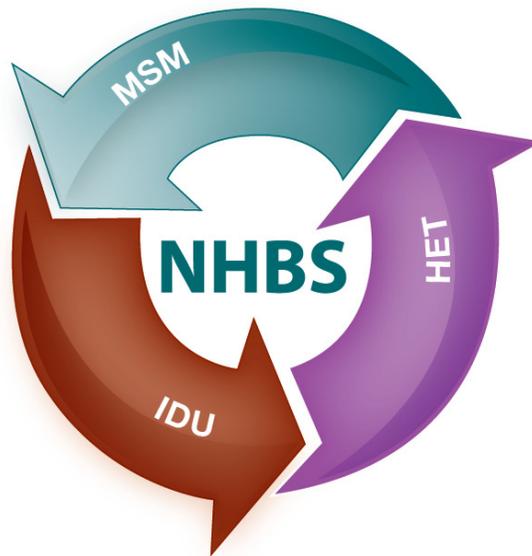


**National HIV Behavioral Surveillance System:
Men Who Have Sex with Men
(NHBS-MSM4)**

OPERATIONS MANUAL



NATIONAL HIV BEHAVIORAL SURVEILLANCE SYSTEM

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

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Contacts

Corresponding Author:

Paul Denning, MD, MPH
Medical Officer
Centers for Disease Control and Prevention
1600 Clifton Rd, Mailstop E-46
Atlanta, Georgia 30333
Telephone: (404) 639-2963; E-mail: pdenning@cdc.gov

Contributing Authors:

Dita Broz, PhD, MPH	Kristen Hess, PhD
Melissa Cribbin, MPH	Brooke Hoots, PhD
Teresa Finlayson, PhD	Amanda Smith, MPH
Kathy Hageman, PhD	

General NHBS Inquiries:

Gabriela Paz-Bailey, MD, PhD, MSc
Team Lead, Behavioral Surveillance Team
Centers for Disease Control and Prevention
1600 Clifton Rd, Mailstop E-46
Atlanta, Georgia 30333
Telephone: (404) 639-4451; E-mail: gpazbailey@cdc.gov

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Acronyms

Acronym:	Definition:
CAPITM	Computer Administered Personal Interview
CBO	Community-based Organization
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments
DBS	Dried Blood Spot
DCC	NHBS Data Coordinating Center
DHAP	Division of HIV/AIDS Prevention
EIA	Enzyme Immunoassay
FWA	Federalwide Assurance
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Syndrome
IFA	Immunofluorescent Antibody
IRB	Institutional Review Board
MOU	Memorandum of Understanding
MSA	Metropolitan Statistical Area
NGA	Notice of Grant Award
NHBS	National HIV Behavioral Surveillance System
NHBS-MSM	National HIV Behavioral Surveillance System among Men Who Have Sex with Men
OMB	Office of Management and Budget
OMT	Oral Mucosal Transudate
OSHA	Occupational Safety and Health Administration
PGO	Procurement and Grants Office
PHRP	(National Institutes of Health) Protecting Human Research Participants
PI	Principal Investigator
QDSTM	Questionnaire Development System
SRP	Self-reported (HIV) Positive
VBS	Venue-based Sampling
VDT	Venue, Day, and Time
VDTS	Venue-Day-Time Sampling (Program)
WB	Western Blot

1.1 Overview

The *NHBS-MSM4 Operations Manual* is designed to guide project staff during the implementation of NHBS. All project staff should read this manual, as well as the *NHBS Round 4 Model Surveillance Protocol* in order to prepare for NHBS activities. Copies of the operations manual and the protocol should also be available for reference during all recruitment events and at the project office.

The operations manual provides a detailed description of the procedures needed to conduct NHBS using venue-based sampling. This includes:

- Staffing the project (**Chapter 2**)
- Preparing materials (**Chapter 3**)
- Creating monthly recruitment calendars (**Chapter 4**)
- Planning and managing recruitment events (**Chapter 5**)
- Recruiting and interviewing participants (**Chapter 6**)
- Closing out recruitment events (**Chapter 7**)
- Conducting HIV testing (**Chapter 8**)
- Reviewing process monitoring reports (**Chapter 9**)
- Performing data management activities (**Chapter 10**)

1.2 Justification

The primary purpose of an operations manual is to develop and document procedural guidelines to be used for conducting NHBS. The manual ensures operational standardization of NHBS activities across all 20 project sites.

1.3 Staff Responsibilities

CDC staff are responsible for writing the *NHBS-MSM4 Operations Manual* and providing technical assistance to project sites during implementation. Local NHBS staff are responsible for conducting the project using the procedures described in the manual

and for submitting all required data to CDC in a timely manner through the NHBS Data Coordinating Center (DCC) data portal.

1.4 Venue-Based Sampling

For NHBS-MSM, venue-based sampling (VBS) is used to recruit men to participate in the survey. The men are recruited at venues attended primarily by MSM (men who have sex with men), such as bars, dance clubs, retail businesses, cafes and restaurants, health clubs, social and religious organizations, sports teams, adult bookstores and bathhouses, high-traffic streets in gay neighborhoods, parks, beaches, gay pride festivals, and dance parties, among others. During what are referred to as “recruitment events,” men are systematically approached at the venues and invited to participate in the survey. If the men agree, they are screened for eligibility. Men are eligible to participate in the survey if they meet the following criteria:

- 18 years of age or older.
- Born male and self-identify as male.
- Resident of the funded MSA or Division.
- Ever had oral or anal sex with another man.
- Able to complete the NHBS survey in English or Spanish.

The venues, days, and times for recruitment events are randomly selected using a two-stage sampling method– the first stage to select the venues where the events will take place and the second stage to select the days and times when the events will occur at each venue. The randomly selected venues, days, and times are then scheduled on a monthly recruitment calendar, which shows the dates and times when project staff will conduct recruitment events at each venue.

1.5 Operations Checklist

The Operations Checklist is found in **Appendix A**. Project sites should complete the checklist, along with the requested attachments, and send them to their CDC project officer at least *two weeks* before the planned start of data collection. If they choose, sites can also send draft sections of the checklist to their CDC project officer as soon as the sections are completed. Once the checklist has been finalized, the CDC project officer will set up a conference call with the site to review the checklist to ensure that all preparatory activities have been satisfactorily completed. Data collection *cannot* begin until the CDC project officer has given approval. Over the course of data collection, sites should update the checklist whenever there are any operational changes and they should promptly send a copy of the revised checklist to their CDC project officer.

2

Staffing, Training, and Evaluation

2.1 Overview

Staffing, training, and performance evaluations are important to the operational success of NHBS. Likewise, a thorough understanding of NHBS's research methodology and enthusiasm for the project are important for ensuring the highest quality operations and data collection.

This chapter provides the recommended staffing structure and position descriptions for conducting NHBS, as well as information on staff training and evaluation.

2.2 Staffing

Because NHBS is considered HIV surveillance, project staff must adhere to the ethical principles and standards for HIV surveillance activities when conducting NHBS operations. Most importantly, they must respect and protect the privacy, confidentiality, and autonomy of participants. In addition, project staff should conduct themselves in a professional manner when interacting with participants, fellow staff members, and the general public. Recommended staff positions and responsibilities are presented in **Tables 2.1** and **2.2** (pages 2-2 to 2-4) and are described below.

2.2a Management staff

Each project site should have the following management positions: principal investigator, project coordinator, and field supervisor. Each position is discussed below. Management staff are responsible for implementing project operations in compliance with all NHBS guidance (e.g., *Model Surveillance Protocol*, *Formative Research Manual*, *Operations Manual*, and *Interviewer Guide*) and locally developed policies.

Principal investigator

The principal investigator (PI) at the directly funded health department is responsible for all matters related to NHBS and is the primary contact for CDC. When appropriate, a secondary PI may be contracted to assist with PI responsibilities. However, the directly funded PI is ultimately responsible for the project's implementation and success. Principal investigators will spend approximately 10% of their time on the project.

Project coordinator

The project coordinator is responsible for the day-to-day management of the project including providing support for key administrative functions. Project coordinators will spend up to 100% of their time on the project. Generally, the project coordinator and field supervisor positions comprise 1.5-2.0 full-time equivalents (FTEs).

Table 2.1 – Recommended positions and responsibilities for management staff

Responsibilities	Principal Investigator (PI)	Project Coordinator	Field Supervisor
<p>Administrative</p>	<ul style="list-style-type: none"> • Oversee the hiring and supervision of project staff. • Tailor the <i>Model Surveillance Protocol</i> per site-specific needs. • Apply for and obtain Institutional Review Board (IRB) approval(s), inform IRB(s) of procedural changes and other revisions, and send IRB approval letters to CDC. • Ensure all subcontracting agencies having contact with human subjects have an active Federalwide Assurance (FWA) number. (Health department only) • Review, monitor, and assure compliance with established Notice of Award guidelines to provide fiscal administration and management of federal funds. This includes administrative supervision to investigate and report financial irregularities. (Health department only) • Oversee preparation and submission of annual cooperative agreement reports, including interim or annual progress reports and financial status reports, to CDC Procurement and Grants Office (PGO). (Health department only) • Oversee the development of local use questions. • Respond to CDC’s requests for input on revisions to the NHBS questionnaire and other supporting documents. • Participate in CDC site visits, PI meetings, conference calls, and national calls. 	<ul style="list-style-type: none"> • Manage contracts related to the project (as applicable). • Assist PI with the hiring and supervision of project staff. • Assist PI with IRB-related activities, cooperative agreement reports and other key administrative functions. • Participate in CDC site visits, trainings, national calls, and regular conference calls. • Act as the primary point of contact with CDC in matters that relate to the project. • Respond to CDC’s requests for input on revisions to the NHBS questionnaire and other supporting documents. • Coordinate the development of local use questions. 	<ul style="list-style-type: none"> • Participate in CDC site visits, trainings, regular conference calls, and, as available, monthly calls.
<p>Project management</p>	<ul style="list-style-type: none"> • Serve as back-up for project coordinator in event of absence or appoint a designee. • Collaborate with local stakeholders and disseminate information and data from the project to garner community support. 	<ul style="list-style-type: none"> • Provide overall project management. • Create monthly recruitment calendar (field supervisor may also assume this responsibility). • Maintain inventory of supplies, materials, incentives, and equipment. • Oversee ongoing formative research efforts. • Serve as back up for the field supervisor and data manager. 	<ul style="list-style-type: none"> • Ensure adequate preparations, including supplies, materials, and equipment for recruitment events. • Assist with field staff-related issues (i.e., training and development, scheduling, team building). • Manage operations and data collection at recruitment events. • Direct recruiter to approach potential participants (if applicable). • Coordinate ongoing formative research efforts and implement changes based upon findings.

Table 2.1 – Recommended positions and responsibilities for management staff (continued)

Responsibilities	Principal Investigator (PI)	Project Coordinator	Field Supervisor
Training and ongoing evaluations	<ul style="list-style-type: none"> • Ensure required trainings have been successfully completed by all project staff. • Conduct staff evaluations in collaboration with the project coordinator and field supervisor. 	<ul style="list-style-type: none"> • Coordinate and conduct pre-implementation and ongoing trainings for project staff in collaboration with the field supervisor. • Conduct staff evaluations in collaboration with the PI and field supervisor. 	<ul style="list-style-type: none"> • Coordinate and conduct pre-implementation and ongoing trainings for project staff in collaboration with the project coordinator. • Conduct staff evaluations in collaboration with the PI and project coordinator.
Data collection, management, analysis, and dissemination	<ul style="list-style-type: none"> • Ensure timely submission and entry of data to the DCC data portal. • Responsible for quality control and data integrity. • Supervise the implementation of recommendations from CDC or the DCC to improve data quality. • Oversee development of policies pertaining to analyses and dissemination of data. (Health department only) • Oversee analyses of site data. • Ensure data is released in accordance with local policy and data use agreements. (Health department only) • Present reports and disseminate study findings. • Use study findings for the development, modification, and evaluation of local prevention programs. 	<ul style="list-style-type: none"> • Ensure daily transfer of data from portable computers to the QDS™ Warehouse. • Ensure that QDS™ Warehouse is maintained. • Ensure HIV testing data, data errors, and recruitment event outcomes are entered into the DCC data portal daily. • Ensure venue and day-time period information is kept up-to-date in the VDTS Program. • Review Process Monitoring Reports, ensure problems are addressed, and improvement seen. • Coordinate and implement policies pertaining to data analysis and dissemination. • Participate in data analysis and dissemination. • Assess need for ongoing formative research and make changes based upon findings. 	<ul style="list-style-type: none"> • Review, tabulate, and reconcile forms and logs used in the field. • Review data errors with recruiters, interviewers, and HIV test counselors. • Oversee documentation of data errors. • Supervise entry of VDTS Program information, HIV testing data, and data errors into the DCC data portal. • Review Process Monitoring Reports, identify issues of concern, and implement changes for improvement.
HIV testing operations	<ul style="list-style-type: none"> • Develop local HIV testing protocol and oversee HIV testing activities. • Ensure procedures are developed for making referrals to care and other services. 	<ul style="list-style-type: none"> • Oversee maintenance of HIV testing supplies. • Ship HIV test specimens. • Receive and log HIV test results from lab. • Obtain CLIA waiver (if applicable). • Develop procedures for making referrals to care and other services. 	<ul style="list-style-type: none"> • Ensure proper documentation of HIV testing activities, including consent. • Ensure adherence to HIV testing procedures. • Ensure adherence to procedures for making referrals to care and other services.
Safety, security, and confidentiality	<ul style="list-style-type: none"> • Responsible for safety, security, and confidentiality of project staff, participants, materials, and data, including the development of local procedures and policies. • Report field incidents and adverse events to CDC within 48 hours of occurrence and to the IRB(s) per local requirements. 	<ul style="list-style-type: none"> • Coordinate development of local procedures for incident reporting, safety, and handling participants known to project staff. • Report field incidents and adverse events to CDC within 48 hours of occurrence and to the IRB(s) per local requirements. 	<ul style="list-style-type: none"> • Assist in the development of local procedures for incident reporting, safety, and handling participants known to project staff; and ensure adherence to all locally developed procedures. • Report field incidents and adverse events to CDC within 48 hours of occurrence and to the IRB(s) per local requirements.

Table 2.2 – Recommended positions and responsibilities for field staff and the data manager

Counter	Recruiter	Interviewer	HIV Test Counselor	Data Manager
<ul style="list-style-type: none"> • Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately. • Maintain counts of men who appear ≥ 18 years old and are attending the venue. • Direct recruiter to approach potential participants (if applicable). • Assist with ongoing formative research as necessary. 	<ul style="list-style-type: none"> • Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately. • Recruit men in accordance with the protocol and as directed by the designated staff member. • Accurately document all men approached on the Intercept Form. • Assist other recruiters with recruiting potential participants. • Check in with field supervisor if recruitment is not successful. • Review all completed Intercept Forms. • Assist with ongoing formative research as necessary. 	<ul style="list-style-type: none"> • Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately. • Accurately document participant information for the eligibility screener, consent form, questionnaire, and Participant Tracking Form. • Maintain data integrity (i.e., all data collected accurately represents the information provided by participants). • Assist with ongoing formative research as necessary. 	<ul style="list-style-type: none"> • Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately. • Conduct HIV counseling and testing per local and NHBS guidelines. • Have knowledge of information in package insert for rapid testing (if applicable). • Document HIV test results. • Accurately document information on lab slips, HIV Test Result Logs, and Specimen Transport/Shipping Log. • For sites with separate interviewers and HIV test counselors: Document communication between interviewer and HIV test counselor to ensure participant consent was provided for HIV testing. 	<ul style="list-style-type: none"> • Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report adverse events to the field supervisor immediately. • Ensure upload of data from the portable computers to the QDS™ Warehouse. • Ensure daily receipt of forms/logs and review errors or concerns with the field supervisor or project coordinator. • Enter information from forms/logs into the DCC data portal. • Maintain QDS™ Warehouse and submit weekly to the DCC data portal. • Maintain data integrity (i.e., each record in the database represents the data an individual provided to the field team). • Review data reports from the DCC as soon as they are received, and provide requested data edits and explanations to resolve data issues via the DCC data portal. • Perform data analyses as needed.

A successful project coordinator has considerable knowledge of HIV/AIDS and surveillance activities, strong leadership and supervisory skills, and high attention to detail. In addition, the project coordinator should have excellent word processing, spreadsheet, and file management skills, as well as a willingness to learn additional computer programs, such as the Questionnaire Development System (QDS™) and the Venue-Day-Time Sampling (VDTS) Program.

Field supervisor

The field supervisor is responsible for assisting with the day-to-day management of the project, particularly overseeing the field staff and recruitment events. Field supervisors will spend up to 100% of their time on the project. As mentioned above, the project coordinator and field supervisor positions comprise 1.5-2.0 FTEs.

A successful field supervisor has considerable knowledge of the communities in which NHBS is conducted, HIV/AIDS, and surveillance activities. In addition, a field supervisor should have strong leadership skills, excellent attention to detail, high motivation, cultural competence, strong computer skills (e.g., word processing, spreadsheets, and file management), and a willingness to learn additional programs, such as QDS™ and the VDTS Program.

2.2b Field staff

Project sites should designate staff for the following field positions: counter, recruiter, interviewer, and HIV test counselor. Each position is discussed below. It is useful for field staff to be trained to perform multiple positions to maximize the flexibility of operations. Field staff are expected to adhere to procedures in accordance with NHBS guidance (e.g., *Model Surveillance Protocol*, *Formative Research Manual*, *Operations Manual*, and *Interviewer Guide*) and locally developed policies.

The field staff are the face of the project and should be outgoing and welcoming. Furthermore, it is important that they are comfortable working with diverse populations.



All field operations must be performed by trained and qualified NHBS staff members. Employees of venues should never perform any NHBS duties, such as counting venue attendees or recruiting potential participants.

Counter

The counter is responsible for counting all men attending a venue during a recruitment event. The count of venue attendees is used to weight the survey data. There should only be one counter during each recruitment event to avoid double counting. Ideally, the field supervisor should not serve as the counter because it may interfere with the field supervisor's management responsibilities.

The counter should have excellent attention to detail and a thorough understanding of venue-based sampling.

Recruiters

Recruiters systematically approach men attending a venue and invite them to participate in the project. The recruiter must always be directed to approach a potential participant by another staff member; the recruiter should never approach a potential participant on their own. The recruiter may be directed by the field supervisor, a staff member designated to direct recruitment, or the counter if the recruitment area is near the entrance to the venue.

An effective recruiter is highly motivated, has excellent communication skills, has considerable knowledge of the local MSM community, and to the extent possible, represents the demographic characteristics of the men attending the venue. In addition, a recruiter should have a sound understanding of venue-based sampling.

Interviewers

Interviewers are responsible for screening participants for eligibility, obtaining informed consent, conducting interviews using portable computers, and providing appropriate health care and social service referrals to participants upon completion of the survey.

A successful interviewer has excellent communication skills, experience working with populations at risk for HIV infection, and considerable knowledge of the communities in which NHBS is conducted. An interviewer should also have strong interviewing and data collection skills and a thorough understanding of the informed consent process.

HIV test counselors

HIV test counselors must be certified to conduct the specific type of HIV test being used by the project site and are responsible for following local HIV counseling and testing standards and NHBS HIV testing guidelines. HIV test counselors are responsible for providing tailored prevention messages to each participant based upon risk behaviors identified during the interview or counseling session. In addition, HIV test counselors must also provide anonymous referrals to medical care and case management and ensure that HIV-positive participants are linked to these services.

An HIV test counselor should have strong counseling skills and a thorough understanding of the informed consent process as well as excellent communication skills, experience working with populations at risk for HIV infection, and considerable knowledge of the communities in which NHBS is conducted.

2.2c Data manager

The data manager is responsible for uploading local data files; ensuring data quality, data entry, and submission to the NHBS Data Coordinating Center (DCC) data portal; and

communicating issues to the DCC, CDC, and other project staff. Data managers must ensure that data are stored in a manner that meets the required security and confidentiality standards for HIV/AIDS surveillance data. Data managers will spend approximately 15% of their time on the project.

A successful data manager has considerable knowledge of the NHBS data system, experience in managing data from multiple sources, excellent organizational skills, and attention to detail. Moreover, the data manager should have strong computer skills (e.g., word processing, spreadsheets, and file management) and have a willingness to learn additional programs, such as QDS™ and the VDTTS Program.

2.3 Spanish-speaking Staff

Project sites that utilize Spanish language materials will need to have Spanish-speaking staff available for interviewing and HIV counseling at recruitment events. Project sites with few monolingual Spanish-speaking participants may not need Spanish-speaking staff at all recruitment events. These project sites should discuss the optimal scheduling of their Spanish-speaking staff with their CDC project officer.

2.4 The Importance of Skill Standardization and Quality Assurance

The quality of NHBS data is dependent upon each staff member's ability to perform their position successfully, consistently, and in the same manner as their NHBS colleagues within and across project sites. Standardization of procedures and quality is an important aspect of all data collection efforts. To ensure standardization of NHBS operations, CDC provides the following tools: (1) NHBS guidance documents, (2) Field Operations Training, (3) project staff evaluation forms with performance recommendations, (4) pre-implementation and ongoing evaluation recommendations, and (5) retraining recommendations.

2.4a What is standardization?

Standardization is important to ensure data quality. It means that participants have very similar experiences regardless of where they are interviewed or by whom. For example, if a participant from Atlanta was interviewed by Interviewer A, his responses should be the same as if he were interviewed by Interviewer B or Interviewer C. Likewise, his responses should be the same as if he were interviewed in Boston, Chicago, or Denver. Although a participant will have the same past behaviors and experiences regardless of interviewer or location of interview, *what* he chooses to report during an interview can be very different depending on the interviewer or setting. These differences cause measurement error.

What a participant chooses to report can be impacted by such things as feeling uncomfortable responding to sensitive questions, the interactions with and demeanor of project staff, distractions during the interview, or privacy-related concerns. Since external factors cannot be completely removed, the best way to minimize these effects is to standardize procedures within and across sites.

2.4b What is measurement error?

Measurement error affects the reliability of data and is a primary concern during any data collection effort. There are two main types of measurement error, random and non-random. **Random measurement error** makes the data less reliable. Reliability refers to the consistency of a measure. An example of random measurement error is when an interviewer accidentally marks a response option that is different from what the participant said or when a participant's recall of a behavior is not precise.

The other type of measurement error is non-random. **Non-random measurement error** occurs when an error can be linked to something systematic or predictable either within the project site or to a specific interviewer. Non-random error is potentially more serious than random error as it can result in incorrect conclusions and estimates. An example of non-random measurement error is if a computer's date is wrong resulting in the miscalculations of time periods for all interviews collected on the computer. To reduce non-random measurement error, it is important that project staff follow procedures to reduce potential systematic variation in how the data are collected.

Interviewer variation or interviewer effect is an important factor that can result in both random and non-random measurement error. Interviewer effect includes such things as an interviewer misreading a question, response option, or instruction; providing non-neutral feedback; or having a lack of rapport with a participant. The best way to minimize interviewer effect is to standardize interviewing within and across sites through performance recommendations, ongoing evaluations, and retraining (**Table 2.3** on pages 2-9 and 2-10).

Table 2.3 – Evaluation and retraining recommendations

Staff Member	Evaluator	Pre-implementation Evaluation and Performance Recommendations	Recommended Ongoing Evaluations Schedule	Retraining Recommendations	Recommended Retraining Evaluation Schedule*
Field Supervisor	PI or PC	Successfully meets NHBS performance recommendations.	Project Management: For the first three weeks, one evaluation per week, and then one per month.	Retraining of any skills below standard by PI or PC.	Successfully meets NHBS performance recommendations.
			HIV Testing Operations: One evaluation per month.	Retraining of any skills below standard by PI or PC.	
Counter	PI, PC, or FS	High level of comfort and accuracy counting venue attendees. <i>Note:</i> There is no evaluation form for counters.	For the first three recruitment events, the counter should be evaluated for 10-15 minutes to ensure that all counting procedures are being accurately performed, and then evaluated once per month.	Minor errors: Retraining or review of necessary skills by PC or FS prior to resuming counting.	Successfully counts venue attendees during another 10-15 minute period at the same event. If evaluation is unsuccessful, follow the retraining and evaluation recommendations for major errors (see below).
				Major errors: Complete retraining by PC or FS prior to resuming counting.	Successfully counts venue attendees during a 10-15 minute period at three consecutive events.
Recruiters	PI, PC, or FS	Successfully meets NHBS performance recommendations, including the ability to address recruitment and participation barriers (see Appendices L and M).	First five approaches at first three recruitment events, and then first five approaches at two events per month. Recruiters should also be evaluated at events where five consecutive men approached refuse intercept.	Minor errors: Retraining or review of any skills below standard by PC or FS prior to resuming recruiting.	Successfully completes the <i>next</i> five approaches. If evaluations are unsuccessful, follow the retraining and evaluation recommendations for major errors (see below).
				Major errors: Complete retraining by PC or FS prior to resuming recruiting.	Successfully completes five consecutive <i>mock</i> approaches.
Interviewers	PI, PC, or FS	Successfully completes two consecutive full mock interviews (screening, consent, and interview).	Two consecutive interviews during the first two weeks, and then one evaluation every ten interviews.	Minor errors: Retraining or review of any skills below standard by PC or FS prior to resuming interviewing.	Successfully completes the <i>next</i> two full interviews (screening, consent, and interview). If evaluations are unsuccessful, follow the retraining and evaluation recommendations for major errors (see below).
				Major errors: Complete retraining by PC or FS prior to resuming interviewing.	Successfully completes two consecutive full <i>mock</i> interviews (screening, consent, interview).

Table 2.3 – Evaluation and retraining recommendations (continued)

Staff Member	Evaluator	Pre-implementation Evaluation and Performance Recommendations	Recommended Ongoing Evaluations Schedule	Retraining Recommendations	Recommended Retraining Evaluation Schedule*
HIV Test Counselors	PI, PC, or FS	<p>Successfully completes two consecutive full mock HIV testing sessions.</p> <p>The following counseling scenarios should be practiced prior to the start of data collection: an HIV-negative test result, a preliminary HIV-positive test result (for rapid tests), a confirmed HIV-positive test result, and discrepant preliminary and confirmatory test results (for rapid tests).</p>	<p>Two consecutive testing sessions during the first two weeks, and then one evaluation every two weeks or, if a part-time counselor, one per month.</p>	<p>Minor errors: Retraining or review of any skills below standard by PC or FS prior to resuming HIV testing.</p>	<p>Successfully completes the <i>next</i> two HIV testing sessions.</p> <p>If evaluations are unsuccessful, follow the retraining and evaluation recommendations for major errors (see below).</p>
				<p>Major errors: Complete retraining by PC or FS prior to resuming HIV testing.</p>	<p>Successfully completes two consecutive <i>mock</i> HIV testing sessions.</p>
Data Manager	PI or PC	<p>Successfully meets NHBS performance recommendations.</p> <p>Successfully uploads data from the portable computers without any data loss.</p> <p>For new data managers, successfully encrypts and submits QDS™ Warehouse containing mock core interviews to the data portal.</p>	<p>One evaluation during the first week of data collection and then one per month.</p>	<p>Retraining of any skills below standard by PC.</p>	<p>Successfully meets NHBS performance recommendations.</p>

PI= principal investigator, PC= project coordinator, FS= field supervisor

*Project staff with major errors during their evaluations should undergo complete retraining before returning to the field and interacting with participants.

2.5 Project Staff Training

The project coordinator and field supervisor are responsible for conducting a field operations training at each site to ensure that all staff members have:

- A thorough understanding of NHBS guidance documents, locally developed procedures, and the ethical principles and standards for HIV surveillance.
- Completed all required trainings.
- Successfully demonstrated their job-specific duties and responsibilities in a manner that meets the recommended performance standards prior to the start of data collection.

2.5a Required trainings

Required trainings for project staff are described below and can also be found in **Table 2.4** on the next page. Completed trainings should be documented in the Operations Checklist (**Appendix A**).

Field Operations Training

The CDC Field Operations Training for the current cycle is implemented via an in-person training and a series of webinars. All live webinars are recorded and provided to project sites for use in their local trainings. The in-person training and live webinars should be attended by the project coordinator and the field supervisor (or lead interviewer). The project coordinator and field supervisor are, in turn, responsible for incorporating the information from the CDC Field Operations Training into their local field operations training.

Required participants: *Project coordinator and field supervisor to attend in-person training and live webinar sessions. All relevant field staff to view either live or recorded webinar sessions.*

Emergency procedures, field safety, adverse events, and field incidents

Project staff should be trained in general field safety and emergency situations. They should be taught how to handle challenges involving the general public, recruitment events, weather, and participants (in particular, de-escalation techniques for unruly participants and emergency procedures for participants who have a negative reaction to the survey or their HIV test result). Trainers should also discuss procedures for handling and reporting field incidents and adverse events, as well as a communication plan for alerting project staff in case of an emergency. Throughout the project cycle, the field supervisor should review safety procedures with the project staff at least once a month to ensure that they can successfully handle difficult situations.

Required participants: *All project staff*

Table 2.4 – Pre-implementation knowledge and trainings

	Guidance Documents							Required Trainings					Recommended Trainings	
	Model Surveillance Protocol	Operations Manual	Formative Research Manual	Interviewer Guide	Questionnaire	Data Management Training Manual	Site-specific HIV testing documents	CDC Field Operations Training	Security and confidentiality of HIV/AIDS surveillance data	Emergency procedures, field safety, adverse events, and field incidents	Project site and job-specific trainings	DCC Data Management	Human subjects ethical training	Cultural diversity course
Project Coordinator	X	X	X	X	X	X	X	Attend training and view live webinars	X	X	X		X	X
Field Supervisor	X	X	X	X	X	X	X		X	X	X		X	X
Counter	X	X	X*					View live or recorded webinars	X	X	X		X	X
Recruiters	X	X	X*						X	X	X		X	X
Interviewers	X	X	X*	X	X				X	X	X		X	X
HIV Test Counselors	X	X	X*				X	X	X	X		X	X	
Data Manager	X	X	X*	X	X	X			X	X	X	X	X	

*If applicable.

