hand, in order to preserve the integrity of the sampling method, recruitment activities may be extended to geographic areas adjacent to the MSA or Division if HIV/AIDS morbidity in those areas is high and CDC has granted approval.

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

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 will provide data on the sexual and drug-use behaviors that place individuals 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 goals² and for guiding national and local HIV prevention efforts. Furthermore, NHBS 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 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.

NHBS-MSM5, NHBS-IDU5 and NHBS-HET5 cycles are designed to monitor HIV prevalence and behaviors that place individuals at risk of HIV infection among MSM, persons who inject drugs (PWID), and at-risk heterosexuals, respectively.

NHBS-MSM only

The HIV epidemic has disproportionately affected MSM. At the end of 2014, 53% of the estimated number of persons aged 13 years and older living with HIV infection in the United States had an HIV diagnosis attributed to male-to-male sexual contact and an additional 8% were attributed to injection drug use *and* male-to-male sexual contact⁵. NHBS and other studies have found that rates of HIV infection among MSM remain persistently high, especially among racial and ethnic minority MSM, and that many HIV-infected MSM are unaware of their infections⁶⁻⁸. These studies have also shown high levels of sexual and drug-use risk behavior⁶⁻⁸.

NHBS-IDU only

Although AIDS diagnoses among PWID have decreased by approximately 90% since their peak in 1993, declines in HIV have slowed in recent years⁹ and injection drug use remains an important route of HIV transmission in the United States. At the end of 2014, 11% of the estimated number of persons aged 13 years and older living with HIV infection in the United

States had an HIV diagnosis attributed to injection drug use and an additional 8% were attributed to injection drug use *and* male-to-male sexual contact⁵. PWID are at increased risk of acquiring and transmitting HIV through the use of non-sterile injection equipment and through unsafe sex and racial/ethnic minorities and women continue to be disproportionately affected⁹ among PWID. Furthermore, recent studies among young PWID reported high levels of injection and sexual risk behaviors underscoring the need for data to inform comprehensive and age-specific HIV prevention intervention.¹⁰ Finally, analysis of the NHBS-IDU4 data found high levels of injection risk practices, including sharing syringes to inject (34%) and sharing other injection equipment (56%). Having unprotected vaginal sex in the past 12 months was reported by 68% of men and 74% of women¹¹.

NHBS-HET only

At the end of 2014, 26% of the estimated number of persons aged 13 years and older living with HIV infection in the United States had an HIV diagnosis attributed to heterosexual transmission⁵. Persons with lower socioeconomic status (SES), racial/ethnic minorities, and women continue to be disproportionately affected by heterosexually acquired HIV^{12,13}. The impact of lower SES was identified through analysis of the NHBS-HET1 data, which found that HIV prevalence was significantly higher among heterosexuals who had less than a high school education, were unemployed, and had annual household incomes \leq \$9,999¹². In addition, women and minority populations continue to bear the greatest burden of HIV infections among heterosexuals. In 2015, 82% of estimated new HIV diagnoses attributed to heterosexual transmission in the United States were among Hispanics and African Americans⁵. Most (86%) of estimated HIV cases diagnosed among female adults and adolescents in 2015 were attributed to heterosexual contact, of which African American and Hispanic women together accounted for 88%⁵.

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 are designed to monitor behaviors that place people at risk for HIV infection and they apply to the data collected for all three project cycles: NHBS-MSM, NHBS-IDU, and NHBS-HET. The NHBS objectives are as follows:

Seroprevalence

- Assess the prevalence of and trends in HIV infection.
- Assess the prevalence of and trends in awareness of HIV infection.

Risk Behaviors

- Assess the prevalence of and trends in 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 and trends in HIV testing, linkage to care, and antiretroviral therapy

Prevention

- Assess the 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 repeated cross-sectional surveys of persons at increased risk of HIV infection. The survey methods used to recruit participants are Venue-Based Sampling (VBS) and Respondent Driven Sampling (RDS). VBS and RDS have 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. MSM, PWID, and heterosexuals at risk of HIV infection are examples of hidden populations.

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

NHBS-MSM only

VBS is a method targeting attendees of MSM-identified venues within local communities that has proven successful in obtaining large and diverse samples of MSM¹⁴⁻¹⁸. Survey methods can be categorized into four principal activities. In the first activity, staff conduct formative assessment to prepare for sampling and recruitment by reviewing scientific, prevention, and commercial literature and interviewing persons knowledgeable about MSM and HIV prevention services. The objectives of these investigations are to construct an initial “universe” of MSM venues, to identify potential sampling and recruitment barriers, and to help construct prevention service measures for the survey. In the second activity, staff assess each venue in the venue universe to determine which venues are eligible MSM venues ($\geq 50\%$ of attending men are MSM). In the third activity, staff assess the venues and day-time periods on the initial “universe” to determine which have a sufficient number of eligible MSM for conducting NHBS-MSM recruitment and are accessible to NHBS operations. These venues and day-time periods are then included on the monthly sampling frames used to randomly select venues and day-time periods for recruiting participants. In the fourth activity, men are recruited to participate in NHBS-MSM at randomly selected venues during randomly selected day-time periods. At these recruitment

events, staff count venue attendees, approach men to ask them to participate in the survey, interview eligible men, and offer HIV tests. Although the four principal activities are initially performed in sequence, sampling frames are continually updated throughout the project cycle.

NHBS-IDU & NHBS-HET only

RDS, a chain-referral sampling strategy similar to snowball sampling¹⁹, is used to recruit PWID and at-risk heterosexuals that are connected by strong social networks and ties. RDS methods have been widely employed by public health officials and researchers to sample PWID for purposes of developing and evaluating HIV/AIDS interventions and for conducting behavioral surveillance.²⁰ RDS has been successfully implemented to recruit PWID and heterosexuals at increased risk for HIV during NHBS rounds 1-4, and will be used in future cycles. 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 incentives for recruiting others; the average amount of these incentives, based on compensation paid by 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.^{19,21}

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 500 eligible respondents per each project site and for each NHBS cycle was determined by considering the presumed HIV prevalence 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 Salganik²² to calculate sample sizes for RDS, the sampling method used for NHBS-IDU and NHBS-HET cycles. We apply the same method for VBS, used for NHBS-MSM, as well. 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 studies²³. Unpublished analysis of weights calculated for NHBS-MSM data also suggest that VBS design effects may approach, but do not exceed 4. If we assume a maximally-conservative estimated prevalence for any indicator – 0.5 – and a design effect of 4, then a sample size of 500 is adequate to detect such indicators with adequate precision.

NHBS-MSM only

The target sample size for each project site is 500 completed interviews with participants who meet NHBS-MSM current MSM criteria (see Chapter 4, section 4). Across the 22 participating project sites in 2017, this would result in a combined sample size of 11,000 current MSM.

NHBS-IDU only

The target sample size for each project site, exclusive of “seeds” (initial recruits), is 500 completed interviews with participants meeting NHBS-IDU eligibility criteria (see Chapter 4, section 4). Across the 22 participating project sites in 2018, this would result in a combined sample size of 11,000 eligible PWID.

NHBS-HET only

The target sample size for each project site, exclusive of “seeds,” is 500 completed interviews with participants who meet NHBS-HET definition inclusion criteria (see Chapter 4, section 4). Across the 22 participating project sites, this would result in a combined sample size of 11,000 heterosexuals at increased risk of HIV.

1.9 Purpose and Use of the NHBS Surveillance 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 the NHBS-MSM5, NHBS-IDU5 and NHBS-HET5 cycles. 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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2.1 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 5 months that precede the implementation of surveillance activities. All 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 strategies for NHBS, both RDS and VBS, require formative assessment activities to ensure that the resulting sample will meet the goals of the surveillance project.

2.1a Goals of formative assessment

NHBS formative assessment goals are to:

All NHBS Cycles

- Garner the support of the community and its stakeholders for NHBS;
- Define the social and demographic characteristics of the NHBS population;
- Develop questions of local interest for HIV prevention; and
- Monitor the on-going implementation of NHBS.

NHBS-MSM only

- Obtain information relevant to field logistics (e.g. potential barriers to participation, appropriate materials and flow for interviews in the field, whether an interview van is optimal, venue owner approval, and ideal attributes of field staff);
- Identify potential venues attended by MSM;
- Identify all eligible MSM venues;

- Assess the accessibility of eligible venues and day-time periods for recruiting participants and conducting surveillance activities;
- Garner the support of venue management and/or ownership; and
- Collect required venue information.

NHBS-IDU & NHBS-HET only

- 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;
- Discuss feasibility and acceptability of collection of phone numbers for seeds (for scheduling purposes);
- 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, street intercept surveys 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; 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 interviewing.
- **NHBS-MSM only** – develop a list of venues frequented by MSM
- **NHBS-HET only** – identify high risk areas (HRAs)

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 implementation 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, focus groups, street intercept surveys, and direct observations.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, and (3) recruiting potential NHBS participants. 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 interest⁶.

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) as well as implementation and logistics-based strategies (e.g., the best days, times, and locations for data collection and barriers to recruitment and participation).

Appendix A contains a model consent form for key informant interviews where compensation 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 being compensated for their time and effort.

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; 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.

2.3c Street Intercept Surveys

Street intercept surveys conducted in key MSA locations are useful for soliciting spontaneous input of community members regarding community support and feasibility of NHBS. They also offer NHBS staff the opportunity to disseminate relevant information about the study. Street intercept surveys should be no longer than five minutes.

2.3d Direct Observations

Observations allow the researcher to build on information gathered from key informant interviews and focus groups by relying solely on what is seen by the researcher.^{6, 10} Observing what is happening "on-the-ground," particularly in such settings as neighborhoods, service organizations, parks, and high drug activity areas, can provide project staff with insight into the behavior of the NHBS population, or issues relevant to the field sites, or a particular topic of interest.

2.4 NHBS-MSM only - Identification of Venues

NHBS-MSM project sites will be required to conduct a number of activities to identify venues. These include identification of venues within the MSA, qualitative data collection such as interviews with key informants, focus group interviews, observation (to collect information on these enumerated venues and to describe the characteristics of those who frequent these venues), and type I and type II enumeration of venues (see section 2.4c).