HIV counseling and testing

HIV test counselors should be trained according to local and NHBS guidelines for HIV risk-reduction counseling, specimen collection, safe handling of specimens, providing test results, and if applicable, giving HIV test results over the phone. HIV test counselors must also hold all locally-required certifications.

Required participants: All HIV test counselors

DCC data management training

Representatives from the DCC will train data managers or other designated project staff on best practices for organizing, editing, and submitting data through the DCC data portal.

Required participants: Data manager, project coordinator, or other designated staff.

2.5b Recommended trainings

Recommended trainings for project staff are described below and can also be found in **Table 2.4** on page 2-12. As with the required trainings, completed trainings should be documented in the Operations Checklist.

Human subjects and scientific ethics training

This free online training covers the historical background of behavioral and biomedical research, the ethical principles for human subject research, and the role of the Institutional Review Board. Online completion time is approximately 30-90 minutes depending upon an individual's familiarity with the material. Courses can be found at either the Collaborative Institutional Training Initiative (CITI) website (<https://www.citiprogram.org>) or the NIH Protecting Human Research Participants (PHRP) website (<http://phrp.nihtraining.com/users/login.php>). Once registered, project staff can complete the course in multiple sittings.

Recommended participants: All field staff

Cultural diversity course

A cultural diversity course is recommended for all project staff who interact with participants. Courses are often offered at local universities, state health departments, medical schools, or companies that specialize in diversity training. The Association of Schools of Public Health also has free online courses: (http://www.asph.org/userfiles/PHTC_FINALCCDiversitybundle.pdf).

Recommended participants: All field staff

2.6 Project Staff Evaluations

To help project sites evaluate pre-implementation and ongoing staff performance, **Table 2.3** on pages 2-9 and 2-10 outlines pre-implementation evaluation and performance recommendations, a recommended ongoing evaluation schedule, retraining recommendations, and a recommended retraining evaluation schedule. In addition, model evaluation forms for each staff position can be found in **Appendices B** thru **G**. Project sites should describe their plans for conducting staff evaluations and retraining in the Operations Checklist and discuss these plans with their CDC project officer.

2.6a Pre-implementation evaluation and performance recommendations

Prior to implementation, each staff member should meet all the performance recommendations for their position to ensure the standardization of skills within and across project sites from the onset of data collection. Performance recommendations are the suggested quality standards that each staff position should attain prior to working in the field and should *maintain* throughout the project cycle. When a staff member no longer performs at the recommended skill level, retraining should occur to address the identified deficiency.

2.6b Ongoing evaluations and retraining procedures

Ongoing evaluations are important for the reliability of NHBS data. All project staff should be evaluated on a regular basis to ensure that standardization and quality data collection are maintained throughout the project cycle. Over time, it can be expected that project staff, even those with extensive experience, will begin to drift from the NHBS performance recommendations, resulting in lack of study standardization. If these deficiencies are not identified and corrected, data quality will be compromised.

Retraining should occur each time a staff member has been identified as not having maintained a performance recommendation. Project staff should successfully complete retraining before re-entering the field to interact with participants.

2.6c Evaluators

The principal investigator, project coordinator, or field supervisor should complete pre-implementation and ongoing evaluations for all project staff to ensure thorough job knowledge and successful job performance. Pre-implementation and ongoing evaluation forms should be kept on file as each evaluation is intended to build upon the previous assessment. To protect staff confidentiality, completed evaluation forms should be stored in a secure and locked location.

When conducting an evaluation, it is important that the evaluator has a thorough understanding of the duties and responsibilities for the position, performance recommendations, and criteria for evaluation (evaluation form). When evaluating

interviewers, it is often helpful to have a portable computer to follow along with the survey.

Recommendations for evaluators:

- To ensure the most accurate assessment of a staff member's skill-level, do not serve as a mock participant and evaluator at the same time.
- Unless a major issue arises (i.e., consent-related, protocol violation, or a data entry error that would result in an entire section of the survey being skipped), do not interrupt a staff member who is with a participant during an intercept, interview, or HIV counseling session. If an evaluator needs to interrupt, it should be done discreetly, with communication directed to the staff member and not the participant.
- Provide positive feedback and recommendations for improvement to the staff member following each evaluation.
- Maintain pre-implementation and ongoing evaluation schedules.
- Discuss staff evaluations and retraining needs with the field supervisor.

2.6d Project staff

Project staff should be evaluated for each position they hold. Prior to their evaluations, they should be familiar with their job-specific evaluation form(s), performance recommendations, and any local requirements. Following each evaluation, the evaluation form should be reviewed with the staff member and positive feedback and recommendations for improvement should be provided.

When a staff member is evaluated during the project cycle, the staff member should follow a locally developed script to explain to the participant why an evaluator would like to sit in on the participant's session. Key points to be discussed with the participant are: (1) an evaluator would like to observe the staff member and *not* the participant, (2) the reason for the evaluation is to ensure quality standards for the project, and (3) it is the participant's *choice* to allow an evaluator to be present.

2.6e Interviewer Report

To help project sites assess the interviewers and provide feedback for improving their techniques, the DCC will produce an *Interviewer Report* containing the following three tables: Interviewer Capacity, Response Validity, and Coding of "Other" Insurance. An explanation of each table is provided in **Section 9.3g** of this manual. Project sites should review the report at least once a week and discuss the findings with their interviewers to identify strengths and areas for improvement.

3.1 Overview

The purpose of this chapter is to describe the preparations that should be made prior to starting data collection. These preparatory tasks include: 1) developing a project logo and marketing materials, 2) requesting access to the NHBS Data Coordinating Center (DCC) data portal, 3) obtaining project supplies, and 4) establishing local safety and field incident reporting procedures. Other preparatory tasks, such as training staff and planning HIV counseling, testing, and referral services are described in **Chapters 2** and **8** of this manual, respectively.

3.2 Project Logo and Marketing Materials

A project logo and marketing materials can be created for local project identification and to promote community awareness of the project. Formative research should guide the development of these materials and members of the community should be asked about the types of logos and marketing strategies that would be most appealing to potential participants. Moreover, marketing materials should be culturally appropriate and respectful of the local MSM community. Before the logo and marketing materials are printed and distributed, they must be reviewed and approved by the local program review panel and the site's CDC project officer.



Content posted on social media, like a Facebook Page, should be treated the same as all other NHBS marketing materials; it must be reviewed and approved by the local program review panel and the site's CDC project officer (see **Section 6.2b** of the *NHBS-MSM4 Formative Research Manual*).

3.3 Access to the DCC Data Portal

As described in **Chapter 10** of this manual, project sites must regularly submit the QDS™ Warehouse with their core surveys to the DCC data portal. They will also use the data portal to enter data into the Venue-Day-Time Sampling (VDTS) Program, the HIV Testing Log, the Hepatitis Testing Log (if applicable), and the Data Error Log. Project staff that need access to the DCC data portal should first receive approval from the principal investigator of the directly funded health department and then apply for access following the instructions in the *NHBS-MSM4 Data Management Training Manual*.

3.4 Project Supplies

This section describes the supplies that project sites should obtain before starting data collection. The Recruitment Event Checklist (**Appendix H**) has a model list of supplies which sites can modify to meet their local needs.

3.4a Portable computers and survey software

NHBS surveys must be conducted using portable computers, such as tablets or laptops. Therefore, project sites should check that their portable computers are functioning properly and ensure that enough are available for use in the field (including at least one backup). Sites that have experienced problems with portable computers during past cycles should discuss this with their CDC project officer and develop strategies for preventing data loss during the current cycle.



Paper surveys *cannot* be used for data collection even if the portable computers are malfunctioning. Data collection must stop if none of the portable computers are operational.

To prevent erroneous dates or times from being entered in the survey database, interviewers should check the date and time displayed on their portable computers before conducting their first survey each day. They should also check the date and time periodically throughout the recruitment event to verify their accuracy.

Project sites must use QDS modules (version 2.6.1) to collect and manage NHBS data. These modules include the Design Studio, Warehouse Manager, and CAPI™. QDS modules using version 2.6.1 may not function properly on computers that also contain earlier versions of the modules, such as versions 2.4 and 2.5. Only the CAPI™ module will be supported for NHBS data collection.

3.4b Materials

Project sites should ensure that they have an adequate number of photocopied consent forms, incentives, flashcards, and other materials needed to conduct NHBS activities. Flashcards that are laminated and attached to a ring may be easiest for interviewers to use in the field.

3.4c Forms and logs for project management

To ensure successful project management and quality data collection, sites should develop procedures for the day-to-day operations of NHBS. Several forms and logs described throughout this manual are used to collect, track, and report information for different operational aspects of NHBS. The field supervisor and other project staff are responsible for completing, reviewing, and correcting the information in these documents in accordance with their local procedures and the *NHBS Round 4 Model Surveillance Protocol*. Sites can customize the documents for local use and they can develop

additional documents to help manage project activities as needed. **Table 3.1** on the next page summarizes some forms and logs that are recommended.



CDC recommends the forms and logs listed in **Table 3.1** for better managing NHBS operations. However, these forms and logs are not federal data collection instruments and are not sent to CDC. They have not received Paperwork Reduction Act (PRA) or Office of Management and Budget (OMB) approval.

Project staff should use a binder to store forms and logs in a central and easily referenced location. Sites providing HIV test results over the phone should refer to the Model HIV Phone Result Protocol (**Appendix K** of the *NHBS Round 4 Model Surveillance Protocol*) and develop a Phone Results Log (**Appendix V** of this manual). Hard copies of forms that contain confidential information (e.g., Appointment Reminder Call Forms, HIV Testing Log, and Phone Results Log) should be stored in a locked file cabinet and handled in a manner which complies with 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 at <http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>). In addition to the aforementioned forms and logs, project staff may want to keep other materials and information in the project binder for easy reference, such as memorandums of understanding (MOUs) with venue owners and managers, venue contact information, and monthly recruitment calendars.

3.4d Prevention and referral materials

All participants who complete at least part of the survey should be provided with HIV prevention and referral materials. Project sites should develop or compile these materials and have them readily available at recruitment events. Examples of prevention and referral materials include:

- **Informational and educational pamphlets.**
 - Data describing the current state of the HIV, STD, and hepatitis epidemics.
 - Modes of transmission for HIV, STD, and hepatitis.
 - Strategies for preventing HIV infection through sex and drug use.
 - HIV, hepatitis, and other testing services.
 - Alcohol and drug treatment services.
- **List of referral agencies** and contact persons to provide to participants who are HIV-positive so that they can receive medical care and case management services. Also, so that project sites can readily make any necessary referrals, they should maintain a list of the names and contact information of health and

Table 3.1 – Summary of forms and logs for project management

Form or Log	Where Used	Purpose	NHBS-MSM4 Operations Manual
<i>Intercept Form</i>	Recruitment events	Record information collected during intercept.	Appendix N
	Project office	Enter recruitment event outcomes into VDTS Program.	
<i>Survey ID Log</i>	Recruitment events	Track survey numbers assigned.	Chapter 5
<i>Participant Tracking Form</i>	Recruitment events	Track participant information and record data edits.	Appendix K
	Project office	Enter data edits into the online Data Error Log (DCC Data Portal).	
<i>Appointment and Phone Results Cards</i>	Recruitment events	Make post-event appointments or appointments for returning HIV test results.	Appendix W
<i>Appointment Log</i>	Recruitment events	Schedule appointments.	Chapter 6
	Project office	Track appointments.	
<i>Rapid Testing Quality Control Log</i>	Recruitment events	Record external rapid test control results.	Appendix P
<i>Rapid Testing Temperature Log</i>	Recruitment events	Record temperatures at which rapid tests and quality controls are stored and run.	Appendix Q
<i>Lab slips</i>	Recruitment events	Identify specimens.	Chapter 8
<i>Specimen Transport/Shipping Log</i>	Recruitment events or project office	Transport or ship specimens to laboratory.	Appendix U
<i>Appointment Reminder Call Form (if applicable)</i>	Recruitment events	Record information for optional reminder call for HIV test results appointment.	Appendix X
	Project office	Make reminder calls to participants.	
<i>Phone Results Log (if applicable)</i>	Recruitment events	Record information to return HIV test results over phone.	Appendix V
	Project office	Return HIV test results over phone.	
<i>HIV Testing Log</i>	Recruitment events	Record HIV testing data.	<i>(Appendix L, NHBS Round 4 Model Surveill. Protocol)</i>
	Project office	Enter HIV testing data into online HIV Test Results Log (DCC Data Portal).	
<i>Recruitment Event Checklist</i>	Recruitment events and project office	Facilitate preparation for, setup and closeout of recruitment events.	Appendix H
<i>Recruitment Event Information & Outcomes Form</i>	Recruitment events	Record recruitment event information, notes, and outcomes.	Appendix J
	Project office	Enter recruitment event outcomes into VDTS Program (DCC Data Portal).	
<i>Project staff evaluation forms</i>	Recruitment events	Observe and evaluate project staff.	Appendices B - G

social service providers in their communities. This list should include HIV and STD clinics, substance abuse treatment centers, mental health service providers, and agencies that offer free HIV, STD, and hepatitis testing. Further information on referrals to care and services are described in **Section 8.8** of this manual.

- **Supplies** used to reduce HIV risk, such as condoms and lubricant.



Some project sites have found that packing prevention and referral materials in creative ways increases their appeal to participants.

3.4e Other supplies and materials

Project sites should obtain any other supplies needed to carry out field operations. In regard to HIV testing, sites should have an adequate supply of test kits, specimen collection devices, protective equipment, biohazard waste containers, and if applicable, package inserts for the rapid test being used.

3.5 Local Safety Procedures

Before starting field work, project sites must develop local safety procedures, document these procedures in the Operations Checklist (**Appendix A**), and train project staff on the procedures. Local safety procedures should include a communication plan for alerting project staff to a general threat, plans for dealing with threatening situations, and procedures for reporting field incidents. Field supervisors should periodically review local safety procedures with project staff to ensure that they stay current on what to do in case of an emergency.

Project staff must be alert to their own safety and to that of their co-workers at all times. A basic awareness of one's surroundings is critical when working in the field. Each staff member is also responsible for maintaining a safe working environment. The field supervisor is generally responsible for crowd control and overall safety. The field supervisor must have emergency contact information for each staff member working in the field and he must have this information readily available at all times. Project sites that use a van should have one staff member monitor the area immediately surrounding the van, as well as control who is allowed to enter the van.

3.5a General principles of field safety

It is important for project staff to prevent problems by using common sense and advance planning:

- Call 911 without hesitation if danger is present.
- Always carry a project or health department identification card.

- Plan ahead, be alert, and use common sense.
- Have a first aid kit available.
- Always have at least 3 staff members at each recruitment event.

3.5b Steps for field safety

Project sites should consider the following steps for field safety:

Plan ahead

- Have an emergency action plan.
 - Know what you are going to do ahead of time in case things go wrong.
 - Know who to contact in case of emergency.
 - Always know the location of all exits at the venue where the recruitment event is being conducted.
- During interviews, always position yourself closest to the door; you do not want an unruly participant between you and the exit.
- Consider developing a code word to call for assistance from a co-worker. For example, you might use the phrase “bring the red folder.” Then, if you are not comfortable interviewing a participant alone or need help with an uncooperative participant, you could ask a co-worker to “bring the red folder” to indicate that you need assistance.

Be alert

- Be aware of your surroundings.
- If a threatening situation arises, remove yourself from the situation immediately. Leave quickly, but do so carefully and in a calm manner.
- Use all of your senses to assess a situation. If your “sixth” sense tells you that the situation is not safe, seek immediate assistance from a co-worker or security person.
- Approach every potential participant as though he is welcoming, but be cautious if you have concerns about him.

Use common sense

- Limit the amount of cash you carry.
- Avoid wearing or carrying articles that look valuable. Jewelry, purses, expensive watches, and cameras invite theft.

- Avoid wearing articles of clothing with political or culturally insensitive images.
- Do not carry illegal weapons.
- Never leave the keys in your car or the doors unlocked.
- Do not use illegal drugs or alcohol while you are working.
- Do not make change or give donations to those asking for money while you are working.
- Do not buy or receive merchandise from participants.
- Do not accept gifts from anyone.
- Do not offer rides to participants or accept rides from them.

3.5c Techniques for handling dangerous or difficult situations

End the interview at any point if you feel threatened by the participant.

Aggressive or threatening individuals

If directly confronted by an individual, employ verbal de-escalation techniques: position yourself at an angle and allow extra space between you and the other person; do not smile; let the participant vent; listen to and acknowledge his concerns; avoid becoming defensive; lower your voice, tone, and tempo; and respond to valid complaints. Local safety officials (police, fire, and rescue) may be able to provide de-escalation training.

Sexual harassment

If a participant is making sexual advances or sexually harassing you, you have the right to terminate the interview. If you feel the participant is behaving inappropriately, you should first remind him that you are only there to interview him and that you are not interested in any sexual offers. If the participant continues, state that you are going to stop the interview if he cannot stay focused on the questions. If this does not work, terminate the interview.

Inebriated, high, or drowsy participants

A participant may not be able to complete the interview or give accurate responses for a variety of reasons. For example, he may be unable to give intelligible answers to the questions or he may nod off during an interview if he has had little sleep or has recently used alcohol or drugs. If the participant is unable to provide coherent answers during eligibility screening, then he should be made ineligible; and if he cannot provide coherent answers during the core survey, his interview should be stopped (see **Section 6.4** of this manual for further guidance).

3.5d Safeguarding portable computers

Carrying and using portable computers may attract attention and could pose a safety risk to project staff. When in possession of a portable computer, project staff should adhere to the following guidelines:

- Store your portable computer out of view in a secure place when you are not using it.
- Try to be inconspicuous when carrying and using your portable computer. *Never* leave it unattended in the field.
- Upload data from portable computers to the central database on a secure data drive after each recruitment event.

3.6 Field Incident Reporting Procedures

Project sites should develop field incident reporting procedures and include them in the Operations Checklist. These procedures should adhere to all local IRB requirements. In the event that an incident occurs, project staff should notify their field supervisor within 24 hours. The field supervisor, project coordinator, or principal investigator should then use a Field Incident Report to notify their CDC project officer of the incident within 48 hours. A model Field Incident Report is provided in **Appendix I** that sites can customize for local use. Incidents that are adverse events should also be reported to the local IRB(s) within 48 hours or earlier if mandated by local IRB requirements (see **Chapter 9** of the *NHBS Round 4 Model Surveillance Protocol*).

4

Monthly Recruitment Calendar

4.1 Overview

The purpose of this chapter is to provide guidance on creating the monthly recruitment calendar. Each month, project sites will create a recruitment calendar listing the upcoming month's recruitment events. Project sites will select and schedule the venues, days, and times (VDTs) when the events will occur using the Venue-Day-Time Sampling (VDTS) Program supplied by the NHBS Data Coordinating Center (DCC). The recruitment calendar for an upcoming month should be made at least one week prior to the start of that month so that CDC project officers can review the calendar and project sites can begin to contact the management of the selected venues.

4.2 Sampling Venues and Day-Time Periods

The VDTS Program will allow project sites to create and randomly sort a sampling frame of venues and their associated day-time periods. The program will output a list of these randomly selected VDTs that sites, in turn, will use to construct their monthly recruitment calendars.

4.2a Constructing the initial sampling frame

To begin sampling frame construction, project sites should review the Venue Universe they created during formative research to identify those venues that are *eligible* venues. As described in **Chapter 5** of the *NHBS-MSM4 Formative Research Manual*, *eligible* venues are venues where 50% or more of the men attending the venue meet the criteria for participation in NHBS-MSM:

- 18 years of age or older.
- Born male and self-identify as male.
- Resident of the funded MSA or Division.
- Ever had oral or anal sex with another man.
- Able to complete the NHBS survey in English or Spanish.

Once all the *eligible* venues have been identified, they should be entered into the VDTS Program (see the *NHBS-MSM4 Data Management Training Manual* for instructions on entering venues). Next project sites should use the information collected in the Venue Universe to determine whether each *eligible* venue is an *accessible* venue, which is a venue where it is logistically feasible to conduct recruitment events (see **Chapter 5** of the *NHBS-MSM4 Formative Research Manual*). An *accessible* venue has a safe

environment, cooperative management who have agreed to allow recruitment events to be held at their venue, and sufficient attendance to make it worthwhile to conduct events. When necessary, an *accessible* venue should also have adequate space for recruitment, interviewing, and HIV testing; and if applicable, parking for a van.

Project sites should also use the information collected in the Venue Universe to determine which days and times (day-time periods) are best for conducting recruitment event at each *accessible* venue. Sites should base this decision on venue attendance, project staff availability, permission from venue management, and willingness of venue attendees to participate in the survey. The day-time periods for each *accessible* venue should then be entered into the VDTS Program (see the *NHBS-MSM4 Data Management Training Manual* for instructions on entering day-time periods). All the *accessible* venues and day-time periods entered in the VDTS Program comprise the initial sampling frame, and are the venues where recruitment events can be conducted and the days and times when the events can occur.

4.2b Constructing subsequent sampling frames

Based on their ongoing formative research, project sites should update the VDTs listed in the VDTS Program prior to sorting an upcoming month's sampling frame. New *eligible* venues should be added to the sampling frame, and the eligibility and accessibility of the prior month's venues should be modified as necessary. For example, if an *eligible* venue closes, it should be made *not* eligible. Similarly, if the managers of an *accessible* venue no longer allow access to their venue, the venue should be made *not* accessible. Day-time periods should be revised too. As attendance patterns at *accessible* venues change, their day-time periods should be adjusted accordingly. Maintaining an up-to-date sampling frame is critical to ensuring efficient operations and productive recruitment.

4.2c Reviewing and editing a sampling frame

Before sorting their sampling frame each month, project sites should review it for accuracy. The VDTS Program will allow sites to view any sampling frame they have created, as well as print a hard copy of it. If any errors are noted, they should be corrected in the VDTS Program. It is important to ensure that a sampling frame is correct before sorting occurs because once a frame has been sorted, it cannot be changed. If errors are detected in a sampling frame that has been sorted, a new version of the frame will have to be created with the necessary changes. This revised frame can then be sorted as described in **Section 4.2d** below.

4.2d Sorting a sampling frame

With venue-based sampling, project sites must randomly select the venues where recruitment events will take place and the days and times when these events will occur. The VDTS Program will automatically perform this random selection for sites by sorting and ordering the venues and day-time periods on their monthly sampling frames. The program will first randomly sort all the venues on the sampling frame and list them by

their selection order. The program will then randomly sort all the day-time periods available for each venue and list them by their selection order. As shown in **Figure 4.1** on the next page, the final product is a line-listing of randomly sorted venues and associated day-time periods that the VDTS Program will use to select the VDTs for a project site's monthly recruitment events.

4.2e Selecting VDTs for recruitment events

To use the VDTS Program to select VDTs for an upcoming month's recruitment events, project sites should first decide how many events they need to conduct that month. Sites should plan on conducting a minimum of 14 recruitment events each month to reach the target enrollment of 500 eligible MSM. Once sites have decided on the planned number of recruitment events, they should classify the events as either random or non-random based on how the VDTs for the events will be selected. VDTs selected for random events will be randomly chosen from the sorted sampling frame by the VDTS Program, whereas VDTs selected for non-random events will be purposefully chosen by sites.

Non-random events can be used to capture special events or to increase representation of important sub-populations, but they should be used sparingly. Accordingly, a maximum of 2 non-random events are permitted each month. This restriction will be relaxed, however, during the month that each project site holds its largest or main pride festival. That month, sites may conduct up to 2 additional non-random events for a total of 4 non-random events. Yet, to be able to conduct these extra non-random events, sites must first gain approval from their CDC project officer by providing written justification for adding the extra events. For example, the added non-random events may help a site enroll an important sub-population that the site is having difficulty reaching. Sites are only allowed to conduct the extra non-random events during the month of their main gay pride festival; they cannot conduct them during the month of a smaller pride festival that targets a specific group, such as a black gay pride festival or a leather festival.



Project sites must enter the VDT for a non-random event in the VDTS Program so that it is available for scheduling, but the program will not include the VDT on the sampling frame. Therefore, the venue selected for a non-random event cannot also be used for a random event.

Project sites will start the VDT selection process by choosing VDTs for any planned non-random events (see the *NHBS-MSM4 Data Management Training Manual* for instructions on selecting VDTs). Ordinarily, in a given month, non-random events should not be held at the same venue as another non-random event. However, under rare circumstances, sites may repeat a non-random event at a venue if they obtain prior approval from their CDC project officer. After sites have selected VDTs for non-random events, they will then enter the anticipated number of random events in the VDTS Program. The maximum number of random events a site can choose each month with the VDTS Program is twice the number of venues on the sampling frame to ensure that events are not held at the same venue more than two times in a single month. The VDTS

Figure 4.1 – Sorted sampling frame.

Venue Code	Venue Name	VDT Pick Order	Start Day	Monthly Frequency	Start Time	End Time
D002	The Eagle	1	Friday	Weekly	9:30 PM	1:30 AM
		2	Saturday	Weekly	9:00 PM	1:00 AM
O010	Evolution Project	1	Thursday	Weekly	4:00 PM	8:00 PM
		2	Tuesday	Weekly	4:00 PM	8:00 PM
B006	Felix's on the Square	1	Saturday	Weekly	10:00 PM	2:00 AM
		2	Friday	Weekly	9:00 PM	1:00 AM
B004	The Cockpit	1	Sunday	Weekly	7:00 PM	11:00 PM
		2	Friday	Weekly	9:00 PM	1:00 AM
		3	Saturday	Weekly	9:00 PM	1:00 AM
D020	Chaparral - Latin Night	1	Friday	Weekly	11:00 PM	3:00 AM
B012	Hideaway	1	Friday	Weekly	8:00 PM	12:00 AM
		2	Saturday	Weekly	8:00 PM	12:00 AM
D001	XS Ultra Lounge (Club 708)	1	Saturday	Weekly	10:00 PM	2:00 AM
		2	Thursday	Weekly	10:00 PM	2:00 AM
B002	BJ Roosters	1	Friday	Weekly	9:00 PM	1:00 AM
		2	Saturday	Weekly	9:00 PM	1:00 AM
		3	Wednesday	Weekly	9:00 PM	1:00 AM
		4	Thursday	Weekly	9:00 PM	1:00 AM
B008	Le Buzz	1	Friday	Weekly	9:30 PM	1:00 AM
		2	Saturday	Weekly	10:00 PM	2:00 AM
X002	Flex	1	Tuesday	Weekly	10:00 PM	2:00 AM
		2	Sunday	Weekly	10:00 PM	2:00 AM
		3	Sunday	Weekly	1:00 PM	5:00 PM
		4	Friday	Weekly	10:00 PM	2:00 AM
		5	Thursday	Weekly	10:00 PM	2:00 AM
		6	Saturday	Weekly	1:00 PM	5:00 PM
		7	Wednesday	Weekly	10:00 PM	2:00 AM
		8	Saturday	Weekly	10:00 PM	2:00 AM

Program will also allow sites to select a certain number of venues to serve as reserve venues. These reserve venues can, if needed, replace any venues that cannot be scheduled on the monthly recruitment calendar because of conflicts with event days or times.

Once project sites have chosen the number of random events and the number of reserve venues, the VDTS Program will display a table of the VDTs selected from the sorted sampling frame (**Figure 4.2** on the next page). The top section of this table of selected VDTs will list any VDTs purposefully chosen for non-random events, the middle section will contain VDTs randomly selected from the monthly sampling frame for random events, and the bottom section will list possible reserve VDTs. Project sites will use the table of selected VDTs to construct their monthly recruitment calendars.

4.3 Constructing a Monthly Recruitment Calendar

The monthly recruitment calendar lists the venues, dates, and times when recruitment events will occur during a month. Project sites will construct their calendars by using the VDTS Program to schedule an upcoming month's non-random and random events. For each recruitment event scheduled on the calendar, sites will also need to identify one or two alternate venues where they could hold the event if it cannot be held at the originally scheduled primary venue.

4.3a Determining staff availability

Before project sites begin scheduling recruitment events on their monthly calendars, they should first determine which dates and times the field staff will not be available to conduct recruitment events because of holidays, vacations, or other planned absences. These dates and times should then be blocked-off the calendar. Sites should also block-off other dates and times when recruitment events cannot occur, such as weekly office hours.

To prevent burnout, project sites may want to establish work limits for their field staff. For example, limiting the number of recruitment events that can be scheduled on consecutive days so that staff can have a day off or not scheduling a morning recruitment event the day after a night event. On the other hand, some sites may have more than one team of field staff. In these cases, if staff are available and burnout can be avoided, sites could conduct more frequent recruitment events (up to a maximum of two events in a single day).

4.3b Scheduling non-random recruitment events

Because non-random events have the highest priority for scheduling, project sites should place them on the monthly recruitment calendar first. VDTs available for non-random events are listed in the top section of the table of selected VDTs that is produced by the VDTS Program.

Figure 4.2 – Table of selected VDTs.

Non-random Events

Venue Code	Venue Name	Start Day	Monthly Frequency	Start Time	End Time	Scheduled?
D025	Vita	Saturday	1 time	9:00 PM	1:00 AM	September 3 Edit Staff:

Random Events

Venue Code	Venue Name	# of VDTs	Repeat?	VDT Pick Order	Start Day	Monthly Frequency	Start Time	End Time	Scheduled?
B028	Lucky Lounge	1		1	Sunday	1 time	3:30 PM	7:30 PM	Add to schedule
O004	Atlanta Executive Network (AEN)	1		1	Thursday	1 time	6:30 PM	10:30 PM	Add to schedule
O007	Atlanta Team Tennis Association	1		1	Saturday	Weekly	1:00 PM	5:00 PM	September 24 Edit Staff:
D020	Chaparral - Latin Night	1		1	Friday	Weekly	10:00 PM	2:00 AM	September 9 Edit Staff:
B011	Model-T	2		1	Saturday	Weekly	9:00 PM	1:00 AM	September 10 Edit Staff:
				2	Friday	Weekly	9:00 PM	1:00 AM	Add to schedule
O030	YouthPride	3		1	Thursday	Weekly	4:00 PM	8:00 PM	September 29 Edit Staff:
				2	Friday	Weekly	4:00 PM	8:00 PM	Add to schedule
				3	Tuesday	Weekly	4:00 PM	8:00 PM	Add to schedule

Reserve Venues

Venue Code	Venue Name	# of VDTs	Repeat?	VDT Pick Order	Start Day	Monthly Frequency	Start Time	End Time	Scheduled?
B004	The Cockpit	6		1	Wednesday	Weekly	8:00 PM	12:00 AM	September 14 Edit Staff:
				2	Thursday	Weekly	8:00 PM	12:00 AM	Add to schedule
				3	Tuesday	Weekly	8:00 PM	12:00 AM	Add to schedule
				4	Friday	Weekly	9:00 PM	1:00 AM	Add to schedule
				5	Saturday	Weekly	9:00 PM	1:00 AM	Add to schedule
				6	Sunday	Weekly	6:00 PM	10:00 PM	Add to schedule
D024	The Havana Club	1		1	Monday	1 time	10:00 PM	2:00 AM	Add to schedule

4.3c Scheduling random recruitment events

Project sites should schedule random events on the monthly recruitment calendar after any non-random events have been scheduled. VDTs available for random events are listed in the middle section of the table of selected VDTs. The venues for these VDTs are arranged in order from venues with the fewest number of day-time periods to venues with the most. Venues with the same number of day-time periods are ranked in the order that they were randomly selected by the VDTS Program. Sites should schedule the venues for their random events in the order that they are listed on the table. By starting with venues with the fewest number of day-time periods, sites will minimize any irreconcilable scheduling conflicts with days or times.

The scheduling of random events should begin with venues with one day-time period. Project sites can schedule these venues on any date that can accommodate their day-time periods. Once this has been completed, sites can start scheduling those venues with more than one day-time period. Before sites can do this, however, they must first randomly select a day-time period for each venue. To facilitate this process, the table of selected VDTs lists all the day-time periods for each venue in the order that they were randomly chosen by the VDTS Program (i.e., the first day-time period randomly selected is listed first, the second randomly selected is listed second, and so on). For each venue, project sites should therefore pick the first day-time period listed for that venue and schedule it on any date that can accommodate this day-time period. If no dates are available to schedule the first day-time period listed for a venue, sites should choose the second day-time period listed. If a date cannot be found for this day-time period either, sites should move down the list of the venue's day-time periods until they find one that can be scheduled on the recruitment calendar. In some rare cases, none of a venue's day-time periods can be scheduled. If this happens, sites should exclude the venue and after they have finished scheduling the remaining random events, replace it with a reserve venue.

Repeat venues

Sometimes a project site plans on conducting more random events than there are venues on its sampling frame. When this happens, a second event must be held at one or more of the venues. Because second events at any venues are scheduled *after* first events for all the venues have been scheduled, the VDTS Program displays the venues to be repeated at the end of the random events section of the table of selected VDTs. Venues to be repeated, like other venues selected for random events, are arranged in order from those with the fewest number of day-time periods to those with the most, and they are scheduled accordingly.

4.3d Scheduling reserve venues

Because of scheduling conflicts, a venue selected for a random event may sometimes have to be excluded and replaced with a reserve venue. Possible reserve venues are listed in the bottom section of the table of selected VDTs. The table lists both the reserve venues and their day time-periods in the order that they were randomly selected by the

VDTS Program. If a venue selected for a random event must be replaced, project sites should pick the first reserve venue listed as the replacement. Project sites will then have to choose a day-time period for this venue and schedule it on the recruitment calendar. As was described above in **Section 4.3c**, sites should pick the first day-time period listed for the venue and schedule it on any date that can accommodate this day-time period. If a date cannot be found for the first day-time period, the second one should be picked, and so on. If dates cannot be found to accommodate any of the venue's day-time periods, sites should move to the next reserve venue on the list. This process should continue until a replacement venue can be scheduled on the recruitment calendar.



Project sites should not schedule any reserve venues as replacements until all the venues selected for random events have been scheduled on the recruitment calendar.

4.3e Assigning alternate venues

Occasionally, a recruitment event cannot be conducted at a scheduled primary venue because of unforeseen circumstances like inclement weather. Accordingly, project sites should schedule at least one alternate venue as a back-up for each planned recruitment event. Under most circumstances, one alternate venue is sufficient. However, because recruitment events are moved to alternate venues at the last minute, it is often prudent to also schedule a second alternate venue in case the first is not available.

Possible alternate venues should have day-time periods that begin up to one hour before the scheduled recruitment event or up to two hours later. In addition, possible alternate venues should not be the same as any venues already scheduled as the primary venue for a recruitment event nor the same as any venues already assigned as alternates. Nevertheless, the restriction on repeating venues can be lifted if there are no other possible alternate venues available for a particular recruitment event. If project sites must repeat venues, they should repeat venues assigned as second alternates before they repeat any venues assigned as first alternates, and they should repeat venues assigned as first alternates before they repeat any primary venues.



Although sites can schedule the same venue as an alternate multiple times in a single month, they can only conduct recruitment events at each venue a maximum of two times per month. Once a venue reaches this limit, the venue can no longer serve as an alternate that month.

When choosing possible alternate venues, project sites should also consider potential logistical and weather problems. For example, sites with venues widely dispersed throughout the city may want to limit possible alternate venues to those located a reasonable travel distance from the scheduled recruitment event. If a recruitment event is scheduled at an outdoor venue, sites may want to choose at least one alternate at an indoor venue in case of inclement weather.

For each recruitment event that has been scheduled on the monthly calendar, the VDTS Program will display a list of possible alternate venues ranked by their random selection order and their scheduling priority (first, unscheduled venues; second, venues scheduled as second alternates; third, venues scheduled as first alternates; and last, venues scheduled as primaries). Starting at the top of the list of possible alternate venues, project sites should choose the first one that can practicably serve as the first alternate venue. After all the scheduled recruitment events have had a first alternate venue selected, sites can use the VDTS Program to choose a second alternate venue for each event. The monthly recruitment calendar is complete when all non-random and random events have been scheduled and at least one alternate venue has been assigned for each event. Because the days and times of some scheduled recruitment events may not overlap with any other venue's day-time periods, project sites may not be able to assign alternate venues for all recruitment events.

4.4 Revising a Monthly Recruitment Calendar

Sometimes project sites may have to revise the monthly recruitment calendar after it has been submitted to their CDC project officer. Because of staffing or logistical difficulties, sites may have to select a new date for a scheduled recruitment event, choose a new day-time period for a venue, or replace a venue. If a problem with a scheduled recruitment event can be addressed by modifying the calendar, sites should do so and not rely on alternate venues (project sites should only use alternate venues for last-minute changes, like inclement weather). Ideally, whenever sites need to revise their recruitment calendar, they should first discuss the proposed changes with their CDC project officer. In cases where it is not feasible to discuss a required change beforehand, sites should report the change to their CDC project officer as soon as possible. Moreover, any revisions to the recruitment calendar must be recorded in the VDTS Program.

4.4a Scheduling a new date for a recruitment event

When a recruitment event cannot be held on the date that it was originally scheduled, project sites should re-schedule the event on any available date that can accommodate the event's day-time period. For example, a recruitment event scheduled on a Monday night could be moved to another Monday night. Any previously scheduled alternate venues should also be moved to the new date. If a date that can accommodate a random event's day-time period is not available, sites will have to randomly select another day-time period for the event's venue (**Section 4.4b** below). If a date cannot be found to re-schedule a non-random event, sites can purposefully choose another VDT for a non-random event or choose a reserve venue for a random event (**Section 4.4c** below).

4.4b Selecting a new day-time period for a venue

To select a new day-time period for a venue chosen for a random event, project sites should first locate the venue and its originally scheduled day-time period on the table of

selected VDTs. Then starting with the originally scheduled day-time period, sites should move down the list of the venue's day-time periods until they find one that can be accommodated on the monthly recruitment calendar. Once sites have selected and scheduled a new day-time period for the venue, they should choose new alternate venues as well.

For example, when the project staff at Site A constructed their June recruitment calendar, they scheduled a random event at Venue B on Friday, June 10 from 6 PM to 10 PM. Subsequently, the project staff learned that Venue B would be closed for maintenance on June 10. Because recruitment events were already scheduled on the remaining Fridays in June, the project staff needed to select a new day-time period for Venue B. On the table of selected VDTs, the first day-time period listed for Venue B was the previously scheduled "Friday 6PM-10PM." Since this day-time period could no longer be accommodated on the recruitment calendar, the project staff moved to the second day-time period listed for Venue B and tried to schedule this day-time period on the calendar. This day-time period could not be accommodated on the recruitment calendar either so the project staff continued to move down the list of Venue B's day-time periods until they found one that could be scheduled.

If none of a venue's day-time periods can be accommodated on the recruitment calendar, project sites should replace the venue with a reserve venue (**Section 4.4c** below) or they can purposefully choose another VDT for a non-random event.

4.4c Selecting another venue

To replace a venue scheduled for a recruitment event, project sites should use the first reserve venue listed on the table of selected VDTs that has not already been scheduled on the monthly recruitment calendar. Sites should start at the top of the list of day-time periods for this reserve venue and then move down the list until they find a day-time period that can be accommodated on the recruitment calendar. If none of the venue's day-time periods can be accommodated, project sites should move to the next reserve venue listed on the table of selected VDTs and try to schedule one of that venue's day-time periods. This process should continue until a replacement venue and its day-time period have been scheduled on the recruitment calendar. Project sites will also have to assign alternate venues for the newly scheduled replacement venue.

5 Recruitment Event Preparation and Management

5.1 Overview

The purpose of this chapter is to provide guidance on planning and managing recruitment events. The chapter describes the forms needed to prepare for and manage recruitment events, the tasks required to plan and set up events, and the methods used to effectively manage events. Procedures for closing out recruitment events are discussed in **Chapter 7** of this manual. The project coordinator or field supervisor should perform the activities described in this chapter. Project sites are responsible for ensuring that activities at recruitment events are well-organized, comply with the protocol, are safe, and treat participants with respect.

5.2 Recruitment Event Information and Tracking Forms

To successfully conduct NHBS-MSM operations, project sites must track and document specific recruitment event information. Three model forms are provided for this purpose: the Recruitment Event Checklist, the Recruitment Event Information & Outcomes Form, and the Participant Tracking Form.

5.2a Recruitment Event Checklist

The field supervisor should use the Recruitment Event Checklist (**Appendix H**) to guide the preparation for, setup, documentation and closeout of recruitment events; this form should be used in conjunction with the Recruitment Event Information & Outcomes Form (**Section 5.2b**). Tasks on the checklist are organized by sections according to when and where they should be completed: 1-2 weeks prior to the recruitment event, right before the event, while setting up at the event, while closing out the event, and at the project office after the event. **Sections 5.3** and **5.4** (below) provide detailed information about the tasks to prepare for and set up at recruitment events.

5.2b Recruitment Event Information & Outcomes Form

The field supervisor should use the Recruitment Event Information & Outcomes Form (**Appendix J**) to record information about each specific recruitment event. The first three sections of the form collect pre-event information needed for setup: the primary and alternate venues that are scheduled, the project staff that are scheduled, and the four code numbers that will be used for the recruitment event (Interviewer ID, Survey ID, Venue Code, and Event Number). The last two sections of the form collect post-event information: notes about the recruitment event and the outcomes of the event. The recruitment event outcomes information on this form will be entered into the VDTS Program on the NHBS Data Coordinating Center (DCC) data portal at a later time by the data manager or other designated staff member.

5.2c Participant Tracking Form

The Participant Tracking Form (**Appendix K**) should be used by project staff to document and track the operational activities completed by each participant. The form is useful because it provides a hard copy of completed activities in the event of data loss, facilitates communication among field staff, and assists with data management. The Participant Tracking Form should also be used to record information for subsequent entry into the portable computer and the DCC data portal. For example, the field supervisor should record the four code numbers (see **Section 5.3d** below) in the appropriate fields on the Participant Tracking Form. The interviewer will later enter this information into the portable computer at the start of an interview. Additionally, responses to the *Previous Positive Questions* should be recorded on the Participant Tracking Form and entered into the HIV Test Results Log on the DCC data portal (see **Appendix Y** and **Section 8.7** of this manual). Finally, interviewers should record data edits on the Participant Tracking Form to be entered into the Data Error Log on the DCC data portal. The Participant Tracking Form can be tailored to add additional fields as necessary for local operations.

5.3 Preparing for Recruitment Events

The following are tasks that should be completed before the recruitment event.

5.3a Recruitment event and calendar information

Prior to going into the field, field supervisors should record the name, address and contact information for the primary and alternate venues on the Recruitment Event Information & Outcomes Form.

5.3b Notify venue owner or manager

Using local discretion, project sites may want to contact the venue owner or manager about 2 weeks before the scheduled recruitment event to confirm that the project staff have permission to conduct field operations at their venue. In addition, it is helpful to ask the venue owner or manager about any changes to the venue since the last time a recruitment event or observation was conducted at the venue. Noting the date and name of the person contacted on the Recruitment Event Information & Outcomes Form may also be useful.

5.3c Schedule project staff

Recruitment calendars are created each month as described in **Chapter 4** of this manual. The field supervisor and a minimum of 2 staff members with defined roles must be present at each recruitment event. The number of project staff needed for an event may vary depending on the volume of people attending the venue, the size of the venue (i.e., space available for interviewing), the use of a van, or the use of designated recruiters. Project staff should be provided with a work schedule as soon as the monthly recruitment

calendar is created. The field supervisor should also determine whether project staff evaluations should be scheduled for the event.

In addition, the field supervisor should consider the dynamics of the venues when scheduling project staff. Although it is optimal to have Spanish-speaking interviewers present at every recruitment event, they should, at a minimum, be scheduled to work at venues that cater to monolingual Spanish-speaking men. Certain types of venues, such as bathhouses, may not allow admittance to women; therefore, field supervisors may need to consider scheduling only male project staff for events at these venues.

5.3d Code numbers

At the start of each interview, the interviewers will enter four different code numbers into their portable computer:

- Interviewer ID
- Survey ID
- Venue Code
- Event Number

To ensure that interviewers enter the correct numbers, the field supervisor should provide the interviewers with a written copy of the four code numbers on the Participant Tracking Form. The field supervisor can refer to the Recruitment Event Information & Outcomes Form to obtain the needed code numbers for the Participant Tracking Form.

Interviewer ID

The Interviewer ID is a unique 1- to 2-digit number assigned to each interviewer. Interviewer IDs are assigned when completing the Operations Checklist (**Appendix A**) and should not be exchanged among different interviewers or re-used during the same project cycle.

Survey ID

The Survey ID is a unique 4-digit number that is assigned to a prospective participant when he is going to be screened for eligibility. Survey ID numbers should begin with 1001 and then increase sequentially by 1 with each additional participant (i.e., the first man who agrees to be screened for eligibility should be assigned 1001, the second man screened should be assigned 1002, and so forth). No breaks should occur in the sequence of Survey ID numbers and numbers cannot be re-used or repeated.

If project sites plan on offering appointments for prospective participants to complete the interview at a later date (i.e., post-event appointments [PEAs]), they must decide whether they will assign Survey ID numbers when the prospective participant is recruited at the venue or when he returns for his appointment to be interviewed (see **Section 6.3h** of this

manual). Sites may choose whichever method is most suitable to meet their local needs. Assigning Survey ID numbers at the time of recruitment can help sites keep track of their appointments, but the drawback is that their database will contain gaps in the sequence of Survey ID numbers if prospective participants do not return for their appointments.

Survey ID numbers must be assigned by the field supervisor. The field supervisor should refer to the Recruitment Event Information & Outcomes Form regarding the next sequential Survey ID that should be used for the first interview at the recruitment event. To keep track of the numbers that have been assigned, the field supervisor should maintain a Survey ID log that contains the following information:

- Survey ID
- Interviewer ID
- Interview date
- Event Number
- *If project sites plan on assigning Survey ID numbers for post-event appointments (PEAs) at the time of recruitment:* Documentation that a Survey ID number was assigned for a PEA
- Comments

Table 5.1 (below) shows an example of a Survey ID log. Project sites may customize their logs and include any additional information needed to support their operations. The field supervisor should complete the required entry fields in the log at the time a Survey ID number is assigned to a prospective participant. If the Survey ID number is assigned for an appointment, the field supervisor should also record the Survey ID number on the prospective participant’s appointment card.

Table 5.1– Survey ID Log

Survey ID No.	Interviewer ID No.	Interview Date	Event No.	PEA	Comments
1001	10	6/4/2014	1		
1002	11	6/4/2014	1		
1003	10	6/4/2014	1		
1004	11	6/4/2014	1		
1005	12	6/7/2014	2		
1006			2	Yes	Appointment- Mon 6/9- 2:00PM
1007	10	6/7/2014	2		
1008	10	6/7/2014	2		
1009	12	6/7/2014	2		

Venue Code

The Venue Code is a unique 4-character alphanumeric code assigned to each venue on the monthly sampling frame and recorded in the VDTS Program. Instructions for creating the Venue Code are outlined in **Chapter 5** of the *NHBS-MSM4 Formative Research Manual*. The Venue Code indicates the primary or alternate venue where participants were recruited during a recruitment event. If a staff member makes a post-event appointment, the Venue Code of the venue where the prospective participant was recruited must be recorded on his appointment card.

Event Number

The Event Number is a unique 1- to 3-digit number that is assigned to each recruitment event conducted by a project site. Event Numbers should begin with 1 and then increase sequentially by 1 with each additional recruitment event. No breaks can occur in the sequence of Event Numbers and numbers cannot be repeated. To determine the next sequential Event Number to be used for a recruitment event, the field supervisor can check the VDTS Program for the Event Number that was entered for the last event conducted. The field supervisor should then record the next sequential Event Number on the Recruitment Event Information & Outcomes Form.

Because recruitment is the first step in the process of enrolling participants in NHBS-MSM, a recruitment event officially starts when a recruiter approaches the first man for recruitment. Therefore, an Event Number should be assigned whenever recruitment is *attempted*, even if no men accept the approach. On the other hand, if no men are approached for recruitment, then a recruitment event has not officially started and an Event Number should not be assigned.

5.3e Check portable computers

Project staff should ensure that all portable computers are charged and working properly before each recruitment event. Power cords and one or two backup portable computers should be available if possible. Field supervisors should ensure that all data from the previous recruitment events have been uploaded from the portable computers. Interviewers should check that the correct date and time are displayed on the portable computers before conducting the first survey of each recruitment event; it is also useful for interviewers to check the date and time periodically throughout the event.

5.3f Gather supplies for the field

The Recruitment Event Checklist has a list of equipment, survey materials, forms/logs, prevention and referral materials, and HIV testing supplies that are needed to conduct recruitment events. Project sites should modify this list to meet local needs.

5.4 Setting up at Recruitment Events

Upon arriving at each scheduled venue, project staff should check in with the venue owner or manager, hold a pre-event meeting, and identify spaces for interviewing and HIV testing. In addition, project staff should count men who are present at the venue prior to the start of the recruitment event, determine where men who enter the venue during the event should be counted, identify where and how recruitment will occur, and decide whether a post-event appointment (PEA) system is appropriate. **Section 6.3h** of this manual provides detailed guidance on procedures for counting, recruiting, and scheduling PEAs.

5.4a Check in with venue owner or manager

Upon arrival at the venue, the field supervisor should check in with the venue owner or manager. Although venue owners or managers should be notified of the scheduled recruitment event one to two weeks prior to its occurrence, it is possible that a different person will be in charge at the venue when the event actually takes place. If this occurs, the project staff should refer to the Memorandum of Understanding (MOU) or other documentation of agreement to prevent any confusion regarding permission to operate in the venue.

5.4b Identify and set up interview and HIV testing spaces

Project staff should consider the unique circumstances of the venue when setting up interview and HIV testing spaces for the recruitment event. Some specific circumstances include weather, safety, venue owner preferences, foot traffic, and available space. Most importantly, interviewing and HIV testing should take place in a quiet area that affords privacy for the participant and the interviewer. Other participants should not be able to hear any conversations or observe someone receiving his HIV test results. Confirmatory HIV testing for reactive rapid tests should also be conducted in a private area out of view of others.

Inside venues

For some recruitment events, it is optimal to conduct both interviews and HIV counseling and testing activities inside venues. Venue attendees who are approached may be more willing to participate if they do not have to leave the venue. However, venue owners or managers must approve of the activities and provide appropriate space for interviewing and HIV counseling and testing. This may not be possible at all venues. For example, the collection of blood specimens for HIV testing may not be allowed at certain venues or space may not be available for conducting rapid tests. In addition, project staff must ensure that private spaces are available for providing HIV test counseling and if applicable, delivering rapid test results.

Outside venues

Project staff should consider conducting operations outside the venue if space inside the venue is very limited or if the venue owner is not willing to allow interviewing or HIV testing inside the venue. For activities conducted outside of venues, project staff should consider setting up seating for participants, such as bringing folding chairs or using park benches where available. If HIV testing is conducted outdoors, project staff should also consider bringing a folding table or other stable surface for collecting blood specimens and running rapid tests. Furthermore, project staff should bring lanterns or flashlights to provide sufficient overhead lighting for reading rapid test results and should store HIV test kits in a cooler or in such a manner that keeps the kits at a temperature within the range indicated in the package insert. Interviewing and HIV testing should be conducted far enough away from other people to ensure the confidentiality of the participants' responses and conversations. The field supervisor, interviewers, and HIV test counselors should also be aware of anyone attempting to interrupt an interview or HIV test and deal with the situation accordingly.

Vans

Project sites that have access to vans may find it practical to use the van instead of space inside a venue for all or some operations. For instance, interviewing could be conducted inside the venue and HIV counseling and testing could be conducted in the van. If interviews are conducted inside a van, project staff can screen potential participants inside the venue or on the sidewalk, and then escort eligible men to the van to complete the interview. This strategy may improve the willingness of the men approached to participate in the project. However, project staff must ensure that the eligibility screener is conducted with the CAPI™ core survey on the portable computer; the screener **cannot** be conducted with another computer program or with a paper questionnaire.

As with interviewing and HIV testing inside a venue, participant confidentiality must be maintained in a van at all times. The van should have a stable surface for collecting blood specimens and running rapid tests. The van should also have adequate overhead lighting for reading rapid test results, as well as storage for biohazard containers and bags so that hazardous materials will not spill when the van is moving.

Project staff should attempt to park the van near the venue so that walking to the van does not create a participation barrier. Depending on parking regulations and availability, it may be necessary to obtain a parking permit for each location or to reserve the location in advance. Some health departments have been able to obtain free parking for their van. If it is necessary to park the van farther away from the venue, a communication system should be in place (e.g., walkie-talkies or cell phones) and the field supervisor must be able to provide adequate monitoring of all staff members. Project sites may want to consider having one staff member monitor the area immediately surrounding the van, as well as control who is allowed to enter the van. Sites using vans should also develop contingency plans in case the van is unavailable due to mechanical or staffing problems.

For instance, recruitment events may need to be conducted outside of the venue or may need to be re-scheduled if the van is not available.



Project sites using a van must indicate this in the Operations Checklist.

5.4c Hold pre-event meeting

Before the recruitment event begins, the field supervisor should hold a meeting with project staff to discuss roles and responsibilities; distribute materials; review Survey ID, Venue Code, and Event Number information; identify the counting, recruiting, interviewing, and HIV testing areas; and observe the environmental and social characteristics of the venue. If recruitment events have previously taken place at the venue, project staff should also discuss what contributed to the success or failure of the event. To assist with recruitment, field supervisors may want to assign recruiters who have demographic characteristics that are similar to those of the venue attendees. These meetings are also a good time to build enthusiasm and raise the energy level of the staff.

Prior to starting the recruitment event, the positioning of project staff at the venue should be discussed. Project staff should be positioned strategically to accurately count, effectively recruit, and safely and the efficiently operate.

5.5 General Guidance for Managing Recruitment Events

5.5a Assurance of Confidentiality and field operations

NHBS-MSM data are covered under the *Assurance of Confidentiality for HIV/AIDS Data* (**Appendix M** of the *NHBS Round 4 Model Surveillance Protocol*). Field operations for data collected under the Assurance of Confidentiality are restricted in a number of ways; these restrictions should be taken into consideration when developing local procedures. The restrictions include, but are not limited to:

- Data must be securely stored as soon as possible after each recruitment event. Data include participant surveys, HIV test results, Participant Tracking Forms, and any other participant-level data. If data cannot be secured in the project office directly after an event, plans should be in place to securely store all forms and equipment until they can be returned to the office.
- Electronic data are to be stored on a secure server.
- Paper data are to be stored in a locked file cabinet in a locked room.
- Once data are secure, they must not go back out into the field. If project sites are planning to return HIV test results in the field, they must get permission from their CDC project officer and document the procedures in the Operations Checklist.

- All data transfers must be conducted in a secure manner in accordance with the local health department’s guidelines for the security and confidentiality of HIV/AIDS surveillance data.

Each NHBS-funded health department has a designated Overall Responsible Party for maintaining data security for HIV/AIDS surveillance data. This person should be consulted if questions arise regarding operations.

5.5b Venue attendees known to project staff

During a recruitment event, some of the men attending the venue may be known to project staff. “Know” means that the staff member knows the man’s name, sees him on a regular basis, or has previously met him in a social or professional setting. When project staff encounter a man they know, they should adhere to the guidance listed below for each type of staff member. Project sites should develop local procedures for implementing this guidance and training their staff on it.

Recruiters

Recruiters may approach a man they know and invite him to participate in NHBS.

Interviewers

Interviewers may *not* interview a man they know. If an interviewer knows a prospective participant, they must have another staff member interview him. Furthermore, during the consent process, the newly assigned interviewer should underscore the confidential nature of NHBS and emphasize that participant information is *never* shared among staff members. In the rare event that all the interviewers at a recruitment event know a prospective participant, he could be offered a PEA to be interviewed by a staff member who is not at the event. If the project site does not offer PEAs, the prospective participant cannot be interviewed (the Intercept Form should be completed as usual and a note should be added to the “Comments” field indicating that the prospective participant could not be interviewed because he was known to all interviewers).

Recruiter-interviewers

If a staff member is a recruiter and an interviewer, they may approach a man they know and invite him to participate in NHBS, but they cannot interview him. Another interviewer who does not know the prospective participant must conduct the interview as described above for Interviewers.

HIV test counselors

As with interviewers, HIV test counselors may not collect specimens from, provide counseling to, or return preliminary rapid or confirmatory test results to a man they know. If an HIV test counselor knows a prospective participant, they must have another staff

member certified in counseling and testing provide counseling and administer the HIV test.

5.5c Alternate venues

Alternate venues should only be used for unforeseen circumstances such as inclement weather, venue closure, denied access to a venue, or a safety incident. Very rarely, alternate venues can be used if recruitment events at the primary venue have a low yield. In this latter circumstance, project staff should begin the event and attempt to recruit attendees at the primary venue. If project staff are unable to enroll any participants within the first hour of the event, they have the option of moving to the scheduled alternate venue if they wish. However, if at least one participant is enrolled within the first hour, project staff should complete the event scheduled at the primary venue and should not move to an alternate venue. Enrollment occurs when the recruited venue attendee has been screened, determined to be eligible, and consented to participate in the survey; the interview does not have to be completed. See **Chapter 4** of this manual for information on scheduling alternate venues.



Although the same venue can be scheduled as an alternate multiple times on the monthly recruitment calendar, recruitment events can only be conducted at the same venue twice in one month. Therefore, once recruitment events have been conducted at a venue two times in a month, the venue can no longer serve as an alternate.

5.5d Length of recruitment events

Most recruitment events should have a standard length of 4 hours. Standardizing the length of events helps ensure that a similar number of men are enrolled at each venue. Nevertheless, some events may be planned for less than 4 hours. For example, an event held at the meeting of a social organization may only last a couple of hours. Project staff should also plan on spending an extra 40 minutes after the scheduled end time to interview and HIV test anyone who may have been recruited at the end of the event.

5.5e Maximum number of interviews per recruitment event

The number of interviews conducted during each recruitment event will depend primarily on the level of attendance at the venue. The number of interviews conducted during an event at a high-attendance venue will usually be much greater than the number of interviews conducted at a low-attendance venue. Thus, to prevent the sample from being dominated by attendees from a few very busy venues, project sites cannot conduct more than 20 completed interviews during an event.

As described in **Chapter 4** of this manual, project sites may conduct up to 4 non-random events during the month of their main or largest gay pride festival. However, adding these extra non-random events raises the concern that too large a proportion of the sample could be recruited from venues related to a single gay pride festival. In order to prevent

sites from having a disproportionate share of the sample come from one large event, sites may conduct no more than 15 interviews per pride-related, non-random event if 4 pride-related, non-random events are scheduled in a month. For example, if a site conducts 4 separate non-random events related to their local gay pride festival, a maximum of 15 men can be interviewed at each of the 4 events (rather than the maximum of 20 interviews at all other recruitment events). On the other hand, if a site conducts 3 or fewer pride-related, non-random events, the site could still conduct the maximum of 20 interviews at each event.