2.4a Venue definition

A potential venue is an area, location, or building where MSM can be approached and recruited to participate in the NHBS-MSM survey. Potential venues for consideration for NHBS-MSM are found within the MSA and are defined as public or private locations that are attended by men for purposes *other* than receiving medical or mental healthcare, social services, or HIV/STD diagnostic testing or prevention services. Support groups for HIV-infected persons and clinical or other settings that routinely provide medical care, mental healthcare, social services, or HIV/STD diagnostic or other prevention services are ineligible for consideration as venues. Venues may include bars, dance clubs, retail businesses, cafes and restaurants, health clubs, social or religious organizations, adult bookstores, bathhouses, street locations, parks, beaches, and special events such as gay pride festivals, raves, and circuit parties. These venues may be considered even though some healthcare, HIV/STD diagnostic, or prevention services may be available on site (e.g., HIV testing services provided in some bathhouses). The list of all potential venues in an MSA is called the venue universe.

2.4b Methods

Venue identification involves the steps described below. These steps result in a universe of potential venues which will be verified with key informant and focus group participants. Project staff will use the venue universe to conduct observations and brief interviews of venue attendees to assess the eligibility and accessibility of venues in the universe. After completing all of these activities, a list of accessible venues will be finalized and used to create the monthly sampling frames (see Chapter 4).

Identify all potential venues and assess for eligibility

The first step in the venue identification process is to identify all potential venues within the MSA to populate the venue universe. During the identification process, NHBS-MSM project staff should be liberal with their assessments; that is, do not exclude any potential venues at this point. The second step is to determine which venues in the universe are eligible MSM venues. An eligible venue is a potential venue where 50% or more of the men attending the venue are MSM. Project sites must enter all eligible venues into the VDTS program, even if they are not accessible for NHBS operations and will not ultimately be included on sampling frames. Staff should verify the list of eligible venues in the MSA by reviewing all local publications that advertise venues and interviewing as many persons as practical from the community who are knowledgeable about venues within the MSA. Interviews may be conducted with community members, staff of health department prevention programs, community-based organizations, community leaders, and venue owners, managers, workers, and patrons who are of various racial and ethnic backgrounds and ages.

Determine accessibility of venues

The next step in the venue identification process is to identify people who can provide insight into the accessibility of the enumerated venues. An accessible venue is an eligible venue where

it is logistically feasible to conduct a recruitment event. This information can be collected from multiple sources in the community, using a combination of qualitative methods described above in section 2.3. Interviews with key informants to elicit eligible venues should also elicit potential barriers to recruiting and interviewing men at each venue. Potential barriers that should be assessed include structural (inadequate space for recruitment), uncooperative management, safety, parking (if interview vans are used), competing outreach activities, and insufficient attendance (discussed in section 2.4c). Identifying potential recruitment and interview barriers will help staff to further assess, clarify, and prevent or minimize sampling barriers. The set of accessible venues will make up the venue sampling frame each month. Venue accessibility should be updated monthly for any changes, such as seasonal changes.

Record days of operation for all accessible venues

Project sites must enter the days of operation of all accessible venues into the VDTS program. The days of operation are defined as the days when a venue is open and eligible ($\geq 50\%$ of the men attending the venue are MSM). For venues with fixed days of operation (e.g., businesses), staff may record the posted days the venue is open as the days of operation. They may also obtain the days of operation from venue management, the internet, or advertisements. For social organizations and special events, the days of operation are the days when the activity is scheduled to occur. For venues that do not have fixed days of operation (e.g., streets, cruising areas, etc.), project sites should determine what days the venue meets the eligibility threshold of $\geq 50\%$ MSM. These days are then entered in the VDTS Program as the days of operation for the venue.

2.4c Assessment of venue attendees

As part of determining venue accessibility, it is necessary to determine if a sufficient number of eligible people attend the venue. This involves collaborating with the venue owners or managers, venue observations, enumerations, and collaboration with other organizations.

Collaboration with venue owners/managers

Project staff should obtain the approval of venue owners or managers before conducting observations or type 1 or type 2 enumerations. Approval is necessary to conduct sampling events just outside of or within these establishments. In meeting with venue owners or managers, project staff should emphasize individual and community benefits of NHBS and that sampling activities will be conducted in ways to minimize burden on venue management and patrons.

Venue observations

The purpose of observations is to assess venue attendance and to make note of key characteristics about the venue and venue attendees that may affect venue selection and future recruitment activities. These include: 1) activities that are occurring at the venue during specific

days and times, 2) the safety and feasibility of conducting interviews at the venue, 3) locations where recruitment should be conducted (inside the venue, near the entrance, etc), and 4) characteristics of venue attendees (age, race, gender, etc).

Type 1 and 2 enumerations

If observations alone are not sufficient, type 1 and type 2 enumerations can be conducted to obtain additional venue information. Type 1 enumerations are conducted by one person and are simple counts of people attending venues during 30- to 60-minute periods. Type 1 is the optimal enumeration method when staff believe that people attending the venue are predominately MSM. Type 2 enumerations are conducted with two project staff who count and briefly interview men on their sexual behavior and eligibility for NHBS-MSM. Type 2 enumeration provides attendance estimates of eligible MSM and is the optimal method when staff suspect that venues are attended by a large number of men who are not eligible to participate in NHBS-MSM (see Chapter 4 for eligibility criteria).

Collaboration with other organizations

Project staff will also need to collaborate with organizations that conduct outreach, prevention, or research activities at identified venues. Project staff should first interview health department HIV/STD prevention staff and community informants about the organizations that are known to conduct these activities and where and when they are conducted. Project staff should then inform managers of these organizations about NHBS-MSM and the need to collaborate. As part of collaborative agreements, monthly outreach calendars should be shared between organizations to prevent activities that occur at the same place, date, and time.

2.5 NHBS-IDU & NHBS-HET only - 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, 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.

2.6 Garnering Community Support

The support of the 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
- 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, state and local health department staff, and respondents of street intercept surveys
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 potential barriers to NHBS, including logistics, community acceptance, and possible ways to overcome those barriers.

2.7 NHBS-HET only - Identification of High Risk Areas (HRAs)

For NHBS-HET cycles, formative assessment should include activities that identify and characterize High Risk Areas (HRAs). HRAs are geographic areas within the MSA where heterosexuals are at higher risk for HIV infection compared to other geographic areas within the MSA. HRAs are defined as areas with high rates of poverty. HRAs will be used to assist in identifying appropriate locations for storefronts or van locations during survey implementation and to assist in identifying seeds. Identifying the HRAs will require project sites to obtain geographic data, identify areas of high poverty, and map the HRAs using a Geographic Information System, or GIS. Officials in the state health department should be involved in the process of identifying HRAs because it entails handling confidential data. Data from the entire MSA (only within the jurisdiction of the NHBS state health department) should be used rather than just using data from the city. HRA identification will be described in greater detail in the NHBS Formative Assessment Manual.

2.8 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.

NHBS-MSM only

Project sites will use a combination of qualitative and quantitative methods to monitor enrollment rates, suitability of venues for recruitment, potential concerns about the percent of eligible respondents at venues, demographic characteristics of the sample, and other relevant indicators of data quality. Ongoing formative assessment will also monitor whether new venues have opened or started attracting a population of MSM during the data collection period and whether these venues would be eligible and accessible for NHBS-MSM recruitment

NHBS-IDU & NHBS-HET only

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.

2.9 References

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3.1 Data Collection Instruments

3.1a NHBS-MSM only – Intercept Form

Each recruiter will use the Intercept Form (Appendix D) during recruitment events to record intercept data on men who are counted and approached. The two questions asked of potential participants during the intercept are whether he has already been asked to participate in the current NHBS-MSM cycle and whether he previously participated in the current NHBS-MSM cycle.

3.1b Eligibility screener

NHBS participants are screened for eligibility before participation in the NHBS survey. Eligibility screening makes efficient use of staff and respondent time by quickly identifying those who are eligible and ineligible. NHBS uses a standardized, interviewer-administered instrument to determine eligibility. The eligibility screener is programmed into a portable computer. Eligibility criteria are described in Chapter 4.

Screening for eligibility is important for ensuring that all persons recruited to participate in NHBS meet the same eligibility criteria for participation, allowing for comparison across all NHBS project sites.

3.1c NHBS-IDU & NHBS-HET only - Network Questions

Information about the size and characteristics of participants' networks, and descriptions of the relationships between the participant and the person who gave him or her 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 seen recently, and who meet the eligibility criteria for the given study. A participant's personal network size is based on how many people he or she knows who fit the eligibility criteria for the current NHBS cycle. Cycle-specific questions to obtain necessary network data are included as part of the NHBS 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) and were used in the IDU and HET pilot studies prior to the current cycle. The network questions for the current NHBS cycle are based on experiences during previous cycles; consultation with NHBS principal investigators and cognitive testing of the network questions used in NHBS-IDU2 and NHBS-HET2 conducted by the National Center for Health Statistics.

3.1d Questionnaire

Questionnaire components

The NHBS questionnaire consists of three components. First, the core questions constitute a standardized main component. Second, participating NHBS project sites may develop and add questions that address topics of local interest. Third, cycle-specific questions are standardized, but they are asked only during the relevant cycle

Core Questions. The core questions will be used by all project sites participating in NHBS 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.

Cycle-specific Questions. The NHBS questionnaire is a single document, with sections used only during each appropriate cycle: MSM, IDU, or HET. These cycle-specific questions are noted in Appendix E. Cycle-specific questions will provide data that will be used for comparisons of risk behaviors, comparisons of HIV testing behaviors, and weighting. The computerized version of the questionnaire will be set for each cycle so that interviewers can only administer the appropriate cycle-specific version. Changes were made to the questionnaire content and format between Round 4 and NHBS-MSM5 (OMB control number 0920-0770).

Development of the questionnaire

Development of the NHBS questionnaire is a collaborative process between participating NHBS project sites and CDC. Changes were made to the questionnaire content and format between Round 4 and NHBS-MSM5. The questionnaire provided in Appendix E of this protocol reflects those changes. Prior to development of the current questionnaire, NHBS project site staff and the Behavioral Surveillance Team evaluated the Round 4 questionnaire and data. In addition, CDC reviewed reports of cognitive testing previously conducted for NHBS items and requests for content modification from participating NHBS sites and other stakeholders. Questions were evaluated and revised as necessary, new questions were identified for inclusion in order to incorporate the need for data on emerging issues. All items were reviewed by subject matter experts. All decisions regarding changes to the questionnaire were made to optimize data quality, provide consistent measurement over time for key NHBS indicators, and reduce respondent burden.