5.5f Target sample size

The target sample size for each project site is to have 500 completed interviews with eligible men who reported having had sex with another man in the past 12 months. The eligibility criteria for NHBS-MSM are:

- Has not previously participated in the current cycle of NHBS-MSM.
- 18 years of age or older.
- Born male and self-identifies as male.
- Resident of the funded MSA or Division.
- Ever had oral or anal sex with another man.
- Able to complete the NHBS survey in English or Spanish.

5.5g Field supervision

Strong supervision is crucial during each recruitment event. Critical components of field supervision are knowing what occurs when men are approached for recruitment, monitoring trends in recruitment refusals and successes, and realizing each staff member's strengths and weaknesses. Other supervisory components include the following:

- Before going to a venue for a recruitment event, the field supervisor should meet with project staff and discuss specific logistical, teamwork, and recruitment strategies needed for the particular event. Always plan ahead; don't wing it.
- The field supervisor should monitor recruitment and enrollment throughout the event to determine individual as well as team performance. The field supervisor should make changes to the recruitment area or system, recruitment techniques, team operations, and appointment systems when necessary.
- The field supervisor should help recruiters troubleshoot difficulties recruiting potential participants. The field supervisor should suggest ways to improve recruitment techniques and address recruitment barriers.

- The field supervisor should observe recruiters to assess whether standard responses to recruitment barriers are being used appropriately and how well the recruiter engages potential participants. The field supervisor should continuously provide feedback to recruiters.
- Project staff should learn recruitment techniques from the field supervisor and benefit from the field supervisor's expertise.
- The field supervisor should maximize staff members' strengths. The field supervisor should identify the best recruiters by reviewing recruitment data and observing recruitment. With this information, the field supervisor should decide who works best at which venues and with which populations.
- The field supervisor should know the protocol and operations manual like "the back of their hand," and know when to follow methods exactly and when local adaptations are allowed.
- The field supervisor should build team morale by recognizing a job well done and encouraging the project staff to support one another.

5.5h Teamwork

The success of each recruitment event is dependent upon each staff member's commitment to the event as well as to each other. Things to incorporate and monitor are as follows:

- When recruitment is occurring, all project staff should remain alert to what is going on. By monitoring what occurs, other staff can lend a hand when necessary.
- Develop communication cues, like hand positioning, to alert staff members that assistance is needed with recruitment. Using the cues, develop and practice appropriate segues (e.g., timing, language, positioning) into existing recruitment methods. Understand how each recruiter approaches a potential participant and develops rapport to assess whether help is needed and when to intervene.
- Project staff should check in to discuss what is working and what is not working throughout the event. They should continually assess the successes and failures of recruitment and brainstorm ways to improve techniques and opportunities for success. Recruiters should learn from one another as well as encourage each other.
- Be alert for indications that staff members may be in danger.

5.5i Recruitment techniques

The keys to successful recruiting are effective communication, strong belief in the value of NHBS, demonstrated motivation, and high energy. How well the project staff operate as a group and how well each staff member demonstrates this positive affect should be continually assessed and improved upon. The field supervisor should work with project staff to brainstorm new ways to improve recruitment and increase participation; additional information on strategies for overcoming recruitment and participation barriers can be found in **Appendices L** and **M** of this manual. To be successful, recruiters should adopt the following methods for approaching men for recruitment:

- The recruiter should incorporate the best style and show enthusiasm for *each* man approached rather than quickly moving onto the next one. The quality of the approach is much more important than the quantity of approaches.
- The recruiter should maintain a high level of energy and salesmanship (e.g., recruiters should introduce themselves with a warm and sincere smile). Men approached and offered participation should feel a level of energy, enthusiasm, and commitment commensurate with the importance of NHBS-MSM for improving HIV prevention for MSM in the local community.
- The recruiter should spend sufficient time with each man approached. It is difficult to build rapport during a 30 to 60 second approach but it is absolutely necessary to increase enrollment. When engaging a man, the recruiter should identify and address any barriers to participation. All this takes time, but is most often worth it.
- The recruiter should approach men as soon as they have been directed. The earlier the recruiter approaches a potential participant, the more time there is to engage him and encourage him to participate in the survey.
- The recruiter should anticipate common reasons for refusal and apply classic and innovative responses to recruitment barriers. The field supervisor and project staff should brainstorm new responses to refused approaches and declined participation.
- The recruiter should apply the “5 Refusal Rule.” When there is a series of 5 refusals to accept the approach or to participate in NHBS, the project staff should stop recruitment, re-group, analyze the problem to determine its cause, and develop a plan to correct the problem. The field supervisor should also evaluate the recruiter’s performance (see **Chapter 2** of this manual). Once a solution has been developed and implemented, recruitment can resume. If no participants are enrolled within the first hour of the event, the field supervisor has the option of ending the event and moving to the scheduled alternate. However, before doing this, the field supervisor should first try all possible solutions to address the recruitment problem.

6 Counting, Recruitment, and Interviewing

6.1 Overview

Project sites will recruit and interview NHBS-MSM participants during recruitment events held at the venues scheduled on their monthly recruitment calendars. At these recruitment events, project staff will perform four main duties: 1) count venue attendees, 2) intercept attendees and recruit them to participate in NHBS-MSM, 3) screen, consent, and interview participants, and 4) provide HIV counseling and testing to those who consent and are interviewed. The field supervisor will manage the recruitment event and three or more additional project staff will be needed to perform all the required duties. One staff member will count all men attending the venue to determine the level of attendance. Other staff members will approach the men attending the venue, tell them about NHBS-MSM, and invite them to participate in the project. Men who wish to participate in NHBS-MSM will be screened for eligibility, and if eligible, consented, interviewed, tested for HIV infection, compensated for their time, given HIV prevention materials, and if necessary, provided with referrals for HIV prevention and health-care services.

6.2 Counting

Project sites must count venue attendees during all recruitment events. Since the attendance counts are used to weight the NHBS-MSM data during analysis, it is extremely important that sites obtain accurate attendance counts. In contrast to NHBS-MSM3, where counting and recruitment were linked, counting and recruitment will be completely separate processes in NHBS-MSM4. The counting methods have been changed in order to better capture the level of attendance at the venues and thereby improve the quality of the weights used during data analysis. These weights are based on the assumption that the count represents the total number of men attending the venue during a recruitment event.

6.2a Counter

During each recruitment event, a member of the project staff should serve as the counter and count venue attendees with a tally counter. The same staff member should serve as the counter for an entire recruitment event so that they can keep track of venue attendees and avoid counting them more than once. Because counting may interfere with the field supervisor's management and oversight responsibilities, the field supervisor should not take on the added role of counter unless a venue has very low attendance and the recruitment event can be easily managed. In contrast, a staff member assigned to be a recruiter or an interviewer cannot also serve as the counter during a recruitment event under any circumstances.

6.2b Where to count

The location and method of counting depends on whether or not a venue has an entrance for accessing the venue, such as a doorway, gate, or similar structural entry. Venues with an entrance are generally indoor venues, such as bars and clubs, whereas venues without an entrance tend to be outdoor venues, such as street corners or parks.

Venues with an entrance

Two counts will be obtained for recruitment events conducted at venues with an entrance: 1) the Pre-Event Count and 2) the Entry Count. For the Pre-Event Count, the counter will count all the men *inside* the venue immediately *before* the recruitment event begins; and for the Entry Count, the counter will count all the men who *enter* the venue *during* the recruitment event. Together these two counts will represent the total number of men who attended the venue during the recruitment event.

Pre-Event Count

The Pre-Event Count is the number of potentially eligible men present inside the venue when the recruitment event begins. After project staff have made their operational plans and have set up at a venue, the counter should obtain the Pre-Event Count immediately before recruitment is ready to begin. Project sites must collect a Pre-Event Count inside the venue even if they conduct recruitment, interviewing, or HIV testing outside the venue. Once the counter has obtained the Pre-Event Count, the field supervisor should promptly record it in the outcomes section of the Recruitment Event Information & Outcomes Form (**Appendix J**). If sites are unable to obtain the Pre-Event Count at a venue, they must document the reason why in this same form.



The counter must obtain all Pre-Event counts. Project sites *cannot* obtain Pre-Event counts from venue managers or venue staff, like bouncers, doormen, cashiers, or attendants.

To obtain the Pre-Event Count, the counter should start counting men at the point farthest away from the primary entrance (i.e., the entrance where most attendees enter the venue). Starting from this farthest point, the counter should count as they move across the venue toward the primary entrance, ending the count at the primary entrance. For example, the counter could begin in the back of a bar and then count men as they move toward the doorway at the front of the bar. By starting at the farthest point from the primary entrance, the counter will be able to capture any men who enter the venue during the Pre-Event Count.

If there are multiple rooms in a venue, the counter should begin counting in the room farthest away from the room with the primary entrance, and if there are multiple floors, the counter should begin counting on the floor farthest away from the floor with the primary entrance. When the rooms or floors in a venue are not arranged in a sequence

that ends with the room with the primary entrance, the counter should decide where to start counting based on the flow of men in and out of each room or on and off each floor. The counter should begin counting in the room or on the floor with the lowest flow of men, progressively move to the room or floor with the highest flow, and then end in the room with the primary entrance. If there is no clear pattern to the flow of men in the venue, the counter should decide where to start counting based on the number of men in each room or on each floor. The counter should begin counting in the room or on the floor with the smallest number of men, progressively move to the room or floor with the largest number, and then end in the room with the primary entrance. **Appendix AA** shows examples of several different venue floor plans and provides guidance for obtaining the Pre-Event Count at each.



Regardless of the number or arrangement of rooms in a venue, the counter should always count the men in the room with the primary entrance last.

In rare cases, the number of men attending a venue may be so large at the start of a recruitment event that it is difficult to obtain the Pre-Event Count. If this occurs, the counter may divide the venue into equally-sized sections, count all the men in one of the sections, and then multiply this count by the number of sections to estimate the total Pre-Event Count. For example, the counter could divide a busy dance club into quadrants, count the men in one quadrant, and then multiply this count by four to estimate the Pre-Event Count for the entire dance club. This method should only be used when the entire venue is extremely crowded and it would otherwise be impossible to obtain the Pre-Event Count. On the other hand, some venues may not become crowded until a certain time. For example, a bar becomes busy at 11 PM when the DJ starts spinning. At these venues, it may be helpful to set up for the recruitment event before the venue becomes crowded. This will make it easier to obtain the Pre-Event Count, as well as to plan and set up for the event.

Project sites that conduct recruitment, interviewing, and HIV testing outside venues may not have collaborated with venue owners or managers during prior cycles of NHBS-MSM. However, if a venue where these sites plan on conducting a recruitment event has restricted or paid access, these sites will have to establish a relationship with the owner or manager of the venue to gain permission to briefly enter the venue to collect the Pre-Event Count. If the venue owner or manager will not grant permission to enter the venue without paying a fee, sites can use NHBS funds to pay the entrance fee for one staff member to enter the venue before the start of the recruitment event to obtain the Pre-Event Count.

Entry Count

The Entry Count is the number of potentially eligible men who enter the venue during the recruitment event. This count should be obtained at the primary entrance to the venue (i.e., the entrance where most attendees enter the venue). The same counter who obtained the Pre-Event Count should obtain the Entry Count. When the project staff are ready to

begin recruitment, the counter should *clear the tally counter to zero* and start counting men who enter the venue. The counter should stop counting when the last man is approached for recruitment or the field supervisor decides to end the event. Counting should be uninterrupted between these start and end points. The counter should continue to count even when all the interviewers are busy with participants. Once the counter has finished counting, the field supervisor should record the Entry Count in the outcomes section of the Recruitment Event Information & Outcomes Form (**Appendix J**).



If the last man approached for recruitment is not eligible to participate in NHBS-MSM or does not consent to participate, the field supervisor must decide whether to restart the event or end it. If the event is restarted, the counter should resume counting men who enter the venue.

The counter may be positioned either inside the venue or outside the venue, but the counter should only count men entering the venue. Men exiting the venue should *never* be counted. Some venues may have multiple entrances. If the counter is able to monitor multiple entrances simultaneously and accurately count men entering the venue through these entrances (e.g., two entrances next to one another), the counter may do so. However, if the counter cannot monitor multiple entrances simultaneously, the counter should only count men entering at the primary entrance. When a venue has additional entrances where men were not counted, the field supervisor should document this in the outcomes section of the Recruitment Event Information & Outcomes Form.

Venues without an entrance

Just one count will be obtained for recruitment events conducted at venues that do not have an entrance. This will be the Entry Count. Since these venues do not have an entrance, the counter will count men entering the recruitment area (see **Section 6.3b** below). The methods for collecting the Entry Count at venues without an entrance are similar to those for collecting the Entry Count at venues with an entrance. When the project staff are ready to begin recruitment, the counter should start counting men who enter the recruitment area. The counter should stop counting when the last man is approached for recruitment or the field supervisor decides to end the event. Counting should be uninterrupted between these start and end points. The counter should continue to count even when all the interviewers are busy with participants. Once the counter has finished counting, the field supervisor should record the Entry Count in the outcomes section of the Recruitment Event Information & Outcomes Form (**Appendix J**). The field supervisor should also note that the Pre-Event Count was not obtained because the venue did not have an entrance.



As mentioned above for venues with an entrance, if the last man approached for recruitment is not eligible to participate in NHBS-MSM or does not consent to participate, the field supervisor must decide whether to restart the event or end it. If the event is restarted, the counter should resume counting men who enter the recruitment area.

The counter should only count men who enter or cross the recruitment area. The counter should not count men who are already in the recruitment area when counting begins. If a man is in the recruitment area when counting begins, leaves the recruitment area, and re-enters it at a later time during the recruitment event, he should then be counted.

6.2c Who to count

The counter should count all venue attendees who appear to be male and at least 18 years of age. These men are potentially eligible to participate in NHBS-MSM. If the counter is unsure of the gender or age of a venue attendee, they should give the attendee the benefit of the doubt and count them. Venue attendees should only be counted once during a recruitment event, even if they enter the venue or recruitment area multiple times.



The counter should count venue attendees who have previously participated in NHBS-MSM. These attendees should also be approached for recruitment just like any other attendee who has been counted. When a recruiter approaches an attendee, the recruiter will ask the attendee whether he previously participated in NHBS-MSM (see **Section 6.3e** below). This information will be collected by CDC and used to adjust the counts from each recruitment event for data weighting.

Some venue attendees should not be counted even if they appear eligible for NHBS-MSM and have entered the venue or recruitment area for the first time. The counter should never count venue employees. Venue employees are working at the venue and are not “attending” it. Similarly, men whose jobs require them to attend a venue, like police officers, delivery persons, and postal workers, should not be counted either.

6.3 Recruitment

During recruitment, the recruiter will briefly describe NHBS-MSM to a prospective participant and determine whether he previously participated in the survey. Venue attendees who have not previously participated in NHBS-MSM will be invited to do so.

6.3a Recruitment plan

At each recruitment event, the project staff should develop a plan for consecutively recruiting men to participate in the survey. Consecutive recruitment means that the recruiter successively approaches one man after another until one of the men agrees to participate in the survey. Recruitment continues as long as there are interviewers available. If there are no interviewers available, recruitment temporarily stops and does not resume until an interviewer becomes available.

At venues without an entrance (usually outdoor venues), the project staff *must* set up a recruitment area where men entering the area are consecutively approached for

recruitment. At venues with an entrance, project staff have more options. They could set up a recruitment area where men entering the area are consecutively approached for recruitment or they could establish an alternative plan for consecutively approaching men attending the venue. Employing an alternative recruitment plan may be helpful at venues with low attendance where there would be few men entering the recruitment area. Examples of alternative recruitment plans are consecutively approaching men seated at a bar or consecutively approaching men standing along a wall. If project staff establish an alternative recruitment plan, the recruiters must follow the prescribed recruitment plan; they cannot arbitrarily recruit any man they want.

If necessary, project staff can adjust their recruitment plan during the event to accommodate changes in the level of attendance at the venue or to address operational challenges. For example, project staff could switch from using an alternative recruitment plan at a poorly-attended venue to using a recruitment area if the level of attendance at the venue increases; or as another example, the project staff could move the recruitment area from one location in a venue to another if the flow of attendees is greater at the new location.

6.3b Recruitment area

The recruitment area is a defined space at the venue where venue attendees who enter or cross the space are consecutively approached and recruited to participate in NHBS-MSM. At the start of each recruitment event, the field supervisor should consult with the project staff and designate a space at the venue as the recruitment area. The recruitment area can be of any size and it can be situated in any location of the venue. However, because a requirement of venue-based sampling is that participants have to be venue attendees, the recruitment area must be defined to ensure that only men attending the venue are recruited to participate in the project.

Size of recruitment area

The recruitment area should be large enough to have a sufficient number of venue attendees who could be recruited to participate in NHBS-MSM. A simple rule of thumb is smaller recruitment areas for venues with a high flow of venue attendees and larger areas for venues with a low flow. During an event, the size of the recruitment area can be adjusted to match changing numbers of attendees. If the flow of venue attendees through the recruitment area is higher than initially anticipated, the size of the recruitment area can be decreased, and if the flow is lower, the size can be increased. When the flow of venue attendees is extremely high, like at a busy street corner, it may also be necessary to restrict recruitment to just those venue attendees who enter or cross the recruitment area from a single direction.

At venues without an entrance (i.e., venues where attendees are counted in the recruitment area), project sites should also consider how the size of the recruitment area impacts counting. The recruitment area should not be so large that the counter becomes overwhelmed and cannot accurately count.

Location of recruitment area

The field supervisor should select a location for the recruitment area based on the logistics of operations at the recruitment event. The location should allow the field supervisor (or other staff member) to effectively direct recruitment and it should also be convenient to the spaces used to interview participants and provide HIV tests.

At venues with an entrance (i.e., venues where attendees are **not** counted in the recruitment area), the recruitment area can be located either inside the venue or outside. Usually, the recruitment area is located inside the venue when interviewing and HIV testing occur inside and it is located outside the venue when interviewing and HIV testing occur outside. Yet, this does not always have to be the case. For example, venue attendees could be recruited inside the venue and then brought outside for interviewing and HIV testing. During previous NHBS-MSM cycles, some project sites that interview and HIV test outside found that recruiting inside increased participation rates.

6.3c Intercept

The process of approaching a venue attendee and attempting to recruit him to participate in NHBS-MSM is called the “intercept.” The field supervisor or another staff member will direct a recruiter to intercept a particular man. The field supervisor or another staff member always decides who the recruiter should intercept; the recruiter should **never** decide who to intercept on their own. The counter can direct recruiters at venues without an entrance (i.e., venues where attendees are counted in the recruitment area), but at venues with an entrance (i.e., venues where attendees are counted entering the venue), the counter can only direct recruiters when the recruitment area is the primary entrance to the venue or is near the primary entrance.



Self-referrals should not be recruited. Self-referrals are people who purposefully try to enroll in NHBS-MSM by approaching the recruiter or entering the recruitment area. Self-referrals may learn about the project from another venue attendee or they may be attracted by the activity generated by recruitment event operations.

During most recruitment events when there are no recruiters or interviewers free, recruitment should stop and venue attendees should not be intercepted. Recruitment should not resume until both a recruiter and an interviewer become free again. Yet, during recruitment events at venues where the flow of attendees is extremely slow, a recruiter may intercept a venue attendee when an interviewer is not free so that there is a prospective participant available when the interviewer does become free. This helps to avoid extended periods when the interviewers are not working. If project sites choose to have prospective participants wait to be interviewed, they should not have them wait for more than 5 or 10 minutes. Furthermore, project sites should have no more than one prospective participant waiting per interviewer (i.e., if one interviewer is working at the recruitment event, project sites can have one prospective participant waiting to be

interviewed; if two interviewers are working at the recruitment event, project sites can have two prospective participants waiting; and so on).

6.3d Recruiter

As mentioned previously in **Chapter 2** of this manual, project sites may choose to have interviewers serve as recruiters or they may choose to have one staff member serve solely as a recruiter. When project sites assign one staff member to be the recruiter, they should pick someone who is outgoing and affable. Sometimes it is also helpful to match the demographic characteristics of the recruiter, like their age or race/ethnicity, with the characteristics of the venue's attendees. For example, project sites could use a young recruiter at a venue attended mostly by young men or an African-American recruiter at a venue attended predominantly by African-Americans. Usually, recruiters should wear a shirt with the project logo or have a clearly visible project ID so that venue attendees immediately recognize that the recruiter is a representative of the local NHBS-MSM project. Yet, if sites believe this will impede recruitment, the recruiter may dress to blend in with the venue attendees.

6.3e Intercept methods

Once directed by the field supervisor or another staff member, recruiters should approach venue attendees in a friendly and confident manner. They should always approach attendees from the front or side so that they do not startle the attendee. Some recruiters find it helpful to extend their hand in greeting; this is a welcoming gesture and often causes the prospective participant to reflexively stop to shake hands. If a venue attendee does not stop, the recruiter should walk with him to continue the intercept. During all intercepts, recruiters should begin with a verbal greeting and a brief statement of purpose:

Hi, I work for (project name or sponsoring agency's name). We're conducting an important community health survey today/tonight.

Some recruiters like to introduce themselves with their first names (e.g., *Hi, I'm Lance and I work for...*) because they feel it establishes a better rapport with the potential participant, whereas other recruiters avoid using their names because they want to maintain professional boundaries. If a venue attendee is engaged in another activity, such as talking to friends or listening to an iPod, the recruiter should first excuse themselves when they intercept the attendee (*Excuse me...*). Furthermore, the introduction should avoid any questions that would allow the prospective participant to readily walk away by answering a quick "no." For example:

Hi, can I ask you some questions?

Hi, do you mind answering some questions?

Immediately after the recruiter greets the venue attendee, they should begin asking the previous participation question on the Intercept Form (**Section 6.3f** below):

During 2014, did you already complete at least part of the health survey

that (project name or sponsoring agency's name) is conducting? It could have been here or at another location.

To differentiate NHBS-MSM from other local surveys or outreach activities, the recruiter should show the venue attendee the project logo and explain that the survey was conducted with a portable computer. If the attendee already participated in the current cycle of NHBS-MSM (including having completed part of the survey), the recruiter should thank him for helping with the project and end the intercept. If the attendee has not previously participated, the recruiter should invite him to take part in the project. The recruiter should briefly explain NHBS-MSM to the prospective participant, describing its purpose, interview procedures, privacy protections, and incentives. For example:

- *Survey is designed to help improve health and HIV prevention services for men in the community.*
- *Survey asks questions about your health and risk behaviors.*
- *Survey is anonymous, which means you won't have to give your name.*
- *Survey will be conducted in a private area to protect your confidentiality.*
- *An optional HIV test is offered with the survey.*
- *You will be compensated 25 dollars for your time taking the survey, and if you agree to receive an HIV test, you will be compensated an additional 25 dollars.*

To help the recruiters and to ensure standardization during intercepts, project sites may want to outline these points in a recruiter script or on a flashcard. The script or flashcard could also contain a greeting and the previous participation question.

When inviting the intercepted attendee to participate in the survey, the recruiter should be up-beat and encouraging:

It would be great if you could help the community by participating in our survey.

A positive request with an appeal to altruism makes it more difficult for the intercepted attendee to decline participation than with unmotivated invitations like:

You can participate if you want.

If you're interested, you can participate.

If a venue attendee declines to participate in NHBS-MSM, the recruiter should encourage him to do so, but the recruiter should never coerce him. A recruiter will be much more likely to be successful encouraging participation if he determines why the venue attendee does not want to participate and then addresses the attendee's specific concerns. To assist recruiters in this effort, **Appendices L and M** contain strategies for overcoming

some common recruitment and participation barriers that project sites have encountered during previous NHBS-MSM cycles. Individuals always have the right to decline participation in NHBS-MSM and efforts to encourage them to participate must respect this right.



Men who decline to participate in NHBS-MSM when they are intercepted **cannot** return at a later time during the recruitment event and ask to participate. Their initial refusal cannot be reversed.

If a venue attendee agrees to participate in NHBS-MSM, the recruiter should escort him to the field supervisor to obtain a Survey ID and to be assigned an interviewer if the recruiter does not interview participants. It is also useful to introduce the prospective participant to other project staff so that they can identify him if he is a previous participant or will be able to recognize him if he tries to participate again.



Recruiters should **never** pre-screen intercepted men for any of the NHBS-MSM eligibility criteria (age, MSA residence, male gender, MSM behavior, or ability to complete the survey). Screening should only be performed by an interviewer using the eligibility screener programmed in the portable computer so that eligibility statistics and data weights can be calculated.

6.3f Intercept Form

Recruiters should record all information collected during an intercept on the Intercept Form. A copy of this form and detailed instructions for completing it are included in **Appendix N**. To ensure that recruitment data are accurate, recruiters must make an entry on the Intercept Form for every venue attendee they attempt to intercept, even if the attendee ignores them and does not stop. In addition, each recruiter should have their own Intercept Form when recruiting. After a recruitment event ends, data from all the Intercept Forms used during the event should be tabulated and entered in the VDTS Program.

Project sites may customize the Intercept Form to meet their own needs, but if they do, they must include all the data elements collected on the model form provided by CDC, with the exception of the optional post-event appointments (see **Section 6.3h** below). Sites may also want to list the previous participation question at the top of the form if they have not included this question in a recruiter script or on a flashcard.

6.3g At-event appointments

Ordinarily, a venue attendee is interviewed immediately after he is intercepted and agrees to participate in the project. Occasionally, however, a venue attendee would like to participate, but cannot do so until a later time **during** the recruitment event. In these cases, projects sites have the option of scheduling a time for the prospective participant to return to be interviewed. This is referred to as an at-event appointment. These

appointments are informal and can be tracked using the “Comments” field on the Intercept Form. In the “Comments” field, sites should indicate the time that the prospective participant will return for screening and they may want to note the prospective participant’s characteristics or manner of dress to help identify him. If the prospective participant does not return for his appointment, sites must update the prospective participant’s data on the Intercept Form. The response in the “Agreed to Screening” field should be changed from “Y” (yes) to “N” (no).

Alternatively, if project sites plan on using at-event appointments frequently during a recruitment event, they could keep track of a prospective participant by including a code number or letter in the “Comments” field on the Intercept Form and giving the prospective participant an appointment card with the corresponding code. The card should list the project name and have fields to record the date of the event, the time that the prospective participant is supposed to return for his interview, and the code assigned to him. On the card, sites should also include any other information that will help them manage and track appointments.

Project sites that offer at-event appointments **cannot** pre-screen prospective participants for NHBS-MSM eligibility. Prospective participants can only be screened for eligibility when they return for their appointments. Sites must therefore make it clear to men scheduled for appointments that their participation in NHBS-MSM is not guaranteed.

6.3h Post-event appointments

In some rare circumstances, a venue attendee can be interviewed **after** a recruitment event has been completed (either at a later time or date). This is referred to as a post-event appointment (PEA). The *NHBS Round 4 Model Surveillance Protocol* does not require project sites to offer PEAs; project sites should decide on their own whether or not to offer them. If project sites do choose to offer PEAs, they should only use them when absolutely necessary. Project sites should conduct the vast majority of their interviews during recruitment events.

PEAs are most commonly used at venues where the flow of attendees starts out high, but then slows or ceases, and at venues where attendees may not have sufficient time to participate in NHBS-MSM. For example, at the meeting of a social organization, attendees might all arrive at the venue around the time the meeting starts. If a recruitment event were conducted at this meeting, recruiters would only have a very brief period during which they could recruit prospective participants. Moreover, venue attendees who agreed to participate in the project might not have enough time to complete the survey before the meeting begins. Accordingly, PEAs could be used to interview prospective participants on another day.

As with at-event appointments, project sites that offer PEAs **cannot** pre-screen prospective participants for NHBS-MSM eligibility. Prospective participants can only be screened for eligibility when they return for their appointments. Sites must therefore

make it clear to men scheduled for PEAs that their participation in NHBS-MSM is not guaranteed.

Scheduling post-event appointments

When scheduling a PEA, the field supervisor or the recruiter should give the prospective participant an appointment card that lists the following information:

- Date of the appointment
- Time of the appointment
- Location of the project office where interviews are conducted
- Project phone number in case the prospective participant needs to change his appointment or needs directions to the project office
- *If the project site plans on assigning Survey ID numbers for appointments at the time of recruitment:* Survey ID number
- Venue Code of the venue where the prospective participant was recruited
- Event Number of the recruitment event during which the prospective participant was recruited
- Date of the recruitment event when the prospective participant was recruited

A model appointment card is shown in **Appendix O** that project sites can modify to meet their local needs.

To keep track of their PEAs, project sites should maintain a log that contains the following information on each appointment:

- Event date
- Event Number
- Venue Code
- *If the project site plans on assigning Survey ID for appointments at the time of recruitment:* Survey ID
- Date of the appointment
- Time of the appointment
- *If appointments will be conducted at more than one location:* Location where the interview is scheduled
- An indication whether the appointment was kept
- Comments

Table 6.1 below shows an example of an appointment log. Project sites may customize their logs and include any additional information needed to support their operations. However, they cannot collect any personal identifiers or contact information from prospective participants to provide appointment reminders. This restriction is necessary to protect the anonymity of prospective participants.

Table 6.1 – Appointment Log

Event Date	Event No.	Venue Code	Survey ID	Appointment			Returned for Appt.	Comments
				Date	Time	Location		
6/4	1	B003	1009	6/9	10:00 AM	Field Office	Yes	
6/7	3	O002	1025	6/8	9:00 AM	Field Office	No	
6/7	3	O002	1029	6/11	2:00 PM	Health Dept.	Yes	

The field supervisor or the recruiter should complete the required entry fields in the log at the time the PEA is scheduled. They may want to record the information in pencil so that changes can be readily made if a PEA needs to be rescheduled. Project sites should use the information collected on the appointment log to fill in the PEA field listed on the event outcomes section of the VDTS Program.