3.2 Translation of Data Collection Instruments

All NHBS 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 and the use of translators is prohibited.

3.3 General Data Collection Procedures

Data for NHBS 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 1a: NHBS-MSM only - Approach

Potential participants will be approached and asked about their interest in participating in NHBS and whether they have previously participated. Intercept information is recorded on the Intercept Form (Appendix D).

Step 1b: NHBS-IDU & NHBS-HET only - Participants present a valid study coupon to NHBS project staff

At a storefront or mobile van location, potential “seeds” (the initial participants recruited by NHBS staff) and subsequently, the peers they recruit will present valid coupons to NHBS project staff. The number on the coupon will be entered into a specialized coupon manager program developed for NHBS (coupon manager) and its validity will be determined. Coupon manager provides a way to keep track of coupon numbers and respondent compensation for those who agree to recruit others into the study. In order to keep coupons from being duplicated, NHBS 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 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 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 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: Participation incentives

Participants will receive a small stipend for participation in NHBS activities. The reimbursement amounts are determined locally by the NHBS project sites, and are based on investigators' previous experience with NHBS cycles or other similar studies. The reimbursement includes compensation 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 disbursement, equivalent reimbursement may be offered (e.g., gift certificates, tokens for public transportation). Cash incentives are highly encouraged if not prohibited by local regulations. Participant compensation for incomplete surveys may be offered in accordance with local policies.

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

Step 7: NHBS-IDU & NHBS-HET only - 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 incentive. 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 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 incentives for recruiting other people (Appendix I). This information will be stored in the coupon manager and destroyed following local procedures (Chapter 8).

Participants who recruit will receive their reimbursement by returning to the storefront where they were interviewed and checking in with the project supervisor. Project staff will use the Unique ID and any visible, physical marks to verify the identity of each recruiter returning to claim reimbursement for distributing coupons. After verification, recruiters will be given approximately \$10 per eligible participant who completed an interview. If a coupon recipient does not complete an interview, his or her recruiter will not be compensated for that coupon. However, project staff have the option of distributing an incentive to these recruiters to compensate them 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 data collection activities.

The NHBS 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 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 personnel will be appropriately trained to conduct NHBS 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 staff periodically. The local NHBS 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 NHBS-MSM only – VBS Methods

There are three main activities that make up venue-based sampling (VBS): 1) undertaking formative assessment to identify and assess MSM venues, 2) sampling venues and day-time periods to create a monthly recruitment calendar, and 3) conducting recruitment events to enroll participants in the project. This section focuses on the latter two activities.

4.2a *Monthly Recruitment Calendar*

Each month, local project staff will create a recruitment calendar to schedule an upcoming month's recruitment events. The venues, days, and times (VDTs) for the recruitment events will be selected using a two-stage sampling method– the first stage to select venues and the second to select days and times.

Constructing sampling frames

Before sampling can begin, project staff will have to construct two sampling frames: a venue frame and a day-time frame. The venue frame is the list of venues *where* recruitment could potentially take place during the upcoming month, and the day-time frame is the list of day and time periods *when* recruitment could occur at each venue. Sampling frames should contain all accessible venues and be continuously updated throughout the project period each month. As attendance patterns at venues change, day-time periods should be adjusted accordingly. If new venues or day-time periods are identified or become accessible, they should be added to the sampling frames. Similarly, if a venue becomes inaccessible (e.g. lost owner approval for NHBS operations) or ineligible (e.g. venue closure) it should be removed from the venue frame. After both sampling frames have been constructed, sampling and VDT selection can begin.

Stage 1 sampling: venue selection

In stage 1 sampling, project staff select venues where recruitment will occur during the upcoming month. First, the staff determine the number of recruitment events they plan on conducting that month and then they randomly select a corresponding number of venues from the venue frame. In most cases, stage 1 sampling is done without replacement, meaning that once a venue has been chosen, it cannot be selected again that

month, although it can be chosen as an alternate venue (see below).

Stage 2 sampling: day-time period selection

In stage 2 sampling, project staff select the day-time periods when recruitment will occur at the venues chosen in stage 1. To facilitate the selection of day-time periods, project staff rank the venues chosen in stage 1 in order from the venue with the fewest number of day-time periods to the venue with the most. Starting with the venue with the fewest number of day-time periods, project staff will randomly select a day-time period and schedule it on the recruitment calendar for the upcoming month. If no days are available on the recruitment calendar to schedule the event, another day-time period should be randomly selected from the remaining ones. Under the rare circumstance that the recruitment calendar cannot accommodate any of the day-time periods for a venue, a replacement venue is randomly selected from those that were not chosen in stage 1. The process of stage 2 sampling is repeated for each of the venues selected in stage 1 until all venues have been scheduled on the recruitment calendar. To minimize irreconcilable scheduling conflicts, venues should always be scheduled in order from the venue with the fewest number of day-time periods to the venue with the most. Although the day-time periods for conducting recruitment events are randomly selected in stage 2, the actual dates of the events on the recruitment calendar are not randomly selected in order to accommodate staffing needs.

Non-random recruitment events

Project staff may non-randomly select up to a maximum of two venues to include on their monthly recruitment calendar. These non-random events can be used to capture special events or to increase representation of important sub-populations, but they should be used sparingly. During the month that each project site holds its largest or main pride festival, they may conduct up to two additional non-random events at venues that are part of the main gay pride festival, for a total of four non-random events.

Alternate venues

Occasionally, recruitment cannot be conducted at a scheduled venue because of unforeseen circumstances like inclement weather or venue closure. Therefore, at least one alternate venue should be scheduled for each planned recruitment event. An alternate venue is randomly selected from among all the remaining venues on the sampling frame that have a day-time period that corresponds to the day-time period of the scheduled recruitment event. The monthly recruitment calendar is complete when all sampled venues have been scheduled and alternate venues have been assigned for each one.

4.2b Recruitment Events

Each month, recruitment events are held at the venues scheduled on that month's recruitment calendar. During these events, project staff count venue attendees, recruit

participants, screen for eligibility, conduct interviews, and test for HIV. Project sites will continue to hold recruitment events until they have enrolled a minimum of 500 MSM or until the NHBS-MSM end date.

Counting

In order to provide a measure of all male attendees ≥ 18 years of age at the venue during the recruitment event project staff will count venue attendees who appear to be male and ≥ 18 years of age during the event. Project staff should arrive at a venue before it becomes busy. Before implementing recruitment, project staff should count attendees present at the venue immediately before recruitment begins, this is the pre-event count. Once recruitment begins, project staff should count attendees as they enter the venue, this is the entry count. An entry line should be defined for counting at venues without a physical entry way (e.g., parks, streets, etc.) or venues where counting at the entry is not possible. To provide the most accurate count of venue attendance during the recruitment event, the pre-event count and the entry count are combined when NHBS-MSM sampling weights are calculated.

Recruiting

Any man attending a venue during a recruitment event is eligible for recruitment. The staff member doing the counting at the entry will direct an interviewer or a designated recruiter to approach the man and attempt to recruit him for participation in the study. Alternatively, the field supervisor or another staff person can direct recruitment. Men should be approached consecutively when interviewers are available. Each recruiter will use an Intercept Form (Appendix D) during each recruitment event to record intercept data on the men who are approached. These intercept data are recorded on the forms in the presence of the potential participants. During recruitment, recruiters will briefly describe NHBS-MSM, ask about previous participation in the survey, and for those who have not previously participated, ascertain willingness to participate. Men who have not previously participated in the survey, but are interested in doing so will be referred to an interviewer for eligibility screening. Men will normally be approached for recruitment in public, but eligibility screening occurs in a private area of the venue or in a designated interviewing space near the venue.

Appointments

In rare circumstances, if a potential participant does not wish to be interviewed at the time of recruitment, he can make an appointment to complete the survey at a later date. A future interview date and time could be scheduled before or after a recruitment event or the potential participant could call the project office to schedule one. In either case, the potential participant will be assigned a Survey ID. This anonymous number will be used to make the interview appointment, as well as to update recruitment monitoring forms. Interviews by appointment should be done sparingly and may only take place before or after a scheduled recruitment event or at the project office. The field supervisor, the interviewer, and at least one additional staff member must be in attendance during all

interviews by appointment.

Eligibility screening and consent

Potential participants will be assessed for eligibility using the eligibility screener (Appendix E). If a potential participant is eligible, the interviewer will obtain informed consent from him by reading the consent form (Appendix F) and obtaining his verbal agreement to participate. Interviewers will address any questions that the participant may have prior to starting the survey.

If a potential participant is not eligible, he will be thanked for his time and interest in the project. No core survey data are collected on men who do not consent. However, they will be asked the reason why they are not interested in participating so that project staff can assess whether any barriers to the study exist.

Interviewing

Participants will be interviewed using the NHBS questionnaire (Appendix E) which is administered using a CAPI program. The interview will take about 30 to 40 minutes. Interviews are conducted in a private area of the venue or in a space near the venue.

HIV testing

Participants who consent to the survey, 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.

4.3 NHBS-IDU & NHBS-HET only – 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 through 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, and helps reduce bias in the sample.

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 race/ethnicity, age, gender, 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 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. If based on previous NHBS cycles, there is concern that a sub-population of interest (e.g. youth, female) is under-represented; seeds can be purposely selected (with approval of the CDC Project Officer) in order to increase the likelihood of reaching that sub-population.
- **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.
- **Seeds cannot be transgender.** For these NHBS activities, transgender

individuals are not the primary population of interest. In order to reduce the total number of transgender participants in the sample, individuals who are transgender may not be used as seeds for NHBS.

- **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 underrepresented during the course of NHBS, adding seeds from this group can be useful.

In addition, Seeds must meet all eligibility criteria for the current NHBS cycle.

NHBS-HET only: Additional eligibility criteria for seeds

- **Seeds cannot report high income.** In order to increase the likelihood that networks will be representative of the HET population (low-income persons), household income will be assessed during the survey. In order to be eligible to recruit other study participants, participants (including seeds) must have a household income at or below 150% of the HHS poverty guidelines adjusted for geographic differences in the cost of living. Individuals whose household income exceeds this threshold may participate in NHBS-HET but will not be eligible to recruit others for NHBS-HET.
- **Seeds cannot report injection drug use (ever).** In order to reduce the total number of persons who inject drugs in the NHBS-HET sample, potential seeds will be asked about injection drug use in the survey. Potential seeds who report ever using injection drugs may participate in NHBS-HET but will not be eligible to recruit others for NHBS-HET. (Note that this criterion applies only to seeds; individuals who are recruited by seeds may report injecting drugs but will not be eligible to recruit others if they have injected drugs in the past 12 months.)
- **Seeds who are male cannot report having male sex partners (ever).** In order to reduce the total number of men who have sex with men in the NHBS-HET sample, potential seeds who are male will be asked about having male sex partners in the survey. Potential seeds who are male and who report ever having male sex partners may participate in NHBS-HET but will not be eligible to recruit others for NHBS-HET. (Note that this criterion applies only to seeds; men who are recruited by seeds may report having male sex partners but will not be eligible to recruit others if they had male sex partners in the past 12 months.)

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 he or she would be willing to go to the field site location to discuss the project further. If the potential seed cannot do so at that time, he or she will be given a referral card to come to the field site location at a time of his or her 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 and interviewing potential seeds, staff will ensure that they do not compromise the confidentiality of the participant; even when conducted on the street, interviews 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 of Seeds

At the field site location, potential seeds will be assessed for eligibility using the eligibility screener (Appendix E). If eligible, seeds will continue with the consent process. If not eligible, the participant will be thanked for their time and interest in the project.

Consent and Interviewing Seeds

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 seed may have, prior to starting the survey interview.

No data are collected from seeds who do not 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 E) which is 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' confidentiality.

HIV and other testing

Seeds 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 and approved by the NHBS project officer.

Training Seeds 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 incentive. After a brief training on the recruitment process, those who agree to recruit will be given up to five coded, non-replicable coupons (Appendix D). The participant will be told to give one coupon to each of up to five individuals he or she knows and has seen in the past 30 days who live in the project area and meet certain cycle specific criteria.

Each coupon will have the current NHBS cycle name, 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 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 4.3a above; however, non-seed participants must be interviewed at a field site location. Eligibility criteria for NHBS participation and recruitment are described in Section 4.4 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 incentive.

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 and have seen in the past 30 days 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 (See Chapter 1).

Obtaining Incentives 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 and the validity of claims for reimbursement for recruiting other eligible participants (Appendix N). This information will be stored in the coupon manager and destroyed following local procedures (Chapter 8).

When a recruiter returns to claim reimbursement for distributing coupons, his or her identity will be verified using the Unique ID and the visible physical marks. After verification, he or she will be given 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 Eligibility Criteria

4.4a NHBS-MSM only

Participant inclusion criteria

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

- Have not previously participated in the current NHBS-MSM cycle
 - Live in the participating MSA or Division
 - Are 18 years of age or older*
 - Were born male and self-identify as male
 - Have ever had oral or anal sex with another man
- 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.

Definition of current MSM

Participants meeting the participant inclusion eligibility criteria who also report having had sex with another man in the past 12 months count toward the required NHBS-MSM sample size of 500 current MSM.

NHBS-MSM ELIGIBILITY CRITERIA		
Criteria	Participant inclusion (eligible to complete interview)	Current MSM (included in analysis and count toward required sample size, n=500)
Has not previously participated in the current cycle of NHBS (i.e., NHBS-MSM5)	X	X
Lives in the participating MSA or Division	X	X
Is 18 years of age or older	X	X
Has ever had oral or anal sex with another man	X	X
Was born male and self-identifies as male	X	X
Is able to complete the interview in English or Spanish	X	X
Has had oral or anal sex with another man in the past 12 months		X

4.4b NHBS-IDU only

Participant inclusion criteria

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

- Present a valid NHBS-IDU coupon
 - Have not previously participated in the current NHBS-IDU cycle
 - Live in the participating MSA or Division
 - Are 18 years of age or older*
 - Have injected drugs without a prescription in the past 12 months
- 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

Participants meeting these criteria count toward the required NHBS-IDU sample size and are eligible to complete the interview and recruit others.

NHBS-IDU ELIGIBILITY CRITERIA		
Criteria	Participant inclusion (eligible to complete interview and recruit; count toward required sample size, n=500)	To be a seed
Presented a valid NHBS-IDU coupon	X	Seeds are recruited by NHBS staff
Has not previously participated in the current cycle of NHBS (i.e., NHBS-IDU4)	X	X
Lives in the participating MSA or Division	X	X
Is 18 years of age or older	X	X
Has injected drugs in the past 12 months	X	X
Is able to complete the interview in English or Spanish	X	X
Is male or female (<u>not</u> transgender)		X

4.4c NHBS-HET only

Participant inclusion criteria

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

- Present a valid NHBS-HET coupon
- Have not previously participated in the current NHBS-HET cycle
- Live in the participating MSA or Division
- Are between 18 and 60 years of age* (inclusive)
- Have had vaginal or anal sex with an opposite sex partner in the past 12 months
- Are male or female (not transgender)

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 The upper age limit for the NHBS-HET cycles is based on unpublished analyses of NHBS-HET1 data and information from CDC's Incidence Surveillance System. The upper age limit is necessary to ensure that the NHBS sample includes age groups most at risk for HIV infection.⁴ In NHBS-HET1, although HIV prevalence was significantly higher among older participants, rates of new HIV diagnoses were higher in participants 25 years old and younger. Similarly, CDC's HIV Incidence Surveillance System found that the largest number of new infections among females occurred between the ages of 30--39 years with incidence dropping precipitously for older age cohorts.⁴ A review of numerous CDC sources of unpublished HIV incidence data suggest that an age cap of 60 is appropriate for NHBS.

HET definition inclusion criteria

To focus on heterosexuals at increased risk of HIV, NHBS-HET utilizes a further set of criteria designed to identify respondents as heterosexuals at increased risk for HIV. These criteria are known as the "HET definition." Participants are said to meet the HET definition if they:

- Meet all NHBS-HET participant inclusion criteria (above);
 - Have low income. Low income is defined as having a household income at or below 150% of the HHS poverty guidelines adjusted for geographic differences in the cost of living; Have not injected drugs without a prescription in the past 12 months;
- and
- If male, have not had male sex partners in the past 12 months.

Only participants who meet the HET definition count toward the required sample size.

To ensure a sufficient sample size for analysis, recruitment methods are designed to take participant inclusion criteria and the HET definition into account. CDC reviewed the literature, held a series of expert consultations, and evaluated a pilot HET population definition during the NHBS-HET1 cycle. The pilot identified that social-structural variables – particularly measures of individual SES – were the most effective means of identifying a representative sample of heterosexuals at increased risk of HIV infection.⁵ These criteria were first applied during NHBS-HET2. All respondents who meet the NHBS-HET participant inclusion criteria are eligible to participate, but participants can only recruit others if they meet the HET definition (i.e., have a low income, have not injected drugs in the 12 months prior to the survey, and if male, have not had male sex

partners in the 12 months prior to the survey). These factors will be assessed during the NHBS interview, and the portable computer will be programmed to inform the NHBS interviewer whether or not to invite participants to be recruiters.

NHBS-HET ELIGIBILITY CRITERIA			
Criteria	Participant inclusion (eligible to complete interview only)	HET Definition (Eligible to recruit; included in analysis; count toward required sample size, N= 500)	To be a seed
Presented a valid NHBS-HET coupon	X	X	Seeds are recruited by NHBS staff
Has not previously participated in the current cycle of NHBS (i.e., NHBS-HET3)	X	X	X
Lives in the participating MSA or Division	X	X	X
Is between 18 and 60 years of age	X	X	X
Had vaginal or anal sex with a person of the opposite-sex in the past 12 months	X	X	X
Is male or female (<u>not</u> transgender)	X	X	X
Is able to complete the interview in English or Spanish	X	X	X
Income does <u>not</u> exceed 150% of the HHS poverty guidelines adjusted for geographic differences in the cost of living		X	X
Has <u>not</u> injected drugs in the past 12 months		X	X
If male, has <u>not</u> had male sex partners in the past 12 months		X	X
Has <u>never</u> injected drugs			X
If male, has <u>never</u> had male sex partners			X

4.5 References

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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.

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.

Other biological specimens may be collected and tested (e.g., hepatitis, sexually transmitted infections) when funds are available and with project officer approval.

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 infection (STI)); and 4) storing leftover specimens for additional tests, including viral load testing 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. For participants who refuse HIV testing, NHBS staff may also provide referrals for local HIV testing locations. 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 HIV specimen collection

Tests using blood are more sensitive to detect HIV infection than oral fluid, especially early infections. Blood specimens for HIV testing are required 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.

NHBS project sites will offer rapid HIV testing to participants with rapid or laboratory-based supplemental 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 test results. Lab-based only HIV testing can be conducted under circumstances in which rapid HIV testing cannot be administered. Rapid test specimens may be collected prior to survey administration, but only if local requirements allow specimen collection to occur without pre-test counseling. Persons who test positive for HIV on a rapid test must be asked to provide a blood specimen for rapid or laboratory-based supplemental testing at the time that preliminary positive test results are given.

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. Results of rapid tests and specimen collection for supplemental 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 (if applicable), 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., STI 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, if applicable, 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 specimen has been collected for supplemental testing. 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 NHBS-MSM & NHBS-IDU only - Other HIV testing

NHBS sites must collect DBS via finger stick or venipuncture for additional testing at the CDC laboratory from participants who consent to long-term specimen storage for additional testing. 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. Additional laboratory tests

can only be done if participants provide consent to specimen storage.

The goal of conducting resistance testing on DBS 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 from the CDC laboratory will not be returned to participants. All HIV-positive participants are referred to local facilities offering HIV care and treatment. HIV viral loads will likely be conducted at these facilities as part of the clinical evaluation of HIV-positive persons.