Project sites should conduct PEAs at a local NHBS-MSM project office, such as their field office, the health department, or the office of a local collaborator. If absolutely necessary, project sites may conduct PEAs in the field before or after a recruitment event, but they should *never* conduct one during an event. When a participant is interviewed via a PEA, at least 3 staff members must be present, including the field supervisor or another senior manager.

6.4 Interviewing

This section provides a brief overview of the interview process and the activities that should be completed by the interviewer. All interviewers and project managers should also review the *NHBS-MSM4 Interviewer Guide* for complete information on conducting NHBS interviews. The NHBS interview is composed of three main sections: the eligibility screener, the consent, and the survey. The interview is conducted using a portable computer and the entire process takes approximately 1 hour to complete. All interviews must be conducted in a quiet area that affords privacy and protects the participant’s confidentiality. Other individuals should not be able to hear the interviewer’s questions nor the participant’s responses.

6.4a Screening for eligibility

The eligibility screener is designed to ensure that participants meet the general and MSM cycle-specific NHBS eligibility criteria. To start the eligibility screener, the interviewer should open the survey file on the portable computer and enter their interviewer ID, the survey ID, the venue code, and the event number. The portable computer will then automatically determine whether the prospective participant is eligible to participate based on the criteria listed below.

General NHBS eligibility criteria:

- Is 18 years of age or older.
- Did not complete any part of the survey (including the eligibility screener) during the current cycle of NHBS-MSM.
- Resident of the funded MSA or Division.
- Able to complete the NHBS survey in English or Spanish.

MSM cycle-specific eligibility criteria:

- Born male and self-identifies as male.
- Ever had oral or anal sex with another man.

Men must meet all the eligibility criteria to be able to participate in the survey. Men who do not meet all the eligibility criteria will be told “the computer has not selected you to participate in the health survey.” If a prospective participant is not eligible, the interviewer should end the interview and thank him for his time.

Previous participants

Some men who already participated in NHBS-MSM may try to take the survey again by denying previous participation when asked about it during the intercept and during eligibility screening. When project staff believe that a man is a previous participant, they should report their suspicions to the field supervisor. If the field supervisor concurs, the field supervisor should tell the man’s interviewer to make him ineligible if he denies previous participation during eligibility screening. If the man responds “no” when asked “During 2014, did you already complete at least part of the health survey that <project name> is conducting? It could have been here or at another location,” the interviewer should select the “Known previous participant” response option so that the portable computer will automatically make the previous participant ineligible.



Only the field supervisor, in consultation with project staff, can make the final determination that a man is a previous participant and should be made ineligible; project staff should not decide this on their own.

Participants thought to be too young (under 18 years)

Some young men may try to participate in NHBS-MSM by reporting a date of birth that is substantially earlier than what would be expected based on their appearance. When an interviewer believes that a man is younger than his reported age, the interviewer should report their suspicions to the field supervisor. If the field supervisor concurs, the field supervisor should tell the man's interviewer to make him ineligible by selecting "No" in the portable computer when asked "Is this person alert and able to complete the Interview in English or Spanish?" The portable computer will instruct the interviewer to specify why the person was not able to complete the survey, and the interviewer should select "Thought to be too young." The portable computer will automatically make the person ineligible.



Only the field supervisor, in consultation with project staff, can make the final determination that a man is younger than 18 and should be made ineligible; project staff should not decide this on their own.

Intoxicated participants

During screening, if an interviewer determines that a man is too intoxicated with alcohol or drugs to competently consent to participate in NHBS or to complete the survey, the interviewer should check "No" in the portable computer when asked, "Is this person alert and able to complete the health survey in English or Spanish?" After checking "No," the portable computer will instruct the interviewer to specify why the person was not able to complete the survey, and the interviewer should check "Not alert." As with a previous participant, the portable computer will automatically make the man ineligible. Before closing the survey file, the interviewer should also add a note to the final comment field that the person was "too intoxicated to consent and complete the survey."

6.4b Obtaining informed consent

The interviewer should read the consent form to each eligible man and answer any questions he may have. Depending on local institutional review board (IRB) requirements, project sites may choose to have the interviewer paraphrase the information in the consent form instead of reading it verbatim. If the local IRB requires informed consent to be obtained before a potential participant is screened for eligibility, project sites must do so. Consent to participate in NHBS-MSM should be obtained orally and recorded in the portable computer (some local IRBs may also require project sites to maintain written documentation of consent). Men can consent to participate in either 1) the NHBS-MSM survey or 2) the NHBS-MSM survey and an HIV test. If applicable, men can also consent to other laboratory tests offered locally or to have their blood stored for future tests.



It is critically important for interviewers to accurately record consent in the portable computer. If a participant's consent is not recorded in the portable computer, the participant's data will be deemed void and cannot be used for NHBS, even if the participant verbally consented.

Participants who change their mind about HIV testing

Participants who initially decline HIV testing will have another opportunity to consent to testing at the end of the core questionnaire. Before the core questionnaire closes out, participants who did not initially consent to HIV testing will be asked, “Did you want the HIV test that is part of today’s survey?” This will give the participant a second chance to consent to HIV testing if he initially declined testing but then changed his mind during the survey.

6.4c NHBS-MSM survey

The interviewer should use a portable computer to administer the NHBS-MSM survey to eligible men who consent to participate. The NHBS-MSM survey will take approximately 30 to 40 minutes to conduct and will consist of the core questionnaire and, if applicable, local questions developed by the project site. To minimize the burden on participants, any local questions should not take more than 10 minutes to administer.

Interviewing skills

Interviewers and project managers should read the *NHBS-MSM4 Interviewer Guide* for explanations of the core survey questions and guidance on interviewing. Major areas of focus include:

- **Reading instructions, questions, and definitions as written:** To help ensure standard data collection among interviewers and across project sites, interviewers must read survey instructions, questions, and definitions completely as written. If a participant does not understand a term or phrase used in the survey, the interviewer should first repeat the item verbatim. If the participant still does not understand, the interviewer should allow the participant to interpret the term or phrase himself (e.g., “whatever it means to you”). The only exceptions are for definitions of sexual behaviors and drug use. If, after repeating a sexual behavior or drug use term, the participant still does not understand, the interviewer may use colloquial language or local terminology.
- **Using flashcards:** Flashcards help participants understand the intent of a question or its responses, thereby facilitating the interview and improving data quality. Interviewers should always use flashcards when indicated by a question and they should read the responses on the cards in case a participant has a low literacy level.
- **Probing:** Interviewers should probe with additional questions whenever a participant cannot remember the answer to a question, gives an unclear response, or gives a response that cannot be coded with one of the available response options.

Core questionnaire

The core questionnaire consists of several sections: demographics, sexual behavior, alcohol and drug use, HIV testing experiences, health conditions, and exposure to prevention services. Participants are asked all sections of the questionnaire.

At the end of the core questionnaire (and before the start of the local questions), the interviewer will be instructed to record his confidence in the validity of the participant's responses using the following scale: "confident," "some doubts," or "not confident at all." Validity refers to whether the participant understood the questions and answered them truthfully and accurately. If an interviewer records that he is "not confident at all" in a participant's responses, then the participant's interview data will not be included in the national NHBS dataset.

Additional guidance and explanations of the core survey questions are contained in the *NHBS-MSM4 Interviewer Guide*.

Ending an interview early

If a participant does not want to continue the survey, is too intoxicated to continue, or is behaving inappropriately, the interviewer should end the interview. For documentation, the interviewer should record the reason for stopping the interview in the data edits section of the Participant Tracking Form (**Appendix K**). When entering this information into the Data Error Log on the NHBS Data Coordinating Center (DCC) data portal, the data manager should instruct the DCC to add the reason for stopping the interview to the "Comments" field of the participant's survey record (variable= INTTXT).

6.5 HIV Counseling, Testing, and Referral

This section summarizes the process of conducting HIV counseling, testing, and referral to care as part of NHBS. More detailed guidance on this process is provided in **Chapter 8** of this manual.

6.5a Counseling and testing

After the interview is completed, participants who have consented to HIV testing should receive counseling and an HIV test. Project sites must conduct all HIV counseling and testing in accordance with the *NHBS Round 4 Model Surveillance Protocol* and their local testing policies. Most importantly, a participant **cannot** receive HIV counseling or his test result before he finishes the core questionnaire. Some project sites are not required to provide pre-test counseling before they collect a specimen for HIV testing. If these sites adhere to the prohibition on counseling and providing results before the end of the core questionnaire, they may collect a specimen for rapid HIV testing prior to starting the survey. This will allow these sites to run a participant's rapid HIV test while he is

being interviewed. When the participant completes his interview, he would then receive HIV counseling and his rapid test result.



Participants who do not consent to an NHBS interview **cannot** receive HIV tests through NHBS. Project sites should refer these individuals to HIV counseling and testing agencies in their local communities.

6.5b Referrals to care and services

All participants who test positive for HIV should be referred to appropriate medical care and HIV case management services at the time they receive their test results (see **Section 8.7b** of this manual). Project sites conducting rapid testing should make referrals to care for participants with preliminary positive results as part of their post-test counseling.

6.6 Participant Compensation

Participants who complete the entire NHBS-MSM survey should be compensated for their time and effort. Those who also test for HIV should receive additional compensation. The *NHBS Round 4 Model Surveillance Protocol* recommends a payment of \$25 cash for participants who just complete the survey and \$50 cash for those who complete the survey and take an HIV test. Nevertheless, local project sites are free to adjust these levels of compensation based on standards in their local communities. Furthermore, if project sites are prohibited from providing cash payments to participants, they may provide an alternative form of remuneration like a gift card or a gift check. Any alternative form of remuneration must protect participant anonymity (e.g., participant names cannot be collected or recorded) and it must have an intrinsic value to members of the community (e.g., gift cards should only be from stores that are locally accessible and well-regarded).

When a prospective participant who travels to the project office for a PEA is found to be ineligible, project sites may wish to provide a small thank you gift, such as bus or subway fare. In addition, project sites that have local funds available (i.e., funds that do not come from the NHBS cooperative agreement) may compensate participants who return for their HIV test results. Project sites should specify the amount of compensation in their consent form and they must obtain approval from both their local IRB and their CDC project officer.

6.7 HIV Prevention Materials and Service Referrals

Providing participants with prevention materials and referrals is an important component of NHBS; it facilitates rapport with participants and trust with local communities. Sites should provide participants with prevention materials such as informational pamphlets on HIV, STD, and hepatitis prevention, as well as condoms and lubricants. Participants in

need of health care or social services should be referred to the appropriate providers in the community.

Based on their formative research, project sites should identify those health care and social service providers most commonly used by MSM in their community. Sites should maintain a list of the names of these providers and their contact information so that they can readily make any necessary referrals. This list should include HIV and STD clinics, agencies that offer free HIV tests, health clinics, mental health service providers, substance abuse treatment centers, and organizations that serve gay and bisexual men.

7.1 Overview

The purpose of this chapter is to provide guidance on closeout procedures at the end of a recruitment event. The first part of the chapter describes closeout tasks that should be completed at the venue, while the second part of the chapter describes tasks that should be completed at the project office. Project sites can use the Recruitment Event Checklist (**Appendix H**) to help manage their closeout activities.

7.2 Closeout at the Venue

Activities for closing out the recruitment event at the venue include holding a post-event debriefing, recording notes summarizing the event, and collecting and reviewing all the forms and logs used during the event.

7.2a Post-event debriefing

At the end of each recruitment event, it is useful to hold a post-event debriefing with project staff to discuss how well the recruitment event went and to identify any problems that may have occurred. This debriefing can take place in a meeting with all project staff or in one-on-one conversations with individual staff members. Some topics for discussion may include:

- In general, how well did the recruitment event go?
- Were there any venue-related issues that affected project operations?
- Were there any barriers to recruitment or participation? What strategies were successful for overcoming these barriers?
- Were there any unusual events during the event (e.g., a participant ended the survey early or a participant initially consented to an HIV test but changed his mind)?
- Were there any problems with the portable computers?
- Were there any errors with the survey data?
- *For project sites conducting rapid testing*, were there any men newly diagnosed with HIV? Were their results returned? Were they anonymously referred to care?
- Were there any problems with HIV test specimen collection or test kits?

The information collected through these debriefings can help project sites more effectively plan and conduct future recruitment events. The field supervisor should record the findings from the debriefing in the Recruitment Event Information & Outcomes Form (**Appendix J**) and in any other relevant forms, such as the HIV Testing Log or the Participant Tracking Form.

7.2b Recruitment event notes

The field supervisor should also record notes summarizing the recruitment event in the Recruitment Event Information & Outcomes Form. The main purpose of these notes is to describe the areas in the venue where project activities were conducted, to document any barriers to operations at the venue, to identify changes in venue attendance or in the demographic characteristics of venue attendees, to collect information on new venues and day-time periods for updating the monthly sampling frame, and if applicable, to explain why the event was moved to an alternate venue. Much of the information collected in the recruitment event notes will be specific to the venue where the event was conducted. Project sites can therefore use this information to better manage operations the next time they conduct a recruitment event at that venue or to assess the utility of continuing to include the venue on their sampling frames. Sites should consider collecting the following information:

- Description of the counting, recruitment, interviewing, and testing areas at the venue.
- Barriers to project operations at the venue and strategies for overcoming these barriers.
- Significant changes in the level of attendance at the venue or in the demographic characteristics of venue attendees since the formative research report was prepared or since the venue was last visited.
- New venues or day-time periods that were suggested during the recruitment event.
- *If applicable*, reason(s) for removing the venue from the sampling frame.
- *If applicable*, reason(s) for modifying the day-time periods for the venue.
- *If applicable*, reason(s) for moving the recruitment event to an alternate venue.
- *If applicable*, reason(s) for not obtaining the pre-event count.

7.2c Forms and logs

At the end of the recruitment event, the field supervisor should collect all forms and logs used by the project staff, review them for accuracy, and make any necessary corrections. Tasks to be performed on the principal forms and logs are described below.

Intercept Forms

The field supervisor should collect the completed Intercept Forms (**Appendix N**) from each recruiter and review the forms for completeness and the proper coding of participant responses. As described in **Appendix N**, the field supervisor should also calculate the column sub-totals for each variable and record them at the bottom of each form. If the project site is using post-event appointments (PEAs), the field supervisor should cross-check the Intercept Forms with the Appointment Log to ensure that all PEAs have been scheduled.

Participant Tracking Forms

The field supervisor should gather any outstanding Participant Tracking Forms (**Appendix K**) from the interviewers or HIV test counselors. The field supervisor should then check all the forms to verify that a response has been recorded for each question. If notes or data edits are recorded on the form, the field supervisor should review them with the interviewer or HIV test counselor to ensure that the issue or problem is clearly communicated without ambiguity. The field supervisor should also check to see if the same data errors are occurring repeatedly, which may indicate the need for additional staff training.

HIV Testing Log

The field supervisor should collect all hardcopy HIV Testing Logs (**Appendix L** of the *NHBS Round 4 Model Surveillance Protocol*) from the HIV test counselors and ask if there were any problems with the test specimens or with specimen collection. Any problems should be noted on the log. The field supervisor should review the logs to make sure that a specimen was collected for each entry on the log and conversely, that an entry was made on the log for each specimen collected. For each standard or confirmatory HIV test conducted, the field supervisor should compare the Lab ID labeled on the test specimen to the Lab ID recorded on the HIV Testing Log to confirm that they are the same. For each rapid HIV test conducted, the field supervisor should make sure that there is either a negative test result or a preliminary positive test result documented on the log; and for each of the preliminary positive rapid tests, that a confirmatory specimen was collected. Lastly, the field supervisor should check the Appointment Log to verify that appointments have been scheduled for returning HIV test results.

Staff evaluation forms

If any project staff were evaluated during the recruitment event (**Appendices B thru G**), the field supervisor should review the completed evaluation forms with those staff members. If any project staff were scheduled for evaluations that did not occur, the field supervisor should note this on the Recruitment Event Information & Outcomes Form so that the evaluations can be rescheduled for the next recruitment event.

7.3 Closeout at the Project Office

Activities for closing out the recruitment event at the project office include handling HIV test specimens, managing data, and entering data in the NHBS Data Coordinating Center (DCC) Data Portal.

7.3a HIV test specimens

The field supervisor should ensure that all HIV test specimens are transported and stored according to the specifications in the package insert for the test and in a manner that preserves the integrity of the specimens. As soon as possible after the recruitment event, the field supervisor should complete the Specimen Transport/Shipping Log (**Appendix U**) and transport or ship the HIV test specimens to the local laboratory using the procedures agreed upon with the laboratory. Dried blood spot (DBS) cards must be allowed to dry before they are packaged for shipping, but the drying time *cannot* exceed 24 hours. Within 24 hours, the DBS cards must be packaged with desiccants and a humidity indicator as described in **Section 8.5b** of this manual.

7.3b Data management

As soon after the recruitment event as possible, the data manager or other designated staff member should upload the NHBS core interview files and the local survey files from the portable computers into their respective QDS™ Warehouses. After uploading the data, the portable computers should be charged and locked up in the project office. If the portable computers are not returned to the project office after the recruitment event, they should be charged and stored in compliance with the project site's data security and confidentiality guidelines (see **Section 5.5a** of this manual). When forms and logs that contain participant data are not being used by project staff, they must be stored in a locked filing cabinet in a secure area of the project office.

7.3c NHBS Data Coordinating Center Data Portal

The data manager or other designated staff member should enter the recruitment event data into the DCC Data Portal on a daily basis or as soon after the recruitment event as possible. Any data edits recorded on the Participant Tracking Forms should be entered into the online Data Error Log on the portal; and data from the hardcopy HIV Testing Log and the self-reported HIV-positive (SRP) data from the Participant Tracking Forms should be entered into the online HIV Test Results Log on the portal. In addition, the column sub-totals from each Intercept Form and the recruitment event outcomes information from the Recruitment Event Information & Outcomes Form should be entered into the Outcomes Section of the VDTS Program on the portal.

8.1 Overview

This chapter provides guidelines for conducting HIV and other tests as part of NHBS. Before data collection can begin, project sites must document procedures for testing, returning results, and making referrals to care in the Operations Checklist (**Appendix A**). Any locally-developed testing forms or logs (e.g., lab slips and risk assessment forms) should be included in the checklist as well. Project sites are also responsible for following local laws, guidelines, or requirements for testing and counseling.

8.2 Testing

In all project sites, individuals who agree to participate in NHBS will be offered HIV testing. Project sites may also offer other testing, such as hepatitis, if funds are available. Testing is voluntary—those who choose to participate in the survey are not required to provide a specimen for testing. Project sites are required to offer HIV testing as part of NHBS. If HIV test kits or specimen collection devices are unavailable, data collection *must* be suspended until these items become available.

All rapid and laboratory-based testing specimens must be collected, tested, and stored anonymously. Project sites unable to perform anonymous HIV testing will not be allowed to participate in NHBS. Similarly, if the state or local health department does not allow anonymous testing for a particular infectious disease, a test for that disease cannot be offered as part of NHBS. Test results and referrals to HIV care must also be given anonymously. Participants cannot be asked to provide a name or any other personal identifiers to receive their test results or a referral to care. Prior to the start of data collection, project sites must develop procedures for making anonymous referrals to care for participants who are newly diagnosed with HIV or any other conditions for which they received testing. Lastly, because testing in NHBS is anonymous, NHBS test results cannot be used for HIV case reporting or any other surveillance system.

Information about NHBS methods, including the survey and testing, is provided to individuals during the consent process (see **Section 6.4b** of this manual). Consent for participation in each activity must be obtained separately and recorded in the portable computer. If consent is not recorded in the portable computer for a test that was conducted, that test result will not be included in the NHBS data set.



Project staff are not able to change the consent variable in the Data Error Log on the NHBS Data Coordinating Center (DCC) data portal. Consent for HIV and other testing can only be recorded in the portable computer.

Project sites should work closely with the staff of their designated laboratory to identify any special requirements for specimen type, storage, processing, transport, and shipping to ensure good specimen quality and the timely return of test results. Sites should also contact their laboratory to find out what types and trade names of tests will be performed on each type of specimen and document this information in the Operations Checklist. Sites will need this information for entering HIV test results into the HIV Test Results Log on the DCC data portal.

8.2a HIV testing

The purpose of HIV testing is to determine the prevalence of HIV infection among NHBS participants and to describe behavioral risk factors associated with infection. Even participants who report that they have previously been diagnosed with HIV should be offered an HIV test. HIV counseling should only be conducted after the survey is completed so as not to bias participant responses. Project sites can choose from a number of HIV testing options, but they must select their testing method, including the test(s) and specimen type(s), before data collection begins. Since data from previous NHBS cycles suggest that blood-based HIV tests have greater sensitivity than oral tests, blood specimens should be used for HIV testing in NHBS whenever possible. The lower sensitivity of oral tests could result in missed infections. Moreover, assays that can detect early HIV infection (e.g., 4th generation immunoassays, NAAT) only use blood specimens.

Participants who initially decline HIV testing will have another opportunity to consent to testing at the end of the core questionnaire. Before the core questionnaire closes, participants who did not initially consent to HIV testing will be asked, “Did you want the HIV test that is part of today’s survey?” This will give the participant a second chance to consent to HIV testing if he changed his mind during the survey. It will also allow the interviewer to make a correction if he erroneously recorded that the participant declined testing. The HIV testing consent at the end of the core questionnaire is the last opportunity for the participant to provide consent for an HIV test. If the participant decides that he wants an HIV test after the core questionnaire has been completed, project sites may still perform the test, but it will not be considered an NHBS test. Therefore, the HIV test result will not be included in the NHBS data set and the participant should not receive an incentive for the test.

Rapid HIV testing

Project sites are encouraged to conduct rapid testing if possible. Experience with previous NHBS cycles has shown that many participants do not return for their laboratory-based test results since these are usually not available for one to two weeks. Although a reactive rapid test result is considered preliminary (i.e., a specimen must be collected for confirmatory testing), participants with preliminary positive test results can be immediately referred to care (see **Section 8.8** below). In addition, receipt of a preliminary positive test result may increase a person’s likelihood of seeking additional testing or care, even if he does not return for his final NHBS test result. Project sites

offering rapid HIV testing must be prepared to collect confirmatory test specimens from participants with preliminary positive test results.

To perform rapid testing, a project site must first obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver:

<http://www.cms.gov/CLIA/downloads/HowObtainCertificateofWaiver.pdf>.

Alternatively, project sites may operate under an existing waiver already held by their organization. There are five rapid tests that are currently CLIA-waived for use in field settings by non-laboratory staff: Clearview COMPLETE, Clearview STAT-PAK, INSTI, OraQuick, and Uni-Gold. The package insert for each of the five rapid tests contains specific instructions for conducting that test as well as running test controls. The insert lists the materials included in the test kit, required materials that are not included in the kit, specimen collection procedures, and testing requirements. Prior to the start of HIV testing, project staff who are administering or overseeing tests must carefully read and understand the package insert, and a copy of the insert should always be available at each recruitment event for reference. Rapid testing must be conducted in an appropriate environment with respect to temperature and lighting. These requirements can be found in the package insert and should be adhered to at all times. Rapid testing should also be conducted in an area with adequate work space.



All rapid test kits should be stored in accordance with the package insert provided with the kits, and project staff should always check the date on the kits before using them to ensure that they have not expired.

Before specimen collection begins, the participant's survey ID number should be recorded on the rapid test device. Project staff for sites conducting rapid testing on oral fluid specimens should explain to participants how to appropriately swab their mouths and they should monitor the participants to assure that the specimens are collected appropriately. Although food or drink consumption has *not* been found to interfere with the oral test, food particles (e.g., gum, candy) can prevent the test collection device from being placed flat against the gums for appropriate oral fluid collection. Therefore, if a participant has recently eaten something or is chewing gum, project staff should have him rinse his mouth to remove the food particles or have him throw out his gum before oral specimen collection. For project sites conducting rapid testing on whole blood specimens collected by fingerstick, some helpful hints for fingerstick blood collection can be found in **Section 8.4b** (below).

During rapid test development, the test face of the device should not be visible to the participant. This is best achieved by conducting testing in an area that is separate from the interview space. If testing is conducted in the same space as the interview, the test face should be turned away from the participant or it should be covered; otherwise, having the test face visible to the participant may cause anxiety or misinterpretation of the test result. Shielding the test face from the participants is particularly important for project sites that collect the specimen before beginning the survey and run the test in the

same room as the interview. In these cases, having the test face visible to the participant could also disrupt the interview. Because counseling cannot be conducted until the core questionnaire is completed, test results cannot be disclosed to participants until the end of this section of the survey.



Rapid and confirmatory counseling and testing should be conducted in a private area to maintain the participant's confidentiality and to avoid identifying those who are receiving confirmatory testing for a preliminary positive test result. For example, operations could be set up so that all participants receive incentives and confirmatory testing in the same private area.

Quality assurance for rapid HIV testing

Project staff should be knowledgeable of the instructions in the package insert for the specific rapid test being used. Rapid tests are CLIA-waived, which allows non-laboratory project staff to conduct HIV testing by following the instructions in the package insert. However, any deviation from the package insert instructions can negatively affect the accuracy of test results. Therefore, project sites should conduct quality assurance monitoring, including the running of controls, to identify any potential issues with rapid HIV testing. Project sites should maintain logs to monitor the following activities:

- 1) Onsite testing records for individual test results, follow-up testing, and follow-up appointments. The NHBS HIV Testing Log (**Appendix L** of the *NHBS Round 4 Model Surveillance Protocol*) can be used for this purpose.
- 2) Scheduled supervisor observed counseling and testing session ensuring the HIV test counselor correctly follows the entire testing process according to protocol instructions. The HIV Counseling and Testing Evaluation Form (**Appendix F**) can be used to document staff performance.
- 3) External test control results recorded with each new test kit lot or other additional intervals determined by site protocols and the test package insert. It is important to note that external rapid test controls should be run in the environment in which testing will occur to ensure the tests are working and conditions are appropriate (e.g., overhead lighting). For example, if a site is doing all the testing in a van, the external controls should be run in the van. A model Rapid Testing Quality Control Log can be found in **Appendix P**.
- 4) Temperatures at which the tests and quality controls are stored and run. A model Rapid Testing Temperature Log can be found in **Appendix Q**.

Rapid test results must be read within the timeframe indicated in the package insert for the specific test being used. In addition to monitoring the activities listed above, project sites should develop a system for recording the time the test was started and the time the

test result was read. For example, these times could be recorded on the HIV Testing Log or the Participant Tracking Form (**Appendix K**).

A good reference guide for Rapid Testing Quality Assurance can be found at http://www.cdc.gov/hiv/pdf/testing_QA_Guidlines.pdf

8.2b Hepatitis testing

The purpose of conducting hepatitis B virus (HBV) and hepatitis C virus (HCV) testing is to determine the prevalence of markers of HBV and HCV infection among NHBS participants and to describe behavioral risk factors associated with these markers. Serologic tests for HBV can be used to determine whether someone is susceptible to HBV infection, immune due to natural infection, immune due to HBV vaccination, or chronically infected with HBV. Likewise, serologic tests for HCV can be used to determine if someone is susceptible to HCV infection or has current or past infection.

Project sites planning on conducting hepatitis testing must discuss their proposed testing method with their CDC project officer and receive approval before specimen collection can begin. **Appendix R** provides additional guidance on testing for HBV and HCV, as well as information on interpreting test results.

8.2c Other and future testing

Project sites may offer other tests, such as for syphilis or herpes simplex virus, or may want to store blood samples for future testing (either locally or at CDC). Options for other and future testing are outlined in the Model Consent Form (see **Appendix F** of the *NHBS Round 4 Model Surveillance Protocol*).

Project sites that want to conduct other tests and return the test results to participants must describe the procedures for each test and the associated care options in their local consent form. Interviewers should document consent for other tests in the portable computer using the question “Do you agree to have other lab tests?” On the other hand, project sites that want to conduct other tests, but will not return the test results to participants must obtain consent to store a blood sample for future testing. Interviewers should document consent for future testing in the portable computer using the question “Do you agree to let us store a sample of your blood for future testing?” For example, project sites conducting HIV incidence testing should record consent for this activity under storage for future testing since test results will not be returned to participants. Project sites should notify their laboratory whenever specimens are to be stored locally for future testing.



Consent for blood storage must be documented to permit any laboratory to conduct additional or future testing. If consent is not documented, the specimen should be discarded. As with the HIV test consent, participants will be given a second chance to consent to blood storage at the end of the core questionnaire.

If participants ask questions about the tests that will be performed on their stored specimens, project sites can use the following talking points:

- *The tests that may be performed on your stored blood sample are for research purposes only and the results will not be returned to you.*
- *An example of a test that may be performed is a test for detecting recent HIV infection.*
- *No information that identifies you will be linked to your blood sample; the laboratory staff performing the tests will not know that the sample is from you.*

8.3 Staffing and Training

Project sites are responsible for hiring, training, and certifying project staff in testing and counseling for HIV and any other tests offered as part of NHBS. When providing training and certification in testing and counseling, project sites must follow local policies and guidelines; CDC will not conduct a national training on testing and counseling procedures.

Project sites that choose to collect blood by venipuncture are required to have a phlebotomist on staff since any person who collects blood via venipuncture must be certified in phlebotomy. Project sites should check their local policies to determine how many hours of phlebotomy training are required for certification. Most states do not have specific phlebotomy regulations. Instead, regulations are developed by the organization overseeing the blood collection (e.g., health department, clinic, or hospital). Project sites are responsible for ensuring that their staff members' phlebotomy training is current.