5.2f Additional tests

NHBS project sites can conduct other tests in addition to an HIV test provided funds are available and local regulations permit anonymous testing. For example, some NHBS sites may conduct testing for hepatitis B virus (HBV) and hepatitis C virus (HCV) using blood collected via venipuncture or testing for STI(s) with oral and vaginal swabs. Project sites must receive project officer approval before conducting other tests among NHBS participants, regardless of the funding source.

Results of these 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 themselves. 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 Reimbursement

HIV testing will be provided at no cost to participants. In addition, participants may be reimbursed approximately \$25 for their time after specimens have been collected. Similar reimbursement 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 performed as part of NHBS) 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
- rapid test(s) results
- 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.

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 (depending on the cycle) for each NHBS cycle:

1. Database of NHBS questionnaire records
2. Database of local questionnaire records
3. Coupon manager database (NHBS-IDU & NHBS-HET only)
4. Recruitment Monitoring Database (NHBS-MSM only)
5. HIV testing database
6. Venue Day Time Sampling (VDTS) Database (NHBS-MSM only)
7. Hepatitis or 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. The electronic NHBS questionnaire will be programmed such that cycle specific (MSM, IDU or HET) questions are asked during the appropriate cycle.

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 each NHBS cycle, 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.

7.1 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 each NHBS population to produce at least one data product or report (fact sheet, epidemiologic profile, surveillance report, peer-reviewed manuscript or other product 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 project sites are expected to disseminate local results to health department officials and the public by presenting results from NHBS at conferences, preparing reports for community planning groups, or publishing the results in peer-reviewed journals. NHBS project sites and CDC may collaborate on articles and reports when appropriate.

7.2 Limitations and Potential Biases

7.2a *NHBS-IDU & NHBS-HET only - 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 race/ethnicity, gender, 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 *NHBS-MSM only - Venue-based sampling*

Findings from venue-based sampling methods can only be generalized to venue attending MSM^{3,4}. Some persons who are otherwise eligible (e.g., by age, sexual behavior, and residence) may not attend the venues eligible for NHBS operations during the surveillance cycle or not attend venues at all. To minimize the effect of this bias, formative assessment is conducted throughout the data collection period to update venue and day-time periods. If new venues or day-time periods are identified or become accessible, they should be added to the sampling frames. Similarly, if a venue becomes inaccessible (e.g. lost owner approval for NHBS operations) or ineligible (e.g. venue closure) it should be removed from the venue frame.

Despite these limitations, venue-based sampling has obtained large and diverse samples in other studies, including earlier cycles of NHBS.

7.2c 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.

8.1 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 handheld 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 an incentive, 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 contact participants to provide test results or potential seeds to schedule appointments. Project sites must receive CDC project officer approval before collecting contact information. Contact information (phone numbers) 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 (participants) or an interview is scheduled (seeds).
- NHBS-IDU & NHBS-HET only – 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.
- All removable storage media (e.g., flash drives for data transfer or back-ups) containing NHBS data must be encrypted. The key for de-encryption must not be written on the device.
- 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 handheld computers) can view incomplete interviews. Portable computers incorporate the use of encryption software. 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 computers. 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 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.

9.1 Institutional Review Board Approval

The protocol for NHBS Round 2 was submitted for review and approved by CDC's Institutional Review Board (IRB) in 2007. In April 2009, the CDC Human Research Protections Office subsequently determined that NHBS is research, but that CDC is "not engaged" in this research. Therefore, the NHBS-HET2 protocol was not reviewed by the CDC IRB. In November 2010, the CDC Human Research Protections Office confirmed their previous decision and determined that NHBS operations constitute research, but that CDC is "not engaged" in this research. This determination expires on December 31, 2015. Effective January 1, 2016, CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Associate Director for Science Office determined NHBS to be a routine disease surveillance activity (Appendix P). 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.

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., hepatitis, 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/STD 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/STD 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.

9.3 Voluntary Participation

Participation in NHBS is completely voluntary. Participants can refuse to participate in the NHBS survey or in the HIV testing component without penalty. Participants are not required to take an HIV test (or any other test offered) to participate in the survey. However, participants will not be able to receive an HIV test (or any other test offered) 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.

NHBS-HET only

An upper-age limit on participation in the NHBS-HET cycles is necessary to ensure that the age groups most at risk for HIV infection are included. A review of CDC sources of published and unpublished HIV incidence data and of newly-diagnosed HIV cases suggest that an age cap of 60 is appropriate for this purpose.

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 his or her 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.

NHBS-IDU & NHBS-HET only

If acceptable, locally allowable, and approved by the CDC project officer, potential seeds may be given the opportunity to provide a phone number to schedule appointments. If contact information (phone number) is 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 recruitment awards to participants who return to collect them. This information will be kept in the coupon manager database for the purposes of accurate reimbursements and will be destroyed after the completion of recruitment, reimbursements, 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 Reimbursement for Time and Effort

Activities that are part of NHBS for all sites include the survey (which is the only activity required for participation) and taking a voluntary HIV test, and may include other voluntary testing for STIs or hepatitis. Participants will receive a small stipend for participation in NHBS activities. The reimbursement amounts are determined locally by the NHBS project sites; amounts included in this document are based on previous experience with NHBS cycles or other similar studies.

Respondents will be reimbursed approximately \$25 in cash for their participation in the NHBS survey. If local regulations prohibit cash disbursement, equivalent reimbursement may be offered in the form of gift certificates; however, all non-cash reimbursements should have appropriate value to the population. The formative assessment process can help verify what types of non-cash reimbursements 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 tests will be provided at no cost to participants. In addition, participants will be reimbursed approximately \$25 for their time and inconvenience. Appropriate risk-reduction counseling will be provided to all participants who elect testing for HIV. Interviewers will tailor prevention messages to specific risks identified 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.

If STI, hepatitis, or other tests are offered through NHBS, these tests will be provided at no cost to participants. Participants may be reimbursed as appropriate for the local context for their time and inconvenience.

Participants will receive their stipend 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 Field Supervisor or the Interviewer dispense the stipend.

NHBS-IDU & NHBS-HET only

In RDS, voluntary recruitment of peers constitutes an additional, voluntary, NHBS activity. Participants who agree to recruit their peers are compensated a small amount for each eligible person they recruit into the project; the average amount of these reimbursements 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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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.
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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 System 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.
 - e. [MSM only] Names of places and social organizations that are attended by men who have sex with men (MSM);
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 [him/her] 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.
 - e. Nombres de los lugares y organizaciones sociales que visitan hombres que tienen relaciones sexuales con hombres o HSH (MSM, por sus siglas en inglés);
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 System 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.
 - f. [MSM only] Names of places and social organizations that are attended by men who have sex with men (MSM).
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 \$25 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 [him/her] 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.
 - f. Nombres de los lugares y organizaciones sociales que visitan hombres que tienen relaciones sexuales con hombres o HSH (MSM, por sus siglas en inglés)
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 System 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 1 ½ 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.
 - d. [MSM only] Names of places and social organizations that are attended by men who have sex with men (MSM)
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 \$25.00 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 \$25 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 *[him/her]* 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.
 - d. Nombres de los lugares y organizaciones sociales que visitan hombres que tienen relaciones sexuales con hombres o HSH (MSM, por sus siglas en inglés)
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 25 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 25 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

NHBS-MSM only - Intercept Form

An illustration of the Intercept Form is provided below. The actual form can be found in a separate Excel file named **Appendix D- Intercept Form.xls**.

Intercept Form

Venue Code: _____ Event Number: _____ Date: ____ / ____ / ____

Venue Name: _____ Recruiter: _____

#	Previously Participated				Post-event Appointment		Agreed to Screening		Comments
1	Y	N	D	R	Y	N	Y	N	
2	Y	N	D	R	Y	N	Y	N	
3	Y	N	D	R	Y	N	Y	N	
4	Y	N	D	R	Y	N	Y	N	
5	Y	N	D	R	Y	N	Y	N	
6	Y	N	D	R	Y	N	Y	N	
7	Y	N	D	R	Y	N	Y	N	
8	Y	N	D	R	Y	N	Y	N	
9	Y	N	D	R	Y	N	Y	N	
10	Y	N	D	R	Y	N	Y	N	
11	Y	N	D	R	Y	N	Y	N	
12	Y	N	D	R	Y	N	Y	N	
13	Y	N	D	R	Y	N	Y	N	
14	Y	N	D	R	Y	N	Y	N	
15	Y	N	D	R	Y	N	Y	N	
16	Y	N	D	R	Y	N	Y	N	
17	Y	N	D	R	Y	N	Y	N	
18	Y	N	D	R	Y	N	Y	N	
19	Y	N	D	R	Y	N	Y	N	
20	Y	N	D	R	Y	N	Y	N	
									← Sub-totals

Page (circle one): 1 2 3 4 5 of ____

Appendix E

Data Collection Instrument

E.1 Summary of Appendix E Contents

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

- 1) English version of the Round 5 NHBS CAPI Reference Questionnaire (CRQ).
- 2) Spanish version of the Round 5 NHBS CRQ.
- 3) NHBS measure reference document – this document provides source and citation information for measures that were adopted or adapted from sources external to the CDC's Division of HIV Prevention.

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

NHBS Round 5 Measure References

The measures in the following table were adopted or adapted from sources external to the CDC's Division of HIV Prevention. Measures that were adapted from the original source are listed as "Adapted from;" other measures listed were adopted as described in the reference listed. Measures not listed were developed for NHBS by the Behavioral Surveillance Team and other subject matter experts at CDC.

Topic	Measure	Variable(s)	Source and citation
Participant Demographic Characteristics			
Ethnicity	Ethnicity, 2011 DHHS data standard	HISPANIC; HSPTYP A; HSPTYP B; HSPTYP C; HSPTYP D; HSPTYPE	Office of Minority Health. Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status. US Department of Health and Human Services website. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=23 . Accessed December 14, 2016.
English proficiency	English proficiency, 2011 DHHS data standard	ENGPF CY	Office of Minority Health. Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status. US Department of Health and Human Services website. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=23 . Accessed December 14, 2016. Adapted from the 2011 DHHS data standard for English proficiency.
Spanish proficiency	Spanish proficiency	SPNPFCY	Office of Minority Health. Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status. US Department of Health and Human Services website. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=23 . Accessed December 14, 2016.
Language spoken	Language, 2011 DHHS data standard	SPKOTLN	Office of Minority Health. Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status. US Department of Health and Human Services website. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=23 . Accessed December 14, 2016.
Poverty	DHHS Poverty Guidelines	POVERTY	Pending. Calculation based on the DHHS Poverty Guidelines for the calendar year before the HET cycle.
General Health Care			
General health care access	Usual source of care	SRCCAREA; SRCCAREB; SRCLOC	Adapted from: Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Questionnaire. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2007-2008. Available at: https://www.cdc.gov/Nchs/Nhanes/index.htm . Accessed December 14, 2016.
General health care utilization	Unmet need for health care, 12m	HCAFF	Adapted from: Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health Interview Survey Sample Adult Questionnaire. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2008. Available at: https://www.cdc.gov/nchs/nhis/data-questionnaires-documentation.htm . Accessed December 14, 2016.