Unless state and local regulations require phlebotomy training in order to perform a fingerstick, project staff do not have to be certified phlebotomists to collect blood via a fingerstick. Many health departments, hospitals, and community-based organizations that perform HIV testing provide training on how to properly perform fingersticks and can train project staff. As another option, the manufacturers of rapid tests often offer fingerstick training.

Projects sites collecting blood specimens by venipuncture or fingerstick must adhere to the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard for universal precautions, personal protective equipment, and sharps disposal. The OSHA standards are available at:

<https://www.osha.gov/SLTC/bloodbornepathogens/index.html>. Project sites are responsible for training their staff in these standards, and may be able to get training support from health departments, hospitals, and community-based organizations that perform HIV testing.



In addition to training local staff in universal precautions, biohazard waste must be disposed of properly. Biohazard waste should not be discarded in regular trash. Non-sharp items used for blood collection, such as gloves, absorbent paper, and cotton balls, should be disposed of in biohazard bags; whereas sharp items, such as needles or lancets, should be disposed of in sharps containers. The health department, clinics, or hospitals may be able to help project staff properly dispose of biohazard bags and sharps containers.

The project coordinator should provide overall management of NHBS testing activities and serve as the primary point of contact for CDC. The project coordinator should work with the field supervisor to determine the most feasible means of testing. Project sites should consult with their local laboratory staff to create a plan for specimen processing, storage, transport, and shipping that ensures good specimen quality. Ideally, project sites should identify a point person in the laboratory to oversee the processing, testing, and storage of NHBS specimens.

8.4 Specimen Collection

Specimens for HIV and other laboratory-based tests can be collected with venipuncture, dried blood spots (DBS), or the oral mucosal transudate (OMT) device.



All testing specimens must be collected from participants during the same recruitment event or appointment as their interviews; specimens cannot be collected at a later date.

8.4a Venipuncture

Using standard venipuncture procedures, blood specimens should be collected in blood collection tubes appropriate for the type of testing that will be performed. Project sites should check with their local laboratory to determine which collection tubes are indicated for the types of tests they will offer. For example, serum “red top” tubes or EDTA “purple top” tubes are commonly used for HIV testing. To ensure an adequate specimen volume for testing, blood collection tubes should be filled completely. If additional tests other than HIV are offered, it may be necessary to collect extra tubes or different types of tubes. It may also be necessary to collect extra tubes if specimens have to be sent to different laboratories.



If the phlebotomist is not available or a blood draw cannot be performed on the participant, an alternate form of specimen collection must be used, such as DBS or OMT. The alternate testing plan should be documented in the Operations Checklist.

The date and survey ID number should be recorded on the collection tubes before blood collection begins. If the tubes contain any type of additive, like EDTA, they should be

inverted several times immediately after collection to mix the additive with the blood.

8.4b Dried blood spots

A list of supplies needed to collect DBS can be found in **Appendix S**. Project sites should begin the DBS collection process by recording the date and the participant’s survey ID number on the DBS card.

Prior to specimen collection, project sites using DBS for laboratory-based HIV testing should partially cut a section of the card containing no more than 2 blood collection circles. Sites should only cut the top part of the card with the blood collection circles. They should not cut the bottom part of the card with the area for recording the date and Survey ID; this section should remain intact to hold the card together during DBS collection. After the DBS have been collected and the card dried, the bottom part of the card should then be cut to separate the card in two. The cards should be cut with a clean pair of office scissors. To clean the scissors, use dish soap and water; **DO NOT** use alcohol. Make sure the scissors are completely dry before cutting the cards. The date and survey ID should be recorded in two places on the card: 1) the part of the card for the CDC laboratory, and 2) the part of the card for the local laboratory. If the local laboratory uses a separate laboratory ID, that ID may also be included on the part of the card that will be sent to the local laboratory. The laboratory ID should not be written on the part of the card that will be sent to the CDC laboratory.

To enable the CDC laboratory to distinguish between the same survey ID numbers from different project sites, a 2-letter code indicating the project site must be added to the beginning of the survey ID. The 2-letter codes have been assigned as follows:

Atlanta	AT	Nassau-Suffolk	NS
Baltimore	MD	Newark	NJ
Boston	BO	New Orleans	NO
Chicago	CH	New York City	NY
Dallas	TX	Philadelphia	PH
Denver	CO	San Diego	SD
Detroit	MI	San Francisco	SF
Houston	HO	San Juan	PR
Los Angeles	LA	Seattle	SE
Miami	FL	Washington, D.C.	DC

For example, survey ID “2475” from Chicago would be labeled as “CH2475” on the DBS card.

DBS from fingerstick

CDC recommends collecting DBS with Whatman cards containing 5 circles.



If using the DBS fixative: One drop of fixative should be added to each of the circles on the DBS card that will be sent to the CDC laboratory. Fixative ***must not*** be added to any circles on the card that will be sent to the local laboratory for standard or confirmatory HIV testing. The fixative should be added to the card immediately before performing the fingerstick, while the tester is organizing the specimen collection materials. Project sites should refer to the fixative package insert for more information on the storage and use of fixative.

To obtain a sufficient quantity of blood, the lancets used for fingersticks should be blades rather than needles (see **Appendix S** for recommended lancets). Some helpful hints for fingerstick blood collection are listed below:

- The best location for the fingerstick is either the 3rd (middle) or 4th (ring) finger of the non-dominant hand. These fingers tend to be used less often and are thus less likely to have calluses or tough skin.
- Warm the participant's hands and fingers to increase blood circulation if possible (an instant hand warmer can be used). To further increase blood circulation, it sometimes helps to massage the whole hand and finger to be stuck, not just the fingertip. While the tester is organizing the specimen collection materials, they can also have the participant open and close ("pump") his hand or squeeze and release a stress ball several times to increase blood circulation. Having the participant hold his hand below the level of his heart before performing the stick increases blood circulation as well.
- Prior to the stick, clean the fingertip with a 70% isopropanol swab and allow it to air dry completely for a few seconds.
- Using a sterile, disposable lancet, make the puncture just off the center of the finger pad at right angles to the ridges of the fingerprint so that the blood does not run down the ridges. Avoid the tip and center of the finger, as well as the edge of the nail bed and the side of the finger where there is less soft tissue. The participant's hand should be laid flat against a hard surface to ensure a deeper stick.
- Wipe away the first drop of blood, which tends to contain excess tissue fluid, with a sterile gauze or cotton ball. Allow a new drop of blood to form before using the specimen collection device.
- Hold the finger downward, below the heart. If necessary, the finger can be massaged at the base or pressure can be applied next to the puncture point to increase blood flow. When massaging the base of the finger, provide intermittent pressure rather than constant pressure; apply pressure in a

“squeeze, release, squeeze, release” pattern. Massaging the whole hand is also effective for increasing blood flow.

- A reference guide for fingerstick blood collection can be found in **Appendix T**.

After making the fingerstick, place the blood collection card close to the puncture site but **DO NOT** touch it to the puncture site at any time during the collection process.

Approach the first circle and allow a large drop of blood to form on the tip of the finger. Without touching the tip of the finger to the card, allow the large drop of blood to barely touch the card inside the first circle; the filter paper will wick the drop of blood away from the finger. Allow the blood to completely fill the circle before moving on to the next circle. If the circle is not completely filled with one drop, allow a second large drop to fall onto the same circle before moving to the next circle. Moving from one circle to the next, fill the remaining circles in the same way. When finished, apply cotton to the puncture site until bleeding stops.



It is very important that a circle be filled completely before moving onto the next circle. If the participant does not bleed for very long and there is only enough blood to fill one circle, then only one circle should be completely filled instead of partially filling multiple circles.

After the DBS have been collected, avoid touching the part of the blood collection card with the spots. Cards should be dried at least 4 hours in a suspended horizontal position. Nevertheless, since the DBS must be dry before packaging, overnight drying is sometimes required; but the drying time should not exceed 24 hours. The drying rack manufactured by Whatman can be used to hold the cards while drying, or the cards can be clipped to test tube racks for drying. If necessary, the Whatman drying racks or test tube racks can be placed in a cardboard box to transport the cards from the recruitment event to the project office for drying and eventual packaging. The cards should remain in the racks until they are dry and ready to be packaged.



Dried blood will appear dark red as opposed to the bright red seen when first collected. Drying times will vary depending on the humidity in the project area. However, the drying time should not exceed 24 hours, and the spots must not be left unpackaged for more than a day.

DBS from blood tubes

Project sites collecting venipuncture specimens for laboratory-based HIV testing can prepare DBS cards from the blood in a collection tube that contains the anticoagulant EDTA, which prevents blood from clotting. The DBS can be made by either the project staff or the laboratory staff before the blood specimen is spun down and separated into plasma. Prior to making the DBS, the blood collection tube should be inverted several times to ensure adequate mixing of the EDTA. A disposable, non-sterile transfer pipette should then be used to remove the blood from the tube. ***If using the DBS fixative***, one drop of fixative should be added to each of the circles on the card before applying the

blood. Please refer to the fixative package insert for more information. As with making DBS from a fingerstick, place the pipette tip close to the blood collection card but **DO NOT** touch the tip to the card at any time during the collection process. Gently squeeze the pipette bulb to allow a drop of blood to fall onto the surface of the card inside the circle. Allow the blood to completely fill the circle before moving on to the next circle. If the circle is not completely filled with one drop, allow a second large drop to fall onto the same circle. After all the circles on the card have been filled, the card should be dried as described above in the “DBS from fingerstick” section.

8.4c Oral specimens

Oral specimens for laboratory-based testing are collected via the OraSure Oral Mucosal Transudate (OMT) device. The OMT devices should be stored and used in accordance with the manufacturer’s package insert. Before specimen collection begins, the date and the participant’s survey ID number should be recorded on the OMT device. Project staff should explain to participants how to appropriately swab their mouths and they should monitor the participants to ensure that the specimens are collected appropriately. The participant should not speak during specimen collection. As with the oral rapid test, project staff should have a participant who has recently eaten something or is chewing gum rinse his mouth to remove the food particles or have him throw out his gum before oral specimen collection.

8.5 Specimen Storage and Processing

8.5a Venipuncture

Blood specimens should be transported to the laboratory and processed within 24 to 48 hours of specimen collection. The time of year the specimens are collected affects the temperature and humidity in which the specimens are stored and transported. Usually, blood collection tubes should remain at ambient temperature (< 86° F) prior to processing. All precautions should be taken to ensure the quality of the specimens collected. No blood specimen, regardless of type, should ever be subject to extreme hot or cold temperatures during temporary storage or transport to the local laboratory. In addition, all blood specimens should be transported or shipped in containers appropriately labeled according to OSHA guidelines to protect staff and public safety.

8.5b Dried blood spots

The DBS cards should be dry or close to dry before packaging. Once they do become dry (this should not exceed 24 hours), the flaps on the recommended Whatman cards can be closed. For project sites using DBS for local laboratory-based HIV testing, the section of the card that was not cut prior to specimen collection should be cut to completely divide the card into the DBS that will be sent to the local laboratory and the DBS that will be sent to the CDC laboratory. The cards should then be placed in low-gas permeable zip-

lock bags. The DBS from each individual recruitment event should be packaged together in the same zip-lock bag, with the date of collection and site name written on the bag.



Every effort should be made to package the DBS within 24 hours of collection. If the DBS cannot be packaged within 24 hours of collection, project sites should record that on the zip-lock bag, indicating the number of hours between collection and packaging. Note that the time of packaging can never exceed 48 hours.

Each zip-lock bag should also contain a handful (a minimum of 10) desiccant packs to remove any residual moisture from the cards and one humidity indicator card to monitor the humidity in the bag. If the humidity level is high in a project area, more desiccant packs should be added to the zip-lock bag. Press as much air out of the bag as possible and seal it shut. Humidity indicator cards and desiccant packs have a color indicator which changes from blue to pink as humidity within the bag becomes unacceptably high. It is important to monitor the humidity indicator cards in the bags on a *daily* basis and to replace the desiccant packs if the indicator cards change from blue to pink to ensure the humidity remains low. The used desiccant packs and indicator card should be discarded, and a new indicator card should be added to the bag along with the new desiccants.



The desiccant packs and humidity indicator cards should be stored in air-tight containers. It is also helpful to add a couple of desiccant packs to the indicator card storage container to help keep it dry.

Once properly packaged, the DBS cards can remain at ambient temperature in a climate-controlled area until they are sent to the laboratory for testing. While awaiting shipment, they should be stored away from direct sunlight and they must be monitored closely for excess humidity.

8.5c Oral specimens

Specimens collected via the OraSure OMT device should be temporarily stored and transported according to the manufacturer's package insert. The insert lists the temperature requirements for storage and the kit lists the expiration date for the OMT devices.

8.6 Specimen Transport and Shipping

8.6a Local transport of venipuncture specimens

As mentioned previously, blood specimen collection and transport should be timed so that specimens arrive at the laboratory and are processed within 24 to 48 hours of specimen collection. Project sites should develop transport procedures in conjunction with their local laboratory. When developing these procedures, they should consider transport time to the laboratory, the days and hours of laboratory operation, specimen

intake procedures, and the days and hours of field operations. A Specimen Transport/Shipping Log (**Appendix U**) should be included with the batches of specimens sent to the laboratory.

8.6b Shipping DBS

Unlike liquid or frozen blood samples, DBS do not require special labeling or mailing. The low-gas permeable zip-lock bags containing the DBS can be shipped at ambient temperature by overnight UPS or FedEx, whichever is most practical for project sites. The DBS should not be frozen before shipping. It is important to check the humidity indicator cards in the bags immediately before mailing them and to replace the desiccant if necessary. Place the bags containing the DBS inside a high-quality bond, anti-tear envelope, such as Tyvek, and seal it for mailing. The bond envelope provides an extra barrier of protection for the specimens during shipping. The sealed, bond envelope should then be placed in a regular UPS or FedEx envelope.



Biohazard labels should not be placed on the envelope or inner DBS packaging since DBS are not considered infectious once dry.

The Specimen Transport/Shipping Log should be used as a shipping manifest and be included in the envelope sent to the laboratory.

Shipping DBS to CDC

Only DBS cards from HIV-positive (i.e., preliminary positive from rapid tests, positive from lab-based testing, and self-reported positive) participants should be shipped to the CDC laboratory for additional tests. They should not be transported to the local laboratory or frozen for storage before shipment to CDC. Additional tests on these specimens will include testing to identify recent HIV infections, and may include testing for HIV drug resistance and testing to quantify HIV viral load.

The DBS must be shipped to the CDC on a *weekly* basis and no more than 10 days after the spots are made. The DBS should be packaged as mentioned above and the Specimen Transport/Shipping Log should be used as a CDC shipping manifest and included in the envelope sent to the CDC. On the day project sites ship the DBS to the CDC, they should send an email to Silvina Masciotra (svm6@cdc.gov), Michele Owen (smo2@cdc.gov), Wei Luo (wfl9@cdc.gov), and their CDC project officer notifying them of the shipment. Sites should also include the UPS or FedEx tracking number in the notification email. Overnight mailing should be used and the packages should be timed to arrive at CDC Monday through Thursday. Shipments should be sent to the attention of Wei Luo:

ATTN: Wei Luo
Centers for Disease Control and Prevention
1600 Clifton Rd NE MS A-25 Room 3017A
Atlanta, GA 30329
Phone: 404-639-0778

Project staff should devise a shipping schedule and record scheduled shipments on a monthly calendar. After arrival at the CDC, the DBS specimens will be stored at the Division of HIV/AIDS (DHAP) laboratory in temperature-controlled freezers until all testing is completed.

8.7 Returning Test Results

Project sites must make final HIV test results available to participants, and they should keep track of the provision of results. After the NHBS survey is completed, project sites offering rapid testing should provide counseling and return negative and preliminary positive test results to participants. Each box of rapid HIV tests comes with a set of “subject information” pamphlets that should be given to the participants when they receive their rapid test results. For those participants with preliminary positive test results, project sites should also collect specimens for laboratory-based confirmatory testing. Participants can receive laboratory-based test results in person or, if permitted by local policies, over the phone. Project sites planning to provide test results over the phone should refer to the Model HIV Phone Result Protocol in **Appendix K** of the *NHBS Round 4 Model Surveillance Protocol*, and they should track results given over the phone using a Phone Results Log (see **Appendix V** of this manual for an example of a log). To properly schedule appointments for returning laboratory-based test results, project sites should check with their local laboratory to find out the test turnaround time.

Appointments for returning test results should be made with the Appointment or Phone Results Cards in **Appendix W**.

Project sites have the option of offering participants a phone call reminder of their appointment to get their laboratory-based test results. As described in **Appendix X** of this manual, the participant’s phone number is collected on an Appointment Reminder Call Form so that project staff can call him to remind him of the day and time of his appointment. When using appointment reminders, project sites can *never* link the participant’s survey ID or laboratory ID to his phone number, and they cannot require that participants use this service. Appointment Reminder Call Forms must be stored in a locked file or file box to keep the participants’ confidential information secure.

Furthermore, appointment reminder procedures must be approved by the project site’s CDC project officer before this service can be provided.

Because only about 30% of participants obtained their laboratory-based test results during previous NHBS cycles, project sites are strongly encouraged to use rapid tests so that participants will at least get a preliminary positive test result and a referral to care. Alternatively, project sites could try to increase the number of participants who return for their laboratory-based test results by scheduling appointments for participants to get the results or by using phone calls to remind participants of their test result appointments.

As discussed in **Chapter 5** of the *NHBS Round 4 Model Surveillance Protocol*, test counselors should target prevention messages to specific risks identified during the survey. Project sites that have separate interviewers and testing staff should develop procedures for communicating risk information between staff. For example, test counselors could administer a separate risk assessment or the interviewer could confidentially pass risk information to the test counselor. The collection of any risk information for test counseling must comply with the Assurance of Confidentiality for HIV/AIDS Surveillance Data (see **Appendix M** of the *NHBS Round 4 Model Surveillance Protocol*). Project sites conducting hepatitis testing can find resources for counseling participants about HBV and HCV at <http://www.cdc.gov/hepatitis/HBV/TestingChronic.htm> and <http://www.cdc.gov/hepatitis/HCV/PatientEduHCV.htm>.

Participants have the right to refuse receipt of their rapid test results. Nonetheless, it is still very important to collect a confirmatory specimen from participants with preliminary positive test results since only the final test result will be included in the NHBS dataset. If a participant states that he does not want to receive his rapid test result before he provides a specimen for rapid testing, the project site should not conduct a rapid test. Instead, they should collect a specimen for laboratory-based testing and if applicable, DBS for storage and future testing. In situations where the participant declines receipt of his rapid test result after a specimen for rapid testing has been collected, project sites should request that the participant provide a specimen for laboratory-based testing so that he can receive his testing incentive (project sites should consult their local IRBs to find out if they can withhold testing incentives from participants who refuse to provide a specimen for confirmatory testing).

Previous Positive Questions

In prior NHBS cycles, some participants disclosed a previous positive test result during test counseling even though they had not reported a previous positive test result during their interview. To collect this information from participants in a standardized manner, the *Previous Positive Questions* were developed (see **Appendix Y** of this manual). These questions should be asked during test counseling to determine whether participants previously tested positive, and if so, the date they first tested positive. Project sites conducting only laboratory-based HIV tests should ask the *Previous Positive Questions* of participants who do not report a previous positive test result during their interview; whereas project sites conducting rapid HIV tests should ask the *Previous Positive Questions* of participants who do not report a previous positive test result during their interview **and** who have a preliminary positive rapid test result. To ensure consistency in the way these questions are asked, test counselors should follow the script in **Appendix Y**. **Appendix Y** also provides instructions for recording the *Previous Positive Questions* on the Participant Tracking Form. Responses to the *Previous Positive Questions* that are recorded on the Participant Tracking Form should be entered into the HIV Test Results Log on the DCC data portal on a daily basis.

8.8 Referrals to Care and Services

All referrals to care, support services, case management, or partner notification services must be made anonymously. Project sites must establish relationships with agencies that accept anonymous referrals before data collection can begin. The policy on anonymous referrals does not just apply to HIV care and services, but also to care and services for other conditions, like hepatitis, STDs, and substance abuse.

The agencies to which participants are referred will have to conduct their own tests to confirm a participant's diagnosis. Furthermore, these agencies should not have access to any NHBS code numbers, such as survey IDs or laboratory IDs, which could link participants to their NHBS data. Finally, the NHBS test result may not be used to report a new diagnosis to the state or local health department for HIV/AIDS surveillance purposes. The HIV test result can only be used for NHBS analysis purposes.

Project sites can strengthen their referral process by collaborating with local entities such as CBOs or STD/HIV clinics. An anonymous referral to care or services should involve more than simply telling a participant where to go to receive care or services. Project sites should make an effort to actually link the participant to the needed care or services. For example, project staff could offer to call an agency to schedule a medical appointment for a participant. Referral to other services and organization that can do the appropriate linkage to care and follow-up are encouraged. When making referrals, project sites should always respect the wishes of the participant; participants have the right to decline any referrals to care or services.



Project sites conducting rapid tests should make immediate referrals to care or services for participants with preliminary positive test results. They should not wait until they receive final test results because the participants could be lost to follow-up.

8.9 Data Management

8.9a HIV testing

While in the field, project sites should record HIV test results on a hard copy of the HIV Testing Log (see **Appendix L** of the *NHBS Round 4 Model Surveillance Protocol*). The hard copy of the HIV Testing Log, as well as any other HIV testing forms or logs, must be secure and in the possession of project staff at all times when in use in the field; otherwise, the forms and logs should be kept locked in a file or file box.

Data from the hard copy of the HIV Testing Log should be entered into the online HIV Test Results Log on the DCC data portal on a **daily basis**. It is important for project sites to enter these data daily so that the process monitoring reports generated by the DCC are up-to-date and reflect each project site's latest data. Project sites should refer to the

NHBS-MSM4 Data Management Training Manual for specific instructions on data entry, a listing of required variables, a data dictionary, and a hard copy of the HIV Testing Log for use in the field. To aid in understanding data entry for laboratory-based testing, a categorical list of the trade names of HIV tests is included in **Appendix Z**. Any data collected solely for local use do not have to be entered into the DCC data portal. Accordingly, project sites should consider developing their own electronic systems for storing these data.

At a minimum, all HIV-positive and indeterminate test results should be validated against the laboratory reports before making the final data submission to the DCC. This can be accomplished by downloading the HIV Test Results Log on the DCC data portal to an Excel spreadsheet, sorting by “Final Result” to group the different results together, and then checking all the positive and indeterminate test results against the laboratory reports. Checking against the laboratory reports will not only allow project staff to ensure that the result was entered correctly, but it will also allow them to determine if any participant records were not entered at all.

8.9b Hepatitis testing

For project sites that received CDC funding for hepatitis testing, data management requirements for hepatitis testing are similar to those for HIV testing. While in the field, project sites should record hepatitis test results on a hard copy of the Hepatitis Testing Log (see **Appendix J** of the *NHBS Round 4 Model Surveillance Protocol*). The hard copy of the Hepatitis Testing Log, as well as any other hepatitis testing forms or logs, must be secure and in the possession of project staff at all times when in use in the field; otherwise, the forms and logs should be kept locked in a file or file box.

Data from the hard copy of the Hepatitis Testing Log should be entered into the online Hepatitis Test Results Log on the DCC data portal on a **daily basis**. It is important for project sites to enter these data daily so that the process monitoring reports generated by the DCC are up-to-date and reflect each project site’s latest data. Project sites should refer to the *NHBS-MSM4 Data Management Training Manual* for specific instructions on data entry, a listing of required variables, a data dictionary, and a hard copy of the Hepatitis Testing Log for use in the field. Sites that conduct hepatitis testing without CDC funding may also enter hepatitis test results into the DCC data portal if they wish. At data closeout, the DCC will then be able to include the site’s hepatitis test results in the site’s final NHBS dataset.

9

Process Monitoring and Ongoing Formative Research

9.1 Overview

Process monitoring and ongoing formative research enable project sites to maintain the highest standards for data collection and will help them meet the overall project objective of enrolling a sample of 500 men who had sex with another man in the previous year. The information sites obtain through these assessment methods will complement the information they gathered during the formative research conducted at the start of the project cycle.

9.2 Process Goals

The NHBS process goals help project sites monitor and evaluate recruitment and enrollment. CDC has established the following goals for the current project cycle:

- 45% of the men approached agree to be screened for eligibility (i.e., 45% screening rate).
- 90% of eligible men complete the interview.
- 90% of survey participants consent to an HIV test.
- A minimum of 500 interviews are completed by men who had sex with another man in the previous year.
- Each month, at least 14 recruitment events are conducted.

Achieving these process goals is critical to the success of NHBS. Failure to meet the goals would jeopardize the external validity of NHBS data and would thereby undermine the generalizability of project findings and recommendations. Project sites should continuously monitor their recruitment and enrollment data. If their data do not meet the target goals, sites should conduct ongoing formative research to identify any operational problems and to develop appropriate solutions (see **Section 9.4** for information on ongoing formative research).

9.3 Process Monitoring Reports

The NHBS Data Coordinating Center (DCC) will produce the process monitoring reports for project sites to assess recruitment and enrollment, sample characteristics, HIV and hepatitis testing, previous participants, and interviewer skills. The reports will be posted

on the DCC data portal and should be reviewed by project sites weekly. Sites should then discuss the findings in the reports with their CDC project officer at least every two weeks. If a problem is identified in the reports, the site's CDC project officer may recommend that the site address the problem by adjusting operations or by providing additional staff training, or the CDC project officer may recommend that the site further evaluate the problem by conducting ongoing formative research. If they wish, sites may also create their own reports to monitor any issues of local interest.

The various process monitoring reports are described below and examples of each are provided in **Appendix BB**.

9.3a Outcomes Monitoring Report

The *Outcomes Monitoring Report* (**Section BB.1** of this manual) provides venue and recruitment information for each recruitment event:

- The code and name of the venue where the event was conducted.
- Whether the venue was a primary venue or an alternate venue.
- Whether the venue was randomly or non-randomly (purposefully) selected.
- The number of men approached.
- The overall number and proportion of men approached who agreed to be screened for NHBS-MSM eligibility (screening rate), as well as the screening rate for each recruiter.
- The number of men counted in the venue before the start of the event (Pre-Event Count) and the number of men counted entering the venue during the event (Entry Count).

This report should be reviewed to monitor the use of alternate venues and non-random events; to assess the completeness of venue attendee counts; and to identify low overall screening rates, low screening rates at particular venues, and low screening rates among specific recruiters.

9.3b Recruitment Monitoring Report

The *Recruitment Monitoring Report* (**Section BB.2** of this manual) provides information on eligibility and enrollment at each recruitment event:

- The number of participants screened.
- The number and proportion of participants screened who were eligible.

- The number and proportion of eligible participants who completed the interview.
- The number and proportion of participants who had sex with a man in the past 12 months.
- The number and proportion of participants who consented to HIV testing.
- If applicable, the number and proportion of participants who consented to other testing (e.g., hepatitis testing).
- If applicable, the number and proportion of participants who agreed to blood storage for HIV incidence and other testing.

This report should be reviewed to identify problems such as low or declining enrollment; a low proportion of eligible participants; a low proportion of participants who had sex with a man in the past 12 months; and a low proportion of participants consenting to HIV testing, other testing, or blood storage.

9.3c Sample Characteristics – Screened Report

The *Sample Characteristics – Screened Report* (Section **BB.3** of this manual) shows the characteristics of participants who were screened for eligibility stratified by whether or not they were eligible to take the survey. The characteristics examined are:

- Eligible
- Age
- Gender
- Race/ethnicity
- MSA Resident
- Known Previous Participant
- Able to Participate (i.e., able to complete the survey in English or Spanish)
- Sexual Behavior (ever)

Project sites should review this report to monitor the proportion of participants screened who were not eligible based on key demographic variables (age, gender, and race/ethnicity) and who were not eligible based on each eligibility criterion (age, MSA resident, known previous participant, able to participate, and sexual behavior).

9.3d Sample Characteristics – Interviewed Report

The *Sample Characteristics – Interviewed Report* (Section BB.4 of this manual) shows the characteristics of participants who completed the interview. The characteristics listed are:

- Age
- Sexual identity
- Race/ethnicity
- Education
- Income
- Recruitment venue
- Geographic Area (Zip Code)

Project sites should review the tables in this report to monitor the demographic characteristics of participants who successfully completed the interview. The demographic characteristics of participants should reflect those of local MSM as described in the project site's formative research reports, including those MSM sub-populations most highly impacted by the HIV epidemic. The productivity of various types of venues should also be assessed.

9.3e Test Results Report

The *Test Results Report* (Section BB.5 of this manual) consists of four tables:

- HIV Rapid Test Result
- HIV Self-reported Test Result
- Hepatitis B Test Result
- HCV (Hepatitis C Virus) Rapid Test Result

Using this report, project sites can monitor their HIV and hepatitis test results. The HIV Rapid Test Result table shows rapid test results compared to final test results, and the HIV Self-reported Test Result table shows whether or not the participant self-reported being HIV-positive compared to his final test result. A lack of concordance between rapid and final HIV test results in the HIV Rapid Test Result table may indicate improper specimen collection or the over-reading of rapid test results, necessitating additional staff training. The lack of concordance could also be due to the lower sensitivity of some laboratory-based confirmatory tests, especially those used for oral specimens. In such cases, the additional testing of specimens may be required. Important information

provided by the HIV Self-reported Test Result table is the proportion of participants with undiagnosed infection (i.e., did not report being HIV-positive, but had a final HIV test result that was positive), and the proportion of possible false-negative HIV test results (i.e., did report being HIV-positive, but had a final HIV test result that was negative or indeterminate).