Topic	Measure	Variable(s)	Source and citation
Sexual Behavior			
Partner-by-Partner Series	Series.	Series.	Overall structure informed by instruments from San Francisco local NHBS surveys (PI: H. Fisher Raymond, hfisher.raymond@SFDPH.ORG) and the InvolveMENT study (PI: Patrick Sullivan, pssulli@emory.edu).
Partner ART use	Partner ART use, last sex	P1ARTDS; P1ONART; P2ARTDS; P2ONART; P3ARTDS; P3ONART	Adapted from measure in the Element study baseline instrument. PIs: Patrick Sullivan (pssulli@emory.edu) and Eli Rosenberg (esrose2@emory.edu). NIH grant # 1R01DA038196.
Alcohol Use			
Current alcohol use	Had 1+ alcoholic drinks, 30d	ALC30D	Adapted from: Centers for Disease Control and Prevention (CDC). Behavioral Risk Factor Surveillance System Questionnaire. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, [2013]. Available at: https://www.cdc.gov/brfss/questionnaires/index.htm . Accessed December 14, 2016.
Alcohol use intensity	Maximum # drinks, 30d	ALCLG30D	Adapted from: Centers for Disease Control and Prevention (CDC). Behavioral Risk Factor Surveillance System Questionnaire. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, [2013]. Available at: https://www.cdc.gov/brfss/questionnaires/index.htm . Accessed December 14, 2016.
Binge drinking	Had 5+ alcoholic drinks, 30d; Had 4+ alcoholic drinks, 30d	ALC530D; ALC430D	Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Questionnaire. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2013-2014. Available at: https://www.cdc.gov/Nchs/Nhanes/index.htm . Accessed December 14, 2016.
Injection Drug Use			
Disposition of used needles	Disposition of used needles	NDLEDSPA; NDLEDSPB; NDLEDSPC; NDLEDSPD; NDLEDSPF; NDLEDSPF	Adapted from: Tookes HE, Kral AH, Wenger LD, et al. A comparison of syringe disposal practices among injection drug users in a city with versus a city without needle and syringe programs. Drug Alcohol Depend 2012; 123(1-3):255-9. and Coffin PO, Latka MH, Latkin C, et al; INSPIRE Study Group. Safe syringe disposal is related to safe syringe access among HIV-positive injection drug users. AIDS Behav. 2007; 11(5):652-62.
Injection equipment sharing, frequency	Syringe sharing, relative frequency, 12m, distributive	GIVENDLE	Contact local NHBS PI. Contact information available at: http://www.cdc.gov/hiv/statistics/systems/nhbs/contacts.html .
Injection equipment sharing, last event	Syringe sharing, last event, distributive	INJL_GIV	Contact local NHBS PI. Contact information available at: http://www.cdc.gov/hiv/statistics/systems/nhbs/contacts.html .

Topic	Measure	Variable(s)	Source and citation
High dead space syringe use	High dead space syringe use, 12m, (y/n); High dead space syringe use, 12m, frequency	INJREM; INJREMFR	Adapted from Dallas local NHBS surveys, in consultation with Dr. William Zule. Zule WA, Bobashev G. High dead-space syringes and the risk of HIV and HCV infection among injecting drug users. <i>Drug Alcohol Depend</i> 2009; 100(3):204-213. Contact information for Dallas local NHBS surveys available at: http://www.cdc.gov/hiv/statistics/systems/nhbs/contacts.html .
HIV Testing and Care			
Linkage to HIV care	Referred to HIV care within 30 days of first positive HIV test	TLDCARE	Adapted from: Centers for Disease Control and Prevention (CDC). Case-Surveillance-Based-Sampling Questionnaire for the Medical Monitoring Project. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, [2012-2013].
Viral load testing	Viral load test, ever; Viral load, last test date; Viral load, last test result	EVRLTST; RCVLTST; VRLTRSLT	Adapted from: Centers for Disease Control and Prevention (CDC). Medical Monitoring Project Standard Questionnaire. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, [2012].
Other Health Conditions			
Disability	Disability status, 2011 DHHS data standard	DISDEAF; DISBLND; DISCOGN; DISWALK; DISCARE; DISERND;	Office of Minority Health. Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status. US Department of Health and Human Services website. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=23 . Accessed December 14, 2016.
STD Diagnosis	Genital herpes diagnosis, ever; Genital warts diagnosis, ever	EVRLHERP; EVRLGWAR	Adapted from: Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Questionnaire. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2007-2008. Available at: https://www.cdc.gov/Nchs/Nhanes/index.htm . Accessed December 14, 2016.
Psychological distress	Kessler 6 (K-6)	FEELNERV; FEELHOPE; FEELREST; FEELSAD; FEELFRT; FEELDOWN	Kessler RC, Barker, PR., Colpe LJ, et al. Screening for serious mental illness in the general population. <i>Arch Gen Psychiatry</i> 2003; 60: 184-189.
Prevention Activities			
PrEP and PEP	PrEP sources, 12m	PRPSRCA; PRPSRCB; PRPSRCC; PRPSRCD; PRPSRCE; PRPSRCF	Adapted from measure in the Element study baseline instrument. PIs: Patrick Sullivan (psulli@emory.edu) and Eli Rosenberg (esrose2@emory.edu). NIH grant # 1R01DA038196.

Topic	Measure	Variable(s)	Source and citation
PrEP and PEP	PrEP use, frequency, 12m	PRPFX12M	Adapted from measure in the Element study baseline instrument. PIs: Patrick Sullivan (pssulli@emory.edu) and Eli Rosenberg (esrose2@emory.edu). NIH grant # 1R01DA038196.
PrEP and PEP	PrEP, how used, 12m	PRPNDLA; PRPNDLB; PRPNDLC; SPECPRU	Adapted from measure in the Element study baseline instrument. PIs: Patrick Sullivan (pssulli@emory.edu) and Eli Rosenberg (esrose2@emory.edu). NIH grant # 1R01DA038196.
Other Topics			
Discrimination due to sexual identity	MSM Discrimination	DISC_VER; DISC_SVC; DISC_WRK; DISC_HC; DISC_ATT	Adapted from: Williams D, Yu Y, Jackson JS, Anderson NB. Racial differences in physical and mental health: Socio-economic status, stress and discrimination. <i>J Health Psychol</i> 1997; 2(3): 335-351.
HIV stigma	HIV stigma;	PHIVDISC; PSUPPHIV; PERFRHIV; PPUNISHH	Adapted from: Herek G, Capitanio JP, Widaman KF. HIV-related stigma and knowledge in the United States: Prevalence and trends, 1991–1999. <i>Am J Public Health</i> 2002;92: 371–377 and Kalichman SC, Simbayi LC, Jooste S. et al. Development of a brief scale to measure AIDS-related stigma in South Africa. <i>AIDS Behav</i> 2005; 9(2): 135-143.
Violence	Physically assaulted, 12m; Sexually assaulted, 12m	PHVIO12M; SXVIO12M	Adapted from: Centers for Disease Control and Prevention (CDC). National Intimate Partner and Sexual Violence Survey (NIPSVS) Questionnaire. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, [2012].

Appendix F

Model Consent Form

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

National HIV Behavioral Surveillance System 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. *[For IDU & HET only]* 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 local laboratory-based HIV or other testing on blood and want to store specimens locally]* If you agree to an HIV test, you will also be asked to have your blood sample stored.
4. *[For sites doing hepatitis C testing]* We will also offer you free hepatitis C testing.
5. *[For sites doing STI testing]* We may 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. You will get no medical treatment in this study.

The HIV test will be done by a rapid test as discussed below.

[For sites doing only one Rapid Test with local Laboratory Testing]

Rapid Test

We will [stick the tip of one of your fingers to obtain a few drops of blood/draw less than 1 tablespoon of blood]. 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/use the blood we drew for the rapid test] 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 that allow HIV test phone results: If you prefer, you can arrange to receive your counseling and confirmatory test results by telephone.]*

[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. You will get referrals to services as needed. 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 already know you are HIV-infected, we may only do one rapid test. *[For sites required/choosing to do laboratory confirmation in addition to the algorithm]* Finally, we will use the blood to confirm your rapid test result in a laboratory. The result of the test will be ready within one week. We will set up a day and time for you to get your results. *[For sites that allow HIV test phone results: If you prefer, you can arrange to receive your counseling and confirmatory test results by telephone.]*

[For sites doing Hepatitis C tests]

Hepatitis C Tests

We will offer you free screening for hepatitis C infection. We will perform a rapid hepatitis C antibody test at the same time as performing the finger prick for your rapid HIV test. Additionally, we will collect a blood sample (about 2 teaspoons) with a needle from your veins. You can get the result of your rapid hepatitis C test within [20-30 minutes/*maximum time for the specific test used*]. You will get counseling about what the test results mean. If the rapid test is positive, that only tells us that you have ever been exposed to hepatitis C. Additional tests are needed to tell us whether you have hepatitis C right now. The result of the additional hepatitis C tests will be ready within [two weeks/*maximum time for local lab to return results*]. 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 prefer, you can arrange to receive your counseling and test results by telephone.]*

[For sites doing STI tests for MSM]

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. 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 prefer, you can arrange to receive your results by telephone.]*

[For sites doing STI Tests for HET (women aged 18-30 only)]

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 swab your vagina to collect samples. 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 prefer, 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 for local laboratory-based HIV or other testing]

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 sex. 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 sample for cloning. You can decline to let us store your sample and still be in this study. If you do not wish to have us store your sample, your sample[s] will be destroyed after this testing is completed. If you agree to have us store your sample, we will destroy your 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. [The fingerstick/drawing blood] may cause temporary discomfort from the needle 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 vaginal samples may cause temporary irritation, discomfort, and mild bleeding.
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]* *[for sites offering hepatitis testing: or hepatitis 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.

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 *[him/her]* 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*]. [*For IDU and HET only*] 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 sample/blood and STD 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
- ☐ You don't want to talk about these topics
- ☐ Some other reason
- ☐ You'd rather not say why

Apéndice F

Modelo de hoja de consentimiento

Grade Reading Level by Flesch-Kincaid Method: 7.9

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. *[Para IDU y HET solamente]* Al final de la encuesta, le podría dar la opción de reclutar hasta 5 personas para que participen en este estudio.

2. Si acepta responder la encuesta, le ofreceremos una prueba del VIH gratuita. Si usted ya sabe que tiene el VIH, de todos modos, quisiéramos ofrecerle hoy una prueba del VIH para enlazar el resultado de esta prueba del VIH que le haremos hoy con los resultados de su encuesta.
3. *[Para los sitios que realizan pruebas del VIH u otras pruebas en sangre en laboratorios locales y quieren guardar las muestras localmente]* Si está de acuerdo en hacerse la prueba del VIH, también le pediremos autorización para almacenar su muestra de sangre.
4. *[Para los sitios que realizan pruebas de la hepatitis C]* También le ofreceremos pruebas gratuitas de la hepatitis C.
5. *[Para los sitios que realizan pruebas de las ITS]* También puede que le ofrezcamos pruebas gratuitas de gonorrea y clamidia.

Si usted acepta hacerse la prueba del VIH, tendrá una sesión de consejería sobre la prevención de la infección por el 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. Usted no recibirá ningún tratamiento médico en este estudio.

La prueba del VIH se hará por medio de un método rápido que se explica a continuación.

[Para los sitios que realizan solo una prueba rápida con un laboratorio local]

Prueba rápida

Le [pincharemos la punta de un dedo para sacar unas gotas de sangre/extraeremos menos de una cucharada de sangre]. Recibirá consejería acerca del resultado de la prueba. Usted podrá obtener el resultado de su prueba del VIH en [1 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/usaremos la sangre que sacamos para la prueba rápida] 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 los sitios que permiten dar los resultados de la prueba del VIH por teléfono: Si lo prefiere, usted puede solicitar que le den los resultados confirmatorios de la prueba y la consejería por teléfono].*

[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 [1 hora/el tiempo máximo para la prueba específica que se usa]. Recibirá consejería acerca del resultado de la prueba. Se le referirá a los servicios si son necesarios. Si la primera prueba rápida es reactiva, haremos una segunda prueba rápida para confirmar sus resultados. Para hacer la prueba rápida adicional, [utilizaremos la sangre que sacamos para la primera prueba/le pincharemos la punta de un dedo para sacar unas gotas de sangre]. Si usted ya sabe que tiene la infección por el VIH, puede que le hagamos solamente una prueba rápida. *[Para los sitios que deben/deciden realizar una prueba confirmatoria en un laboratorio además del algoritmo]* Finalmente, utilizaremos la muestra de sangre para confirmar en un laboratorio el resultado de la prueba rápida. El resultado de la prueba estará listo en una semana. Le diremos el día y la hora en que podrá obtenerlo. *[Para los sitios que permiten dar los resultados de la prueba del VIH por teléfono: Si lo prefiere, usted puede solicitar que le den los resultados confirmatorios de la prueba y la consejería por teléfono].*

[Para los sitios que realizan pruebas de la hepatitis C]

Pruebas de la hepatitis C

Le ofreceremos pruebas gratuitas de detección de la infección por hepatitis C. Realizaremos una prueba rápida de anticuerpos contra la hepatitis C al mismo tiempo que realizamos el pinchazo del dedo para la prueba rápida del VIH. Además, le sacaremos con una aguja una muestra de sangre (unas 2 cucharaditas) de sus venas. Usted podrá obtener el resultado de su prueba rápida de la hepatitis C dentro de [20-30 minutos/el tiempo máximo para la prueba específica que se usa]. Recibirá consejería acerca del resultado de la prueba. Si el resultado de la prueba es positivo, eso solo nos informa que alguna vez estuvo expuesto a la hepatitis C. Se necesitan pruebas adicionales para que sepamos si actualmente tiene hepatitis C. Los resultados de las pruebas adicionales de la hepatitis C estarán listos dentro de [2 semanas/el tiempo máximo que tiene el laboratorio local para devolver los resultados]. 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 lo prefiere, usted puede solicitar que le den los resultados confirmatorios de la prueba y la consejería por teléfono].*

[Para los sitios que realizan pruebas de ITS para HSH]

Pruebas de gonorrea y clamidia

Le ofreceremos pruebas gratuitas 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. Los resultados de las pruebas de gonorrea y clamidia 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 gonorrea y clamidia por teléfono: Si lo prefiere, usted puede solicitar que le den los resultados por teléfono].*

[Para los sitios que realizan pruebas de ITS para HET (solo mujeres de 18-30 años de edad)]

Pruebas de gonorrea y clamidia

Le ofreceremos pruebas gratuitas 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 la vagina para recolectar muestras. Los resultados de las pruebas de gonorrea y clamidia 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 gonorrea y clamidia por teléfono: Si lo prefiere, usted 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 guardar muestras para pruebas adicionales del VIH u otras pruebas en laboratorios locales]

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 sexo. 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 muestra para clonaciones. Usted puede negarse a permitirnos almacenar su muestra y de todos modos participar en este estudio. Si no quiere que almacenemos su muestra, la destruiremos después de completar esta prueba. Si está de acuerdo en que almacenemos su muestra, la podremos destruir en un plazo de 10 años.

C. Puntos a considerar

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 lo hagan sentirse incómodo.
2. [El pinchazo del dedo/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 vaginales puede causar irritación, malestar y sangrado leve temporal.
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] [*para los sitios que ofrecen pruebas de la hepatitis*: o los resultados de las pruebas de la hepatitis] es/son negativos, 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.

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*]. [*Para IDU y HET solamente*] 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 llamarlo para hacerle cualquier pregunta que tenga sobre su participación en el estudio.

Si tiene preguntas acerca de sus derechos como participante o si considera que ha sido perjudicado, comuníquese con el *[Comité de Revisión Independiente (Independent Review Board, 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]*. *[SOLO PARA LOS CENTROS DE RDS]* Usted también puede optar por no reclutar a otras personas.

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 (ETS) (si se las ofrecen)?

- ☐ Sí
☐ No

¿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
☐ No quiere hablar sobre estos temas
☐ Alguna otra razón
☐ Prefiere no decir el motivo

Appendix G

Model Consent Talking Points

English Version; Grade Reading Level by Flesch-Kincaid Method: 8.1

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 without penalty. The survey will take about 40 minutes.
4. I'll offer you an HIV test. This will involve *[sticking your finger with a needle/drawing a small amount of blood using a needle]*. Your results will be ready within *[1hour/1 week]*. *[Explain how participant will receive results of any non-rapid (standard or confirmatory) tests]*. *[If conducting local laboratory –based HIV or other testing and want to store specimens locally]:* 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 C tests. This will involve a rapid hepatitis C test and drawing an additional small amount of blood using a needle for follow-up tests. The results of your rapid test will be ready within *[20-30 minutes/max time]*. Results of follow-up testing will take up to *[two weeks/max time for local lab to return results]*. *[Explain how participant will receive results of any non-rapid hepatitis tests]*. *[If conducting STD testing]:* We will also offer you free testing for gonorrhea and chlamydia. This will involve *[Explain gonorrhea and chlamydia testing process]*. If you agree, we'd also like to store any specimen left over from these tests for future studies.
5. *[IDU & HET only]* 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. *[Sticking your finger/drawing blood]* may cause temporary discomfort from the needle stick. 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)]*. *[IDU & HET only]* 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 STD testing?
16. *[if applicable]* Do you agree to have your blood or other specimens 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 sin que se le penalice. La encuesta tomará aproximadamente 40 minutos.
4. Le ofreceré hacerse una prueba del VIH. Esto incluye *[un pinchazo de su dedo con una aguja/sacarle una pequeña cantidad de sangre con una aguja]*. 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 C. Esto requerirá una prueba rápida de hepatitis C y sacarle otra pequeña muestra de sangre usando una aguja para pruebas adicionales. El resultado de la prueba rápida estará listo dentro de *[20-30 minutos/el tiempo máximo]*. Resultados de las pruebas adicionales estarán listos en *[2 semanas/el tiempo máximo que el laboratorio devuelva los resultados]*. *[Explique como el participante recibirá los resultados de las pruebas adicionales de hepatitis.]* *[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 las pruebas de gonorrea y clamidia]*. Si usted lo acepta, también guardaremos los especímenes restantes de estas pruebas para futuros estudios.
5. *[IDU & HET only]* Le puedo dar la opción de invitar hasta 5 personas para participar en el estudio.