If hepatitis B test results were entered into the Hepatitis Test Results Log on the DCC data portal, they will appear in the Hepatitis B Test Result table; and if hepatitis C test results were entered, they will appear in the HCV Rapid Test Result table. The data in both these reports can be used to monitor hepatitis prevalence in participants. The Hepatitis B Test Result table also shows the project staff's interpretation of the final hepatitis B test result that they entered into the DCC data portal compared to the interpretation calculated by the DCC from the individual HBsAg, anti-HBs, and anti-HBc values. A lack of concordance between the staff's interpretation of the test result and the calculated interpretation may be due to incorrect data entry or it could indicate an incorrect interpretation by the staff. Project sites should ensure that both interpretations match so that participants are given the correct test result and appropriate counseling and referrals. The HCV Rapid Test Result table compares hepatitis C rapid test results to hepatitis C EIA test results. If only one type of hepatitis C test is conducted, the table will just show the results for that test.

All pending test results will be coded as "Unknown" in the tables, and project sites that do not conduct rapid HIV tests, hepatitis B tests, or hepatitis C tests will have those test results coded as "Not done."

9.3f Possible Previous Participant Report

To help project sites identify participants who may have taken or tried to take the survey more than once, the *Possible Previous Participant Report* (Section BB.6 of this manual) contains a table listing participants who have the same date of birth, gender, and race/ethnicity. The table shows all participants with matching data even if the interviewer identified the person as a previous participant during eligibility screening or determined that he was not providing honest answers during the interview (i.e., the interviewer coded his confidence in the validity of the participant's responses as "3 – Not confident at all"). By including all participants, regardless of their eligibility and the validity of their responses, project sites can evaluate how well their interviewers are able to identify previous participants.

To help assess whether participants with the same date of birth, gender, and race/ethnicity are the same person, the participants' educational levels and zip codes are also listed in the *Possible Previous Participant Report*. In addition to the variables in the report, project sites may want to examine other variables that should not change over time (e.g., country of birth, age of sexual debut) or variables that are not likely to change during the data collection period (e.g., circumcision status, injection drug use) to help them determine whether two participants are the same person. When project sites identify two

participants with valid, completed interviews who have the same or similar information, they should discuss their findings with their CDC project officer and decide whether the second record should be treated as that of a previous participant and deleted from the analysis dataset.



Although the record of a previous participant should be removed from the analysis dataset, it should be retained in the QDSTM Warehouse and the NHBS dataset.

9.3g Interviewer Report

The *Interviewer Report* (Section **BB.7** of this manual) consists of the following tables:

- Interviewer Capacity
- Response Validity
- Coding of “Other” Insurance

Project sites should review the tables in this report to identify possible interviewer deficiencies or areas for improvement. Whenever interviewers perform below acceptable standards, project sites should provide them with any additional training needed and closely monitor their progress. If the interviewers fail to show improvement, sites should remove them from their position until they can demonstrate sufficient competence.

The Interviewer Capacity table shows the number of interviews completed by each interviewer and the amount of time each spent on eligibility screening, the consent process, and the core survey. Project sites should compare each interviewer’s screening, consent, and survey times to the overall times to check for any extreme values which may indicate a need for further training or more frequent monitoring. Interviewers who spend more time completing a section of the survey may be having difficulty administering that section, whereas interviewers who spend less time may be administering the section too hastily or incompletely.

The Response Validity table lists the interviewers’ responses to the validity question (“How confident are you of the validity of the respondent’s answers?”). Project sites should monitor how often each interviewer selects the response options “2 – Some doubts” and “3 – Not confident at all.” A high proportion of interviews with questionable validity, especially the option “3 – Not confident at all,” may indicate that an interviewer is not adequately screening potential participants or that people are providing fraudulent answers so that they can enroll in the survey.

Whenever an interviewer selects “Some other health plan” for the type of health insurance that a participant has, the specific name of that “other” plan will be listed in the Coding of “Other” Insurance table. Project sites should review this table to ensure that

interviewers are not selecting “Some other health plan” for a type of insurance that could be coded as one of the existing response options (“Private health plan,” “Medicaid,” “Medicare,” “Some other government plan,” “TRICARE (CHAMPUS),” or “Veterans Administration coverage”). If project sites find “other” health plans that should have been coded as one of the existing response options, they should make the necessary corrections in the Data Error Log on the DCC data portal. Moreover, they should provide their interviewers with refresher training on the principal health insurance plans in their locality and give the interviewers instructions on how to properly code these plans as one of the available response options. Further information on coding insurance plans is included in the *NHBS-MSM4 Interviewer Guide*.

9.4 Ongoing Formative Research

Ongoing formative research is the collection and assessment of additional quantitative and qualitative data to improve project operations. Project sites should use ongoing formative research to evaluate and address operational problems that have been identified through process monitoring or reported by field staff. Sites should also use ongoing formative research to update the venues and day-time periods on their sampling frames. Ongoing formative research may involve examining existing recruitment and enrollment data, reviewing recruitment event notes, observing venues, having informal conversations with participants, conducting street intercept surveys, or discussing operational issues or potential venues and day-time periods with key informants or focus groups. Sites should refer to the *NHBS-MSM4 Formative Research Manual* for additional information on ongoing formative research and for instructions on formative research methods.

When conducting ongoing formative research, project sites should begin with the least labor-intensive and time-consuming methods (e.g., the review of existing data, observations, and informal conversations) and then, if simpler methods do not yield results, they should proceed to more labor-intensive and time-consuming methods (e.g., street intercept surveys, key informant interviews, and focus groups). Sites should also assess whether an operational problem is associated with a particular demographic sub-population, venue, or staff member. **Table 9.1** provides examples of some operational problems and the methods that could be used to evaluate them.

Project sites should only use ongoing formative research to investigate operational problems that have been identified. They should not use it to conduct sub-studies or to evaluate new research questions. Before starting ongoing formative research, project sites should always discuss their plans with their CDC project officer.

Table 9.1 – Operational problems and potential evaluation methods

Operational Problem	Potential Evaluation Methods
Low screening rates	<p><i>Quantitative:</i></p> <p>Project sites should review the <i>Outcomes Monitoring Report</i> to determine if the screening rate (the percentage of men approached who agree to be screened for eligibility) is low overall, is lower among certain recruiters, or is lower at certain venues or types of venues. A low overall screening rate indicates a general participation barrier that requires further examination. To aid in this examination, sites can use the “Comments” field on the Intercept Form to collect the reason why men approached do not agree to be screened for eligibility.</p> <p>A low screening rate among a specific recruiter may indicate the need for additional training. Alternatively, a recruiter with a low screening rate may not have the personal characteristics to be an effective recruiter or their demographic characteristics may not reflect those of the local MSM population, either of which may necessitate a staffing change.</p> <p>A low screening rate at a venue or type of venue may indicate a specific barrier to participation at that venue or type of venue. For example, men may be less likely to participate in the project at a small, crowded bar because of confidentiality concerns or men may be less likely to participate in the project at dance clubs because participation conflicts with their aim of going out dancing. A low screening rate can also occur at a venue if the day-time periods selected for that venue are ones when men are less willing to participate in the project, like during a popular drag show at a bar.</p> <p><i>Qualitative:</i></p> <p>For general and venue-specific participation barriers, project sites should observe recruitment and operations to assess recruitment methods and messages and to identify barriers to participation (see the <i>NHBS-MSM4 Formative Research Manual</i> for information on potential participation barriers and Appendices L and M of this manual for strategies for overcoming recruitment and participation barriers). Field</p>

Table 9.1 – Operational problems and potential evaluation methods (continued)

Operational Problem	Potential Evaluation Methods
<p>Low screening rates (continued)</p>	<p>staff should be debriefed as well to gain their insight. Sites can also have informal conversations with men who decline participation in the project to determine the reason(s) why. Similarly, sites can have informal conversations with venue attendees to gauge interest in the project and to identify possible participation barriers. If further information is required, sites should conduct more in-depth evaluation methods, such as key informant interviews or focus groups. Whenever sites identify participation barriers through informal conversations, interviews, or focus groups, they should also inquire about possible solutions for overcoming those barriers.</p> <p>For low screening rates among a specific recruiter, project sites should observe the recruiter in the field to evaluate recruitment techniques and messages. Observing the recruiter during mock recruitment scenarios may also prove helpful. Additional training should be provided to address any shortcomings identified. If the recruiter does not demonstrate improvement, a staffing change may be necessary. If some recruiters are more effective than others at certain venues or with certain MSM sub-populations, sites should assign the recruiters to those events where they will be most successful.</p>

Table 9.1 – Operational problems and potential evaluation methods (continued)

Operational Problem	Potential Evaluation Methods
<p>Low or declining enrollment</p>	<p>Quantitative:</p> <p>Project sites should review the <i>Recruitment Monitoring Report</i> to determine how many men have completed interviews at each recruitment event. Events with low enrollment should be cross-checked against the <i>Outcomes Monitoring Report</i> to determine whether low enrollment is due to a low screening rate. If it is, sites should address the low screening rate according to the guidance provided in the examples on pages 9-8 and 9-9. If low enrollment is not due to a low screening rate, it may be an indication that the venue or day-time period does not have sufficient attendance to be included on the sampling frame. Nevertheless, even if a venue or day-time period has low attendance, a site may still keep the venue or day-time period day on their sampling frame if the men enrolled at the venue or during the day-time period represent an important MSM sub-population that the site would not otherwise be able to enroll.</p> <p>Declining enrollment at subsequent recruitment events held at a venue may indicate that most of the eligible men who attend the venue have already been interviewed. This is referred to as venue “saturation” and it often occurs at social organizations with a limited number of members. Sites can verify whether a venue has become saturated by examining the proportion of “yes” responses to the Previous Participation question on the Intercept Form. An increasing trend in the proportion of “yes” responses to the Previous Participation question at subsequent recruitment events is consistent with a venue becoming saturated.</p> <p>Qualitative:</p> <p>Project sites should use informal conversations with venue attendees and staff, as well as venue observations to identify day-time periods with the highest attendance. Sites must also ensure that these day-time periods are the ones when venue attendees would be most willing to participate in the project. Assessing willingness to participate may require more labor-intensive evaluation methods, like brief intercept surveys or focus groups.</p>

Table 9.1 – Operational problems and potential evaluation methods (continued)

Operational Problem	Potential Evaluation Methods
<p>Demographic characteristics of participants do not match those of the local MSM population</p>	<p><i>Quantitative</i></p> <p>Project sites should review the <i>Sample Characteristics – Interviewed Report</i> to determine if the demographic characteristics of the men interviewed reflect the demographic characteristics of the local MSM population described in the Secondary and Primary Data Reports. If they do not, sites should examine the <i>Sample Characteristics – Screened Report</i> to assess whether men from the underrepresented sub-populations are less likely to be eligible to participate in the project. Sites can also generate their own reports to examine the reason(s) why these men are not eligible. Most notably, sites should check to see if men from the underrepresented sub-populations are less likely to report ever having sex with another man.</p> <p>Project sites may want to use the “Comments” field on the Intercept Form to track approaches to men from the underrepresented sub-populations to determine whether they are less likely to agree to screening. If they are, sites should address the low screening rate according to the guidance provided in the examples on pages 9-8 and 9-9.</p> <p><i>Qualitative</i></p> <p>Project sites should assess the venues and day-time periods on their sampling frames to ensure that they include venues and day-time periods attended by MSM from the underrepresented sub-populations. Sites should begin this assessment with informal conversations with MSM from the underrepresented sub-populations, and then progress to key informant interviews and focus groups if necessary. In previous NHBS-MSM rounds, the primary reason MSM sub-populations were underrepresented among participants was the lack of a diverse and comprehensive set of venues and day-time periods on the site’s sampling frame.</p>

10

Data Submission and Management

10.1 Overview

The purpose of this chapter is to briefly describe NHBS data submission and management procedures. Project sites will submit their data to the NHBS Data Coordinating Center (DCC), which is managed by ICF International. Specific instructions on how to submit data to the DCC are described in the *NHBS-MSM4 Data Management Training Manual*. The DCC will also provide an in-person training that the data manager from each project site is required to attend.

10.2 Data Submission

The DCC is responsible for managing NHBS data nationally, including the review and editing of all data. The DCC will also produce the process monitoring reports described in **Chapter 9** of this manual. Project sites are responsible for entering or submitting the following data via the DCC data portal:

- Monthly recruitment calendar
- Recruitment event outcomes
- QDS™ Warehouse containing the NHBS core interview files
- HIV test results
- *For sites that received CDC funding for hepatitis testing, hepatitis test results*
- Data corrections

Sites should observe the schedule in **Table 10.1** on the next page for entering or submitting their data through the DCC data portal, and they should refer to the *NHBS-MSM4 Data Management Training Manual* for specific guidance on using the portal.

10.3 Data Management

Project sites must develop a local data management plan that outlines the activities necessary for ensuring the systematic, complete, and timely submission of NHBS data. The local plan should also identify the specific staff member(s) (and back-ups) who will submit the QDS™ Warehouse; enter the VDTs Program data, HIV and hepatitis test results, and data corrections; and serve as the DCC's point-of-contact. Another essential element of the local plan is a system for tracking surveys and data corrections. Project

sites should use the Participant Tracking Form (**Appendix K**) to track key survey information (e.g., survey ID, interview date, eligibility status), as well as to record any needed data edits. Project sites should always review and process their data in accordance with their local plan and the *NHBS Round 4 Model Surveillance Protocol*. Moreover, project sites should *promptly* respond to all DCC communications with either the requested information or a date when the requested information will be sent.

Table 10.1 – Data entry and submission schedule

Data	Action	Frequency
Monthly recruitment calendar	Enter in the VDTS Program	<i>Monthly</i> , at least one week prior to the 1 st of the month
Recruitment event outcomes	Enter in the VDTS Program	<i>Daily</i> , after each recruitment event
QDS™ Warehouse	Submit through the data portal	<i>Weekly</i>
HIV test results	Enter in the HIV Test Results Log	<i>Daily</i> , after rapid or confirmatory test results are obtained
Hepatitis test results (if applicable*)	Enter in the Hepatitis Test Results Log	<i>Daily</i> , after final test results are obtained
Data corrections	Enter in the Data Error Log	<i>Daily</i> , as soon as errors are identified

*Applicable to project sites that received CDC funding for hepatitis testing.

	Funded Health Department IRB	Other Local IRB (if applicable)	Other Local IRB (if applicable)
Name of IRB			
Date FR IRB Package Submitted			
Date FR IRB Approval Received			

Instructions for completing the table:

Name of IRB: List the name of each IRB that reviewed your formative research package (do not list an IRB that is deferring to another one).

Date FR IRB Package Submitted: For each applicable IRB, list the date you sent the formative research package to the IRB.

Date FR IRB Approval Received: For each applicable IRB, list the date you received approval to conduct formative research.

b. Complete the following table on your IRB submission for NHBS-MSM4:

	Funded Health Department IRB	Other Local IRB (if applicable)	Other Local IRB (if applicable)
Name of IRB			
IRB FWA Number			
FWA Expiration Date			
Date IRB Package Submitted			
Expedited or Full IRB Review			
Date IRB Approval Received			
Date Amendment Approval Received (if applicable)			

Instructions for completing the table:

Name of IRB: List the name of each IRB that reviewed your NHBS-MSM4 package (do not list an IRB that is deferring to another one).

IRB FWA Number: For each applicable IRB, list the human subjects Federal Wide Assurance (FWA) number. This information can be found on:
<http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>

FWA Expiration Date: For each applicable IRB, list the expiration date for the FWA. This information can be found on: <http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>

Date IRB Package Submitted: For each applicable IRB, list the date you sent the NHBS-MSM4 package to the IRB or sent an amended package from a previous NHBS cycle.

Expedited or Full IRB Review: Record *Expedited* or *Full* to indicate whether the NHBS-MSM4 package underwent an expedited or full IRB review.

Date IRB Approval Received: For each applicable IRB, list the date you received approval to conduct NHBS-MSM4.

Date Amendment Approval Received: If you submitted an amendment to any of your IRBs, list the date when approval was received for the amendment.

c. Did any of your local IRBs defer to another?

Yes No

c1. **If Yes:** Specify which IRBs were involved:

c2. **If Yes:** Attach letter(s) or other documentation for each IRB deferral.

d. Attach the letter(s) of approval from your IRB(s).

e. Attach your local consent forms, including the Spanish versions if applicable.

f. According to your IRB requirements, how will interviewers read the consent form to participants? (*check all that apply*)

Read consent form verbatim

Read summary of consent form (*attach summary*)

Read bulleted list of key consent elements (*attach bulleted list*)

Read highlighted excerpts from the consent form (*attach highlighted form*)

g. Will participants provide verbal consent or written consent?

Verbal consent Written consent

g1. **If written consent:** Describe how you will protect the confidentiality of participants:

(*e.g., by having the participant sign the consent form with his survey ID instead of his name, by having the interviewer sign the consent form, by not recording a survey ID or any other linkages to NHBS data on a signed consent form*)

II – Project Identification

- a. Record your NHBS-MSM4 project name:
- b. Insert or attach your NHBS-MSM4 project logo:

III – Van

- a. Indicate whether you will use a van for interviewing or HIV testing:
 - Will use a van for interviewing *only*
 - Will use a van for HIV testing *only*
 - Will use a van for *both* interviewing and HIV testing
 - Will *not* use a van for interviewing or HIV testing
- a1. *If you will use a van for interviewing or HIV testing:* Describe your contingency plans if the van is not available due to mechanical problems:

IV – Recruitment Event Code Numbers

- a. At each recruitment event, the field supervisor should provide the interviewers with a written copy of four code numbers: 1) Interviewer ID, 2) Survey ID, 3) Venue Code, and 4) Event Number. Will you use the Participant Tracking Form for this purpose?
 - Yes No
 - a1. *If No:* Describe the system the field supervisor will use to provide a written copy of the four code numbers to the interviewers:
- b. Describe the system your project site will use to keep track of Survey IDs assigned during a recruitment event:
 - b1. *If a Survey ID Log will be used:* attach an example.

V – Post-event Appointments

- a. Will you use post-event appointments (PEAs)?
 - Yes No

a1. **If Yes:** Describe how PEAs will be scheduled:

a2. **If Yes:** List all locations where PEAs will be conducted (including any locations using a van):

Name & Address	Project Staff	Days & Hours	Field Site ID

Instructions for completing the table:

Name & Address: List the name of any organization housed in the field site where PEAs will be conducted and the address of the site. If using a van, list the address(es) where the van will be parked.

Project Staff: List the project staff that will be working during the PEA (e.g., field supervisor, number of interviewers, number of test counselors).

Days & Hours: List the days and hours PEAs will be conducted.

Field Site ID: List the 1- or 2-digit ID code for each field site where PEAs will be conducted.

VI – Phone

a. List your project phone number(s) (write *pending* if a phone number has not been obtained yet):

Phone #: _____

Phone #: _____

Phone #: _____

b. Is voicemail activated on your project phone?

Yes No

b1. **If Yes:** Describe your procedures for protecting participant anonymity:

VII – Incentives

a. What is the amount and type of compensation that each participant will receive?

a1. Interview– Amount: _____ Type: _____

a2. HIV testing– Amount: _____ Type: _____

b. In the following table, list the amount and type of *additional* compensation that each participant will receive. If you will not provide that additional compensation, record “N/A” for not applicable in the “Amount” field.

Local compensation provided for:	Amount	Type
Ineligibles		
Participant who passed the eligibility screener but completed only part of the interview		
Returning for HIV test result <i>(NOTE: only non-NHBS funds can be used)</i>		
Other activity or test (<i>specify</i>):		

c. In total, what is the maximum amount of compensation that each participant could potentially receive: _____

VIII – Project Staff Training and Evaluation

a. In the following table, list the project staff and the trainings they have completed:

Name of Staff Member					
Position					
ID Code (if applicable)					
Received Confidentiality Training?					
Date Signed Confidentiality Agreement					
Read NHBS-MSM4 Operations Manual?					
Read NHBS-MSM4 Interviewer Guide? <i>(for field supervisor and interviewers)</i>					

Read Package Insert for Rapid HIV Test <i>(for test counselors conducting rapid tests)</i>					
Date HIV Counseling and Testing Certification Expires <i>(for test counselors)</i>					
Viewed NHBS-MSM4 Formative Research Webinar					
Attended NHBS-MSM4 Field Operations Training					
Attended NHBS-MSM4 Data Management Training					
Other Training <i>(specify type and dates):</i>					
Other Training <i>(specify type and dates):</i>					
Evaluated and Met Performance Criteria for Position(s)?					

Instructions for completing the table:

Name of Staff Member: List the name of each staff member. Add more columns to the table if necessary or make a second copy of the table.

Position: List each staff member's position(s).

ID Code: If applicable, list the 1- or 2-digit ID code for the staff member.

Received Confidentiality Training: Prior to the start of data collection, all project staff must receive confidentiality training and they must sign a confidentiality agreement. Record *Yes* to indicate that a staff member received confidentiality training.

Date Signed Confidentiality Agreement: List the date that each staff member signed the confidentiality agreement.

Read the NHBS-MSM4 Operations Manual: Prior to the start of data collection, all project staff must read the *NHBS-MSM4 Operations Manual*. Record *Yes* to indicate that a staff member read the manual.

Read the NHBS-MSM4 Interviewer Guide: Prior to the start of data collection, the field supervisor and all interviewers must read the *NHBS-MSM4 Interviewer Guide*. Record *Yes* to indicate that these staff members read the guide.

Read Package Insert for Rapid HIV Test: All HIV test counselors conducting rapid HIV tests must read the information in the package insert for the test being used. Record *Yes* to indicate that an HIV test counselor read the test package insert.

Date HIV Counseling and Testing Certification Expires: All HIV test counselors must have valid HIV counseling and testing certification. List the date that each HIV test counselor's certification expires.

Viewed NHBS-MSM4 Formative Research Training Webinar: Record *Yes* to indicate that a staff member viewed either the live or recorded webinar.

Attended NHBS-MSM4 Field Operations Training: Record *Yes* to indicate that a staff member attended this training.

Attended NHBS-MSM4 Data Management Training: Record *Yes* to indicate that a staff member attended this training.

Other Training: Using a separate row, list each local or CDC-sponsored training that project staff have completed. Include the name of the training and the date(s) that it was conducted. Add more rows to the table if necessary.

Evaluated and Met Performance Criteria for Position(s): Prior to the start of data collection, all project staff must be evaluated and meet the performance criteria for their position(s). See **Appendices B thru G** of the *NHBS-MSM4 Operations Manual* for evaluation forms listing the performance criteria for each position. Record *Yes* to indicate that a staff member was evaluated and met these criteria.

- b. Based on the evaluation recommendations in **Table 2.3** of the *NHBS-MSM4 Operations Manual*, describe your plans for evaluating project staff during data collection (specify who will conduct the evaluations and estimate their weekly time commitment for this task):
- c. Since the field supervisor will be busy managing operations during data collection, the principal investigator or project coordinator should ideally conduct staff evaluations. If the field supervisor will also evaluate staff, describe how you will ensure that this added responsibility does not interfere with the field supervisor's ability to manage operations:
(*e.g., assign an experienced staff member to serve as acting field supervisor when the field supervisor is conducting evaluations*)

IX – HIV and Other Testing

a. Rapid HIV Testing

a1. Will you conduct rapid HIV testing?

Yes No

If Yes: Complete the remainder of section IXa (Rapid HIV Testing).

a2. Type of specimen collected:

- Blood from fingerstick
- Blood from venipuncture
- Oral

a3. Trade name of rapid HIV test: _____
(e.g., Clearview Complete, Unigold)

a4. Will you use a Rapid HIV Test Algorithm?

- Yes
- No

If Yes: Indicate the trade names of the 2nd and 3rd rapid tests used:

2nd rapid test: _____

3rd rapid test: _____

a5. Do you have a CLIA certificate of waiver?

- Yes
- No

a6. Describe the procedures you will use to ensure that rapid test results are read during the time frame indicated in the test package insert:

a7. Will you run the rapid test in a different room than the one where the participant is being interviewed?

- Yes
- No

If No: Describe the steps you will take to ensure that the interview will not be disrupted and that the participant will not be able to see the test results:

b. Laboratory-based HIV Testing: Standard Testing and Confirmatory Testing for Rapid Tests

b1. Type of specimen collected:

- Blood from venipuncture
- Dried blood spot (DBS)
- Oral

b2. **If collecting blood via venipuncture**, will an alternative specimen collection method be offered if venipuncture is not possible (i.e., phlebotomist is not available, venipuncture is not possible on participant)?

Yes No N/A

If Yes: Describe your alternative testing plan:

b3. Trade name of laboratory-based screening assay: _____
(e.g., *Abott Architect Ag/Ab Combo*, *Avioq HIV-1 Microelisa*, *Bio-Rad GS HIV-1/HIV-2 Plus O EIA*, *Bio-Rad GS HIV Combo Ag/Ab EIA*)

b4. Trade name of laboratory-based confirmatory test: _____
(e.g., *Fluorognost HIV-1 IFA*, *Gen-Probe APTIMA HIV-1 RNA*, *GS HIV-1 Western Blot*, *Multispot HIV-1/HIV-2 Rapid Test*, *OraSure HIV-1 Western Blot*)

b5. If applicable, trade name of 2nd laboratory-based confirmatory test: _____
(e.g., *Fluorognost HIV-1 IFA*, *Gen-Probe APTIMA HIV-1 RNA*, *GS HIV-1 Western Blot*, *Multispot HIV-1/HIV-2 Rapid Test*, *OraSure HIV-1 Western Blot*)

b6. If applicable, trade name of 3rd laboratory-based confirmatory test: _____
(e.g., *Fluorognost HIV-1 IFA*, *Gen-Probe APTIMA HIV-1 RNA*, *GS HIV-1 Western Blot*, *Multispot HIV-1/HIV-2 Rapid Test*, *OraSure HIV-1 Western Blot*)

b7. Name and contact information for the laboratory performing testing:

b8. Attach your laboratory specimen slip or form.

c. Specimen Storage, Transport, and Processing

c1. Describe how you will dispose of biohazard materials in the field, including where biohazard bags and sharps containers will be discarded once full:

c2. Describe how and where specimens will be stored before they are sent to the laboratory:

c3. Describe the schedule for sending specimens to the laboratory:

c4. Describe how the specimens will be sent to the laboratory:
(e.g., *courier*, *project staff*, *FEDEX*)

- c5. Describe how project staff will communicate to the laboratory which specimens are from participants who are self-reported HIV-positive:
NOTE: Regardless of the results of any screening tests performed, specimens from self-reported HIV-positive participants must receive confirmatory testing.
- c6. Will you obtain consent to store specimens for future testing (e.g., incidence testing)?

Yes No

If Yes: Describe how project staff will communicate to the laboratory which specimens should be stored because the participants gave consent and which should be destroyed because the participants did not give consent:

If Yes: Will you use the optional DBS fixative provided by CDC?

Yes No

d. HIV Counseling and Testing Procedures

- d1. Stepwise, describe your HIV counseling and testing procedures:
- d2. Attach any other HIV testing forms or logs that you plan on using (e.g., specimen transport/shipping log, risk assessment forms).

e. Test Results and Referrals to Care

- e1. Describe your procedures for returning either standard or confirmatory laboratory test results:
- e2. Will you use the optional phone reminder system (see **Section 8.7** of the *NHBS-MSM4 Operations Manual*)?

Yes No

If Yes: Attach your Appointment Reminder Call Form.

- e3. Describe your procedures for referring HIV-positive participants to care:

f. Hepatitis Testing

- f1. Will you conduct hepatitis B virus (HBV) or hepatitis C virus (HCV) testing?

Yes No

If Yes: Complete the remainder of section IXf (Hepatitis Testing).

f2. Name and contact information for the laboratory performing testing:

f3. Attach your laboratory specimen slip or form.

f4. **If conducting HCV testing**, will you be using a rapid test?

Yes No

f5. **If conducting HCV testing**, trade name of HCV screening EIA: _____
(e.g., Ortho HCV Version 3.0 ELISA, Abbott HCV EIA 2.0, VITROS Anti-HCV, AxSYM Anti-HCV, Architect Anti-HCV, Advia Centaur HCV)

f6. **If conducting HCV testing**, type of laboratory-based HCV confirmatory test:

Nucleic acid test (NAT)

None

f7. **If conducting HBV testing**, trade name of HBV screening EIA:

Trade name of Hepatitis B surface antigen (HBsAg): _____
(e.g., VITROS system [from Ortho Clinical Diagnostics], Abbott AxSYM and Abbott Prism, Siemens Advia Centaur, ETI-MAK-2 assay by Diasorin)

Trade name of antibody to HBsAg (anti-HBs): _____
(e.g., VITROS system [from Ortho Clinical Diagnostics], Abbott AxSYM and Abbott Prism, Siemens Advia Centaur, ETI-MAK-2 assay by Diasorin)

Trade name of total antibody to hepatitis B core antigen (anti-HBc): _____
(e.g., VITROS system [from Ortho Clinical Diagnostics], Abbott AxSYM and Abbott Prism, Siemens Advia Centaur, ETI-MAK-2 assay by Diasorin)

f8. Describe your procedures for referring HBV- and HCV-positive participants to care:

f9. Describe your procedures for referring participants for hepatitis A and B vaccination:

g. Other Testing

g1. List any other (non-HIV, non-hepatitis) tests you plan on conducting:

Test: _____

Will you return test results to participants?

Yes No

g2. Describe how other (non-HIV, non-hepatitis) tests will be incorporated into NHBS operations:

X – Local Questions

a. Will you ask participants local use questions after they have completed the NHBS core questionnaire?

Yes No

a1. ***If Yes:*** Attach the QDS™ interviewer version of your local use questionnaire. This is an ***.rtf*** file that you can create with the QDS™ Design Studio [under the “Build” tab, select “Questionnaire (Interviewer)”. Also include the Spanish version if you plan on conducting interviews in Spanish.