6. Existen riesgos mínimos por participar en este estudio. [El pinchazo del dedo/extracción de sangre] puede causar molestias temporales debido al pinchazo de la aguja. 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)]*. *[IDU & HET only]* 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 participar en la encuesta?
13. ¿Acepta hacerse la consejería y prueba del VIH?
14. *[Si se aplica]* ¿Acepta hacerse la prueba de hepatitis?
15. *[Si se aplica]* ¿Acepta hacerse las pruebas de ETS?
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

‹#›	<h1 style="margin: 0;">Project ASK</h1>	‹#›
<p>If you are selected, you can earn up to \$100.00!</p> <p><< Call 1-888-865-4327 for an appointment or more information >></p>		
	<p><u>When:</u> Tuesdays and Wednesdays 1 PM - 9 PM Fridays and Saturdays 10 AM - 6 PM</p> <p><u>Where:</u> 7125 Central Avenue, 2nd Floor <i>(Directions are on back of coupon.)</i></p>	
<p>Coupon is not active before: / / Coupon expires on: / /</p>		

BACK

<p>Madison Avenue</p> <p>Main Street</p> <p>Creekdale Place</p> <p>Brick Road</p> <p style="text-align: center;">Central Avenue</p> <p style="text-align: center;">7125 Central Avenue</p> 	<h2 style="margin: 0;">Project ASK</h2> <p>is located at 7125 Central Avenue between Main Street and Brick Road across from the Salvation Army</p> <p style="font-size: 1.5em; font-weight: bold;">1-888-865-4327</p> <p style="font-weight: bold;">PLEASE CALL FOR AN APPOINTMENT</p> <p>(IT'S A FREE CALL FROM ANY PAYPHONE)</p>
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Appendix I

Model Recruiter Training Talking Points

Who to Recruit

- We're going to give you *[insert #]* coupons to give to friends, relatives, or people you associate with so that they can be in the study too.
- Give the coupons to people you know and who are between 18 and 60 years old.
- 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.
- Your coupons cannot be replaced if they are lost or the person you recruited is not selected for the study.
- ***If a project site is using photo coupons:*** Instead of handing out your coupons, you can take a photo of each one and text or email it to someone you want to recruit.
- ***If a project site is using photo coupons:*** Keep the message you send general to protect the person's privacy. For example: *You can use this coupon to take a health survey and earn up to \$[total incentive amount]*.
- ***If a project site is using photo coupons:*** Coupon photos will not be accepted if the coupon number cannot be clearly seen or if the photo shows more than one coupon.
- ***If a project site is using photo coupons:*** If more than one person tries to use the same coupon photo, only the first person using it will be allowed to participate in the study.

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. This includes people who are too drunk or high to complete the interview.

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 and who are between the ages of 18 and 60.

Appendix J

Model Hepatitis Testing Log

Hepatitis B:

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

Hepatitis C:

<i>SURID</i>	<i>Specimen collected for hepatitis testing?</i>	<i>Lab ID# (if different from HIV test ID)</i>	<i>Specimen Collection Date</i>	<i>Hep C Rapid Test Result</i>	<i>Hep C Ab EIA/CIA Result</i>	<i>Hep C RNA Result</i>	<i>Hep C RNA Viral Load Result</i>	<i>Hepatitis C Result Interpretation</i>	<i>Participant received Hep C test result?</i>	<i>Comments</i>

Note: Shaded columns are redundant in each log. If conducting both Hep B and Hep C testing, 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. For Hep C RNA result, if “Negative/Not Detected”, then the Hep C RNA viral load result should be written as <15 ug/mL.

Appendix K

Model STD Testing Log

Log for STD Testing:

Survey ID	Collection date	Pharyngeal (throat)				Vaginal				Consent for storage (Y/N)	Comments*
		Lab ID / barcode	Testing not done	Gonorrhea test result	Chlamydia test result	Lab ID / barcode	Testing not done	Gonorrhea test result	Chlamydia test result		

** If unable to collect a pharyngeal/vaginal 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	Rapid Test Method ¹	Rapid Test Result ²	Self-reported HIV+ during interview? (Y/N)	For preliminary HIV+ if did not self-report HIV+ during interview: Self-reported HIV+ during counseling session? (Y/N)	Returned Rapid Test Result (Y/N)	For preliminary HIV+: Collected Lab Specimen (Y/N)	Lab ID ³	For preliminary HIV+: Type of Lab Specimen ³	Comments ⁴
		Ag+ Ab+ Ag/Ab+ Neg Invalid Not Done							

¹ Project sites performing a multiple rapid test algorithm should modify the log accordingly to display each method used and the results.

² Sites NOT using the Determine rapid test should circle Ab+ for a reactive rapid test.

³ If site is sending specimens to local lab for supplemental testing.

⁴ If unable to collect a confirmatory specimen, provide reason in comments section as well as any other comments.

Log for Laboratory-based HIV Testing:

Survey ID	Lab ID	Specimen Type	Self-reported HIV+ during interview? (Y/N)	<i>If did not self-report HIV+ during interview:</i> Self-reported HIV+ during counseling session? (Y/N)	Test Type ¹	Test Result ¹	Final Test Result Returned (Y/N)	Comments ²

¹ The log will contain a column for each type of test (EIA, Western Blot, NAAT, etc) performed

² 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 THE NATIONAL HUMAN IMMUNODEFICIENCY VIRUS (HIV) SURVEILLANCE SYSTEM (NHSS) AND SURVEILLANCE-RELATED DATA (INCLUDING SURVEILLANCE INFORMATION, CASE INVESTIGATIONS SUPPLEMENTAL SURVEILLANCE PROJECTS, RESEARCH ACTIVITIES, AND EVALUATIONS)

The national HIV surveillance program is being coordinated by the HIV Incidence and Case Surveillance Branch (HICSB) and the Behavioral and Clinical Surveillance Branch (BCSB) of the Division of HIV/AIDS Prevention (DHAP), in the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), 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 HIV infection at any clinical stage of disease, 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 cases; and from surveys or investigations that interview persons in recognized HIV risk groups or known to have a diagnosis of HIV.

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. 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 304 and 306 of the Public Health Service Act (42 U.S.C. 242b and 242k) as part of the HIV 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 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. 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 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 other components of CDC, or to agencies of the federal, state, or local government, or to select members of the public 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 in HICSB, BCSB, and in the Quantitative Sciences and Data Management Branch (QSDMB), their contractors, guest researchers, fellows, visiting scientists, authorized external collaborating researchers, 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 the National Human Immunodeficiency Virus (HIV) Surveillance System (NHSS) and Surveillance-Related Data (including surveillance information, case investigations, 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



REQUEST for Project Determination & Approval - NCHHSTP ADS/ADLS OFFICE

This form should be used to submit proposals to the NCHHSTP ADS/ADLS Office for determination that have not begun and do not require routing to the CDC Human Research Protection Office at this time. Projects eligible for this classification are (1) non-research activities; (2) research that does not involve identifiable human subjects; (3) human subject research in which CDC is not "engaged".

Project Title:

National HIV Behavioral Surveillance System-HET4, MSM5, IDU5, HET5, & MSM6

Project Location/Country(ies): U.S.

Project Officer(s): Gabriela Paz-Bailey, MD

Division: DHAP

Telephone: 404-639-4451

Proposed Project Dates: Start: 1/1/2016

End: 12/31/2021

Laboratory Branch Submission: ☐

Please check appropriate category and subcategory:

- ☒ **I. Activity is not human subjects research.** Primary intent is public health practice or a disease control activity.
- ☐ A. Epidemic or endemic disease control activity; collected data directly relate to disease control (e.g. Epi-AIDs; provide Epi-AID number & documentation of request for assistance, if division policy). Epi-AID #
 - ☒ B. Routine disease surveillance activity; data used for disease control program or policy purposes.
 - ☐ C. Program evaluation activity; data are 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.** 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 and/or support; development of patient registries; needs assessments; and demonstration projects intended 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 which are 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) of the following are required:
 - ☐ 1. No contact with human subjects is involved for the proposed activity...and...
 - ☐ 2. Data or specimens are/were collected for another purpose...and...
 - ☐ 3. No extra data/specimens are/were collected for this purpose...and...
 - ☐ 4. Identifying information was: (one of these must be checked)
 - ☐ a. not obtained
 - ☐ b. removed prior to this submission, or prior to CDC receipt, so that data cannot be linked or re-linked with identifiable human subjects
 - ☐ c. protected through an agreement. (*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 below: 'A' indicates the project is funded, 'B' or 'C' indicate there is no current funding
- ☐ A. This project is funded under a grant/cooperative agreement/contract award mechanism.
ALL of the following 3 elements are required:
 - ☐ 1. CDC employees or agents will not intervene or interact with living individuals for research purposes.
 - ☐ 2. CDC employees or agents will not obtain individually identifiable private information.
 - ☐ 3. Supported institution must have a Federalwide Assurance (FWA) and project must be reviewed by a registered IRB linked to the supported institution's FWA.

Supported Institution/Entity Name:
Supported Institution/Entity FWA #
Expiration Date of IRB approval:

FWA Expiration Date (mm/dd/yyyy):
*Attach copy of the IRB approval letter.
 - ☐ B. CDC staff provide technical support that does not involve possession or analysis of identifiable 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).

Approval Initials & printed name:

Dean Betoli 5/2014
Branch Chief ACS Date

LA Valenz 6/9/14
ADS/ADLS or Division Director Date

Division Notes/Comments:

Project Title: National HIV Behavioral Surveillance System-HET4, MSM5, IDU5, HET5, & MSM6

NCHHSTP ADS/ADLS Review

Date received in NCHHSTP ADS /ADLS office:

June 9. 2014

☒ Concur, project does not require human subject research review beyond NCHHSTP at this time

☐ Project constitutes human subject research that must be routed to CDC HRPO

Comments/Rationale for Determination:

- ⊙ All participating partners and sites need to receive approval for this project/site protocols as required by their Review and approval process and 45 CFR 46 Regs.
- ⊙ Adherence to all regulations, laws, policies, and procedures for protecting rights, welfare, and data of participants and integrity of the project is required.

Signed:

Salam Semaan, MPH, DrPH

June 25, 2014

Name

Associate (or Acting or Deputy Associate) Director for Science, NCHHSTP

OR

Associate Director for Laboratory Science, NCHHSTP

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Date

TRANSLATION CERTIFICATION

This is to certify that the following translation delivered by Maria Natalia Hamilton as an attachment to this letter is to the best of my knowledge and ability, a true and accurate translation of the original text (source) delivered to us by Melissa Cribbin.

Title of the document in English:

NHBS Spanish Model Consent Form

File name of source document:

Appendix F_Model Consent Form_Round 5_Dec. 2018

Certified Translator / Approving Official: Maria Natalia Hamilton

Date delivered: 1/2/2019

Source language: English

Target language: Spanish

Order #: 300646

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true.

I hereby agree to keep the contents of this translation confidential according to the ethical and legal standards of the translating profession. I furthermore agree not to discuss, evaluate, transfer, distribute, or reproduce any material related to this assignment with any person(s), or any other parties related to this assignment, other than the direct representative of the client, as this would constitute a violation of our agreement.



Verify at www.atanet.org/verify

Any changes made to the delivered document, no matter how small, will make this certification void for all purposes.

MARIA NATALIA HAMILTON

JANUARY 2nd, 2019