XI – Data Management

a. List the name(s) and contact information for your data manager(s):

Name	Phone	E-mail

b. List the name(s) and contact information for the staff member(s) responsible for submitting NHBS data to the DCC data portal. Also indicate the type of data that each will submit (recruitment event outcomes, surveys, test results, or data edits):

Name	Phone	E-mail	Data Type

c. Attach the following documents:

c1. Data security policy

c2. Data confidentiality policy

c3. Data transfer protocol (i.e., how data are transferred from the point of collection to the point of upload to the DCC data portal)

XII – Local Safety and Field Incident Reporting Procedures

a. Attach the following documents:

a1. Local safety protocol

a2. Field incident reporting procedures

XIII – Prevention and Other Informational Materials

a. Attach any written prevention or informational materials that will be distributed to participants.

XIV – Public Health Insurance Plans

a. List your local public health insurance plans and indigent care programs. This could be a local name for a national plan, such as Medicaid being called MediCal in California, or it could be a plan administered by your state, city, or county, such as the Texas Gold Card. You should include all plans that are administered or subsidized by the local, state, or federal government and have income, age, or disability as an eligibility criterion. You should also include any HIV-related care programs, like Ryan White.

This information should be used to train your interviewers how to properly code responses to the health insurance question in the core questionnaire. In addition, CDC data analysts will use the information to classify a participant’s health insurance as either “public,” “private,” or “other.”

Name of Insurance Plan or Indigent Care Program	Administered By	Eligibility Criteria	Comments

Instructions for completing the table:

Name of Insurance Plan or Indigent Care Program: Specify the name of the local insurance plan or care program. Add more rows to the table if necessary.

Administered By: Indicate whether the plan or program is administered by the *federal, state, or local* government, or another entity. If administered by another entity, specify what that entity is.

Eligibility Criteria: Indicate what general criteria are used to determine eligibility for the plan, such as *income, age, disability, or HIV infection*. There is no need to provide detailed eligibility criteria, like income cutoffs.

Comments: Include any additional information that may help identify or categorize a health insurance plan or care program. For example, *MediCal is the name for Medicaid in California*.

Appendix B

Field Supervisor – Project Management Evaluation Form

A model Field Supervisor Project Management Evaluation Form is shown below and on the following pages of this appendix. The actual form can be printed or modified using the Word file named **Appendix B - Field Supervisor Project Management Evaluation Form**.

General Instructions: <ul style="list-style-type: none"> To be conducted by the principal investigator or project coordinator. Shaded areas are NHBS performance recommendations. 		
Field Supervisor:	Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation	
Evaluation Date:		
Evaluator:		
Management of Staff	Rating	
1. Has trained staff members as back-ups for field supervisor, counter, recruiter, and data manager.	1 No	5 Yes
2. Has adhered to evaluation schedule for counter.	1 No	5 Yes
3. Has adhered to evaluation schedule for recruiters.	1 No	5 Yes
4. Has adhered to evaluation schedule for interviewers.	1 No	5 Yes
5. Has adhered to evaluation schedule for HIV test counselors.	1 No	5 Yes
Recruitment Event Operations Setup		
6. All supplies were prepared and tasks completed per Recruitment Event Checklist.	1 No	5 Yes
7. Information for recruitment event was documented on Recruitment Event Information & Outcomes Form.	1 No	5 Yes
8. Field site was adequately staffed (a minimum of 2 staff members in addition to the field supervisor).	1 No	5 Yes
9. Checked-in with venue owner/manager upon arrival. <input type="checkbox"/> N/A	1 No	5 Yes
10. Identified and set up spaces for interviewing and HIV testing.	1 No	5 Yes
11. Identified and set up counting area and recruitment area.	1 No	5 Yes
12. Conducted a staff meeting before recruitment event.	1 No	5 Yes

Recruitment Event Management					
13. Maintained a log of non-duplicated and sequential Survey IDs.	1 No		5 Yes		
14. Provided interviewers with a written copy of the four code numbers (Interviewer ID, Survey ID, Venue Code, and Event Number) for each participant screened.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
15. Ensured PEAs were scheduled and appointment card provided with Venue Code, Event Number, and, if applicable, Survey ID. <input type="checkbox"/> N/A	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
16. Managed recruitment by monitoring when an interviewer was available for the next participant.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
17. Checked in with recruiters periodically to assess recruitment success and, if necessary, made adjustments.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
18. Met with recruiter when five consecutive approaches were unsuccessful. <input type="checkbox"/> N/A	1 No		5 Yes		
19. Met each potential participant prior to the interview.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
20. Checked in with interviewers after each interview.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
21. Managed participant flow by monitoring when the HIV counselor was available for the next participant. <input type="checkbox"/> N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
22. Ensured participants' privacy was protected at all times.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
23. Handled attempts by outsiders to interrupt an interview or testing session. <input type="checkbox"/> N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
24. Remained aware of each team member's whereabouts.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
25. Maintained security of staff and study materials.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
26. Monitored staff interactions with participants, venue staff, and the general public.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
27. Assisted field staff when necessary. <input type="checkbox"/> N/A	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
28. Treated participants and staff with courtesy and respect.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
29. Distributed and documented participants' reimbursements.	1 No		5 Yes		
30. Ensured counting continued until the last participant was approached.	1 No		5 Yes		
31. Ensured staff were knowledgeable of safety procedures.	1 No		5 Yes		
32. Has emergency contact information for each staff member.	1 No		5 Yes		
33. Maintained Phone Results Log. <input type="checkbox"/> N/A	1 No		5 Yes		
Post Recruitment Event Management					
34. Held debriefing at completion of field site activities.	1 No		5 Yes		
35. Reviewed Participant Tracking Forms including data edits.	1 No		5 Yes		
36. Collected, reviewed, and tabulated Intercept Forms.	1 No		5 Yes		

37. Recorded recruitment event notes and outcomes in the Recruitment Event Information & Outcome Form.	1 No	5 Yes			
38. Reviewed consent forms for each participant. <input type="checkbox"/> N/A	1 No	5 Yes			
39. Reviewed HIV Test Results Log.	1 No	5 Yes			
40. Reviewed staff evaluation forms from PI or PC. <input type="checkbox"/> N/A	1 No	5 Yes			
41. Verified that all participants who consented to HIV testing had either an HIV rapid test conducted or a laboratory specimen collected.	1 No	5 Yes			
42. Portable computers and forms that contain confidential information (i.e., HIV Test Results Log, Phone Results Log, Appointment Reminder Call Forms, and Participant Tracking Forms) were kept in a locked file cabinet.	1 No	5 Yes			
43. Demonstrated adherence to the protocol including VBS methods.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
Criterion #	Skill Description, Recommendations, Accolades, and Additional Comments				
Evaluator: Please ensure that the following steps are completed with the field supervisor.					
<input type="checkbox"/> Reviewed evaluation form with the field supervisor. <input type="checkbox"/> Provided time for field supervisor to ask questions. <input type="checkbox"/> Provided the field supervisor with recommendations for improvement. <input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard.					

Appendix C

Field Supervisor – HIV Testing Operations Evaluation Form

A model Field Supervisor HIV Testing Operations Evaluation Form is shown below and on the following page of this appendix. The actual form can be printed or modified using the Word file named **Appendix C - Field Supervisor HIV Testing Operations Evaluation Form**.

General Instructions			
<ul style="list-style-type: none"> To be conducted by the principal investigator or project coordinator. Shaded areas are NHBS performance recommendations. 			
Field Supervisor:	Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation		
Evaluation Date:			
Evaluator:			
Specimen Collection, Storage, and Disposal			Rating
1. Maintains a paper log (e.g., HIV Testing Log) with no personal identifying information that links the Survey ID and the Lab ID. <input type="checkbox"/> N/A	1 No	5 Yes	
2. Only uses specimen processing and tracking forms approved as part of the Operations Checklist.	1 No	5 Yes	
3. Blood tube specimens are stored and transported in coolers that are appropriately labeled according to OSHA regulations. <input type="checkbox"/> N/A	1 No	5 Yes	
4. DBS are handled, transported to main office, packaged, and stored per the <i>Operations Manual</i> . <input type="checkbox"/> N/A	1 No	5 Yes	
5. All blood collection devices and personal protective equipment are disposed of in appropriate biohazard containers. <input type="checkbox"/> N/A	1 No	5 Yes	
6. Collects all required HIV testing variables per HIV Testing Log, Specimen Transport/Shipping Log, etc.	1 No	5 Yes	
7. Tracks whether participants have returned for their results.	1 No	5 Yes	
8. Monitors which specimens can be stored and which must be disposed of properly based on whether or not the participant provided consent for storage. <input type="checkbox"/> N/A	1 No	5 Yes	
Security and Confidentiality			
9. HIV testing forms, logs, lab results, and print outs are kept in a locked cabinet when not in the immediate possession of a staff member.	1 No	5 Yes	
10. Ensures that data from the hard copy of the HIV Testing Log are entered into the HIV Test Results Log on the DCC data portal as soon as the test results are available.	1 No	5 Yes	
11. Sensitive information, such as Appointment Reminder Call Forms, are stored and shredded according to the <i>NHBS Model Surveillance Protocol</i> .	1 No	5 Yes	

Rapid Testing <input type="checkbox"/> N/A			
12. HIV test package inserts are available for reference at the field site.	1 No	5 Yes	
13. Monitors temperature at which test kits are stored and records temperature on quality assurance logs.	1 No	5 Yes	
14. Monitors temperature at which testing is conducted and records temperature on quality assurance logs.	1 No	5 Yes	
15. Runs controls in accordance with the test package insert and records results on quality assurance logs.	1 No	5 Yes	
16. Monitors data for discordant test results (i.e., reactive rapid test and non-reactive confirmatory test).	1 No	5 Yes	
17. Conducts evaluations for all new testing staff and then every 2 weeks thereafter.	1 No	5 Yes	
Criterion #	Skill Description, Recommendations, Accolades, and Additional Comments		
<p>Evaluator: Please ensure that the following steps are completed with the field supervisor.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Reviewed evaluation form with the field supervisor. <input type="checkbox"/> Provided time for the field supervisor to ask questions. <input type="checkbox"/> Provided the field supervisor with recommendations for improvement. <input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard. 			

Appendix D

Recruiter Evaluation Form

A model Recruiter Evaluation Form is shown below and on the following page of this appendix. The actual form can be printed or modified using the Word file named **Appendix D - Recruiter Evaluation Form**.

General Instructions:					
<ul style="list-style-type: none"> To be conducted by the principal investigator, project coordinator, or if necessary, the field supervisor. Shaded areas are NHBS performance recommendations. 					
Recruiter:			Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation		
Evaluation Date:					
Evaluator:					
Introduction			Rating		
1. Approached venue attendees ONLY when directed.			1 No		5 Yes
2. Approached attendees in a calm and friendly manner.			1 Not at all	2 Poorly	3 Okay
3. Introduced self appropriately.			4 Well	5 Very well	
4. Stated the name and objective of the project.			1 Not at all	2 Poorly	3 Okay
			4 Well	5 Very well	
Intercept					
5. Recorded each approach in the number (#) column on the Intercept Form, even for those who did not stop.			1 No		5 Yes
6. Asked the <i>Previous Participation Question</i> of those who stopped. <input type="checkbox"/> N/A			1 No		5 Yes
7. For each approach, recorded a response to the <i>Previous Participation Question</i> on the Intercept Form, even for those who did not stop.			1 No		5 Yes
8. Did not pre-screen participants based on any eligibility criteria.			1 Pre-screened		5 Did not pre-screen
Invitation to Participate					
9. All participants who answered "No" or "Don't Know" to the <i>Previous Participation Question</i> were invited to participate in the project. <input type="checkbox"/> N/A			1 No		5 Yes
10. Clearly explained purpose and benefits of the project. <input type="checkbox"/> N/A			1 Not at all	2 Poorly	3 Okay
			4 Well	5 Very well	

Recruitment Technique					
11. Appeared enthusiastic about the study.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
12. Addressed barriers to <u>recruitment</u> in an appropriate and effective manner. <input type="checkbox"/> N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
13. Addressed barriers to <u>participation</u> in an appropriate and effective manner. <input type="checkbox"/> N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
14. Demonstrated effective interaction conducive to encouraging enrollment (e.g., walked with person, neither coercive nor meek).	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
Criterion #	Skill Description, Recommendations, Accolades, and Additional Comments				
Evaluator: Please ensure that the following steps are completed with the recruiter. <ul style="list-style-type: none"> <input type="checkbox"/> Reviewed evaluation form with the recruiter. <input type="checkbox"/> Provided time for the recruiter to ask questions. <input type="checkbox"/> Provided the recruiter with recommendations for improvement. <input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard. 					

Appendix E

Interviewer Evaluation Form

A model Interviewer Evaluation Form is shown below and on the following pages of this appendix. The actual form can be printed or modified using the Word file named **Appendix E - Interviewer Evaluation Form**.

General Instructions <ul style="list-style-type: none"> To be conducted by the principal investigator, project coordinator, or, if necessary, field supervisor. It is recommended that the evaluator have a portable computer to follow along during the interview. Permission must be obtained from the potential participant before an evaluator joins an interview. The evaluator should only interrupt the interview for major issues, be discreet when doing so, and direct questions to the interviewer. Shaded areas are NHBS performance recommendations. 					
Interviewer:	Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation				
Evaluation Date:					
Evaluator:					
Time to Complete Survey	Time				
1. Eligibility screener	Start: _____	End: _____	Length: _____		
2. Consent process	Start: _____	End: _____	Length: _____		
3. Core questionnaire	Start: _____	End: _____	Length: _____		
4. Local questionnaire <input type="checkbox"/> N/A	Start: _____	End: _____	Length: _____		
Set-up	Rating				
5. Checked date and time on portable computer before starting.	1 No		5 Yes		
6. All materials needed were prepared & organized before starting (flashcards, consent forms, prevention materials, referral information, pens, etc.).	1 No		5 Yes		
7. Was knowledgeable of safety procedures.	1 No		5 Yes		
Consent Process					
8. No personal identifiers (e.g., name, address) were recorded.	1 Recorded		5 Not recorded		
9. <u>All</u> aspects of informed consent were followed per local IRB requirements (i.e., read as written if required; covered all relevant points if summarized).	1 No		5 Yes		
10. Provided the participant a copy of consent form to follow along.	1 No		5 Yes		
11. Offered the participant a copy of the consent form to keep.	1 No		5 Yes		
12. Provided an opportunity for questions about the project and consent process.	1 No		5 Yes		
13. Ensured participant understood anonymous nature of NHBS (i.e. will NOT ask for participant name; participant names NEVER linked to interviews or test results).	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well

14. Obtained a <u>separate</u> consent for the interview.	1 No		5 Yes		
15. Obtained a <u>separate</u> consent for HIV testing.	1 No		5 Yes		
16. Obtained a <u>separate</u> consent for specimen storage or additional testing. <input type="checkbox"/> N/A	1 No		5 Yes		
17. Pace of reading the consent was...	1 Too slow	1 Too fast	5 Just right		
Survey Administration					
18. Oriented the participant by reading introductory statement for core survey.	1 No		5 Yes		
19. Read questions, definitions, & transition statements as written.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
20. Followed survey instructions to read or not read response options.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
21. Reread and clarified instructions, questions, and responses, when needed. <input type="checkbox"/> N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
22. Recognized inconsistent responses, clarified with participant, and corrected data in the portable computer or on the Participant Tracking Form. <input type="checkbox"/> N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
23. Probed incomplete, unclear, and, as appropriate, "don't know" responses. <input type="checkbox"/> N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
24. Used <u>neutral</u> probes (i.e., probed without influencing response).	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
25. Ensured participant was never able to view the portable computer screen.	1 No		5 Yes		
26. The amount of time given for responses was...	1 Too short	1 Too long	5 Just right		
27. Pace of reading the screener was...	1 Too slow	1 Too fast	5 Just right		
28. Pace of reading the questionnaire was...	1 Too slow	1 Too fast	5 Just right		
Flashcards					
29. Used flashcards when instructed.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
30. Oriented the participant to the flashcard response options (i.e., pointed to responses as being read).	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
31. Read the flashcards as written.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
Establishing and Maintaining Rapport					
32. Established and maintained a good yet neutral rapport with participant (i.e., demonstrated interest, empathy, appropriate tone, and, if needed, refocused participant).	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
33. Maintained eye contact with participant throughout interview.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
34. Provided neutral feedback throughout the interview.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
35. Remained engaged with participant and his responses throughout the survey.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
36. Demonstrated a professional demeanor.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always

Criterion #	Skill Description, Recommendations, Accolades, and Additional Comments

Evaluator: Please ensure that the following steps are completed with the interviewer.

- Asked the interviewer how any unclear responses were entered into the portable computer.
- Reviewed how the interviewer coded the question regarding the validity of answers.
- Reviewed evaluation form with the interviewer.
- Provided time for interviewer to ask questions.
- Provided the interviewer with recommendations for improvement.
- If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard.

Appendix F

HIV Counseling and Testing Evaluation Form

A model HIV Counseling and Testing Evaluation Form is shown below and on the following pages of this appendix. The actual form can be printed or modified using the Word file named **Appendix F - HIV Counseling and Testing Evaluation Form**.

General Instructions <ul style="list-style-type: none"> To be conducted by the principal investigator, project coordinator, or, if necessary, the field supervisor. Permission must be obtained from the participant before an evaluator joins the HIV testing session. The evaluator should only interrupt the session for major issues, be discreet, and only direct questions to the counselor. Shaded areas are NHBS performance recommendations. This form may be modified to reflect local counseling and testing regulations. 						
HIV Test Counselor:		Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation				
Evaluation Date:						
Evaluator:						
Test Preparation		Rating				
1. Prepared all necessary materials prior to starting (HIV testing kit, phlebotomy and DBS materials, HIV Testing Log, referrals, information handouts, personal protective equipment, etc.).		1 Not at all	2	3 Some	4	5 Fully
2. Verified on Participant Tracking Form that consent for HIV testing was provided.		1 No		5 Yes		
3. Verified with participant that he is interested in getting tested and has provided appropriate consent(s), including specimen storage and other tests if applicable.		1 No		5 Yes		
4. Discreetly obtained relevant behavioral risk information from interviewer. <input type="checkbox"/> N/A		1 No		5 Yes		
Testing Procedures						
5. Conducted test in an appropriate environment (temperature, lighting, adequate work space, etc.).		1 No		5 Yes		
6. Labeled all specimens or test devices with survey ID or lab ID.		1 No		5 Yes		
7. Did not record any personal identifiers, other than for reminder call if applicable.		1 Collected identifiable info		5 Did not collect identifiable info		
8. Adequately counseled participant on what to expect during specimen collection.		1 No		5 Yes		
9. Collected DBS from fingerstick according to procedures in the <i>NHBS Operations Manual</i> . <input type="checkbox"/> N/A		1 No		5 Yes		
10. Adhered to OSHA regulations for universal precautions (gloves) and for proper waste disposal in approved biohazard and sharps containers.		1 No		5 Yes		

11. Provided a phone number or scheduled appointment to obtain HIV test result. <input type="checkbox"/> N/A	1 No	5 Yes			
12. Provided appointment card and counseled participant that card must be presented to obtain HIV test result. <input type="checkbox"/> N/A	1 No	5 Yes			
13. Offered an appointment reminder call to the participant. <input type="checkbox"/> N/A	1 No	5 Yes			
Rapid Testing <input type="checkbox"/> N/A					
14. When opening pouch with test cassette, checked for desiccant pack and discarded test cassette if no desiccant pack was present.	1 No	5 Yes			
15. Knew the information listed in the package insert, including critical elements such as the temperature ranges for storage and testing.	1 No	5 Yes			
16. Performed test <u>exactly as directed by the package insert</u> . (Critical element: To ensure consistency, evaluator must use the package insert for every evaluation of tester's performance.)	1 No	5 Yes			
17. Read rapid test result within the appropriate time frame for test performed (INSTI: immediately, Unigold: 10-20 min, Clearview: 15-20 min, Oraquick 20-40 min).	1 No	5 Yes			
18. Participant could not view rapid test during test development.	1 No	5 Yes			
19. Read test result under adequate lighting.	1 No	5 Yes			
20. Knew how to read a positive, negative, or invalid test result; and knew what steps to take when returning these test results.	1 No	5 Yes			
21. Recorded test result and properly completed all steps for returning result.	1 No	5 Yes			
22. Gave participant the subject information pamphlet from test kit.	1 No	5 Yes			
Test Counseling					
23. Conducted pre-test counseling <i>after</i> the survey was completed. <input type="checkbox"/> N/A	1 No	5 Yes			
24. Collected self-reported HIV status according to the guidance in the <i>NHBS Operations Manual</i> .	1 No	5 Yes			
25. Provided HIV information regarding transmission, risk factors, etc.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
26. Clarified misconceptions of HIV and corrected false information. <input type="checkbox"/> N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
27. Assessed barriers to risk reduction and explored methods to reduce or remove those barriers.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
28. Developed risk reduction steps that were participant-driven, appropriate for participant's situation, explicit, and achievable.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
29. Targeted prevention messages to specific risks identified during the survey and risk assessment.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
30. Returned test result in a manner that preserved participant's privacy. <input type="checkbox"/> N/A	1 No	5 Yes			
31. Ensured participant fully understood the HIV test result. <input type="checkbox"/> N/A	1 No	5 Yes			

32. Discussed disclosure of HIV status to partner(s) and discussed how to ask partner's HIV status.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
33. Provided and explained referral to medical care and case management. <input type="checkbox"/> N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
34. Provided informational materials on prevention, testing resources, medical services, and other support services; and when necessary, provided referrals to those services.	1 No		5 Yes		
35. Allowed participant to ask questions and raise concerns, and provided appropriate answers.	1 No		5 Yes		
36. Spoke at the participant's level of understanding.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
Criterion #	Skill Description, Recommendations, Accolades, and Additional Comments				
<p>Evaluator: Please ensure that the following steps are completed with the HIV test counselor.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Reviewed evaluation form with the HIV test counselor. <input type="checkbox"/> Provided time for HIV test counselor to ask questions. <input type="checkbox"/> Provided the HIV test counselor with recommendations for improvement. <input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard. 					

Appendix G

Data Manager Evaluation Form

A model Data Manager Evaluation Form is shown below and on the following page of this appendix. The actual form can be printed or modified using the Word file named **Appendix G - Data Manager Evaluation Form**.

General Instructions <ul style="list-style-type: none"> To be conducted by the principal investigator or project coordinator. Shaded areas are NHBS performance recommendations. 		
Data Manager:	Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation	
Evaluation Date:		
Evaluator:		
Data Management	Rating	
1. Ensured daily receipt of the Participant Tracking Form (including data edits), Recruitment Event Information & Outcomes Form, Intercept Forms, HIV Testing Log, and other forms, if applicable.	1 No	5 Yes
2. Successfully uploaded data from each portable computer to the desktop computer.	1 No	5 Yes
3. Reviewed QDS™ data files from each portable computer and compared the Survey IDs with the Survey IDs recorded on the Participant Tracking Forms or similar forms.	1 No	5 Yes
4. Transferred records from QDS™ data files (e.g., files with *.QAD extension) to the QDS™ Warehouse successfully.	1 No	5 Yes
5. Did not delete QDS™ data files on the portable computer until after confirming the records were added to the QDS™ Warehouse.	1 No	5 Yes
6. Reviewed data discrepancies and concerns with the field supervisor or project coordinator to determine resolutions.	1 No	5 Yes
7. Documented data discrepancies and their resolution on the Participant Tracking Form. <input type="checkbox"/> N/A	1 No	5 Yes
8. Entered data edits from the Participant Tracking Form into the online Data Error Log on the DCC data portal daily. <input type="checkbox"/> N/A	1 No	5 Yes
9. Successfully entered HIV testing data, including laboratory test results, into the online HIV Test Results Log on the DCC data portal.	1 No	5 Yes
10. Successfully entered recruitment event outcomes into VDTs Program on the DCC data portal after each event. <input type="checkbox"/> N/A	1 No	5 Yes
11. Successfully encrypted NHBS data using PGP software.	1 No	5 Yes

General		
12. Knows how to ask the DCC questions and understands how to access information on the DCC data portal.	1 No	5 Yes
13. (Weekly) Submits QDS™ Warehouse containing core interview files to the DCC data portal. (Note: Please contact the DCC before sending a mock data warehouse to test this procedure.)	1 No	5 Yes
14. (Weekly) Reviews Process Monitoring Reports and communicates discrepancies with DCC.	1 No	5 Yes
15. (Monthly) Reviews DCC Data Management Reports and responds to inquiries on a timely basis.	1 No	5 Yes
16. Responds to DCC communications on a timely basis.	1 No	5 Yes
Criterion #	Skill Description, Recommendations, Accolades, and Additional Comments (continued)	
<p>Evaluator: Please ensure that the following steps are completed with the data manager.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Reviewed evaluation form with the data manager. <input type="checkbox"/> Provided time for the data manager to ask questions. <input type="checkbox"/> Provided the data manager with recommendations for improvement. <input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard. 		

Appendix H

Recruitment Event Checklist

The Recruitment Event Checklist is shown below. The actual checklist can be printed or modified using the Word file named **Appendix H - Recruitment Event Checklist**.

1 – Tasks to Complete 1-2 Weeks Prior to Recruitment Event

- Record the recruitment event and calendar information in **Section I** of *Recruitment Event Information & Outcomes Form* (alternatively, this information could be output from the VDTs Program and attached).
- Contact the venue owner, manager or other designated contact person to notify them that the team will be in or near the venue conducting a recruitment event on the specific day and time.
- Obtain a permit to block off a van parking space near the venue (if applicable).
- Schedule project staff and record in **Section 2** of *Recruitment Event Information & Outcomes Form*.
- If applicable, schedule evaluations for project staff and record in **Section 2** of *Recruitment Event Information & Outcomes Form*.
- Record Interviewer IDs in **Section 2** of *Recruitment Event Information & Outcomes Form*.

2 – Tasks to Complete Right Before Recruitment Event

- Check that batteries for the portable computers are fully charged and working properly.
- Check that data from the previous recruitment event have been uploaded from the portable computers to the QDS™ Warehouse.
- Check that correct date and time are displayed on portable computers.
- If applicable, make sure the van has a full tank of gas, the septic tank has been emptied, the propane or natural gas supply checked, and the water supply replenished.
- Have emergency contact information for project staff readily accessible.
- Determine the next sequential Survey ID and Event Number and record them in **Section 3** of *Recruitment Event Information & Outcomes Form*.
- Gather recruitment event supplies.

Equipment:

- Portable computers (1 for each interviewer and backups)
- AC adaptors for portable computers
- Tally counter (i.e., “clicker”)
- Communications equipment (e.g., 2-way radios or cell phones)
- Other equipment: _____

Miscellaneous items:

- Consent forms for each interviewer and the expected number of participants
- Flashcards (**Appendix E** of *NHBS Round 4 Model Surveillance Protocol*)
- Interview and test incentives to cover the expected number of participants
- Incentive log, receipt book, or other forms of incentive tracking
- The current month’s recruitment calendar
- Signed Memorandums of Understanding (if applicable)
- Other items: _____

Blank forms or logs:

- Survey ID Log
- Intercept Forms
- Participant Tracking Forms
- Appointment and Phone Results Cards (if applicable)
- Appointment Log (if applicable)
- Appointment Reminder Call Form (if applicable)
- Phone Results Log (if applicable)
- HIV Testing Log (**Appendix L** of *NHBS Round 4 Model Surveillance Protocol*)
- Rapid Testing Quality Control Log (if applicable)
- Rapid Testing Temperature Log (if applicable)
- Lab slips
- Specimen Transport/Shipping Log
- Field Supervisor- Project Management Evaluation Form
- Field Supervisor- HIV Testing Operations Evaluation Form
- Recruiter Evaluation Form
- Interviewer Evaluation Form

- HIV Counseling and Testing Evaluation Form
- Other forms or logs: _____

Prevention and referral materials:

- Informational and educational pamphlets
- List of referral agencies and contact persons
- HIV risk reduction supplies (e.g., condoms, lube)
- Other materials: _____

Guidance documents:

- NHBS Round 4 Model Surveillance Protocol*
- NHBS-MSM4 Formative Research Manual*
- NHBS-MSM4 Operations Manual*
- NHBS-MSM4 Interviewer Guide*
- Other documents: _____

- Gather HIV testing supplies.

Rapid testing supplies (if applicable):

- Tests
- Lancets
- Fingertstick blood collection devices (i.e., pipettes or loops)
- Test reagents (i.e., developer solution, wash solution, and running buffer)
- Package inserts for the specific rapid test being used
- Other rapid testing supplies: _____

Standard or laboratory testing supplies:

- Whole blood specimen collection tubes (if applicable)
- Phlebotomy equipment (e.g., butterfly needles, tube stopper, tourniquet)
- DBS collection cards
- DBS collection devices (i.e., blade lancets if from fingerstick or transfer pipettes if from blood tube)
- Oral fluid collection devices (if applicable)
- Other laboratory testing supplies: _____

Miscellaneous testing supplies:

- Alcohol swabs
- Dry sterile gauze or cotton balls

- Band-aids
- Biohazard “sharps” container for lancets and needles
- Biohazard bags for non-sharp blood waste (e.g., gloves, chucks, band-aids)
- Personal protective equipment (i.e., latex gloves, lab coat [optional])
- Absorbent paper (e.g., chucks)
- Disinfectant cleaner (e.g., wipes, diluted Lysol, 10% bleach solution)
- Other testing supplies: _____

3 – Tasks for Setting Up at Recruitment Event

- Check-in with venue owner, manager, or designated contact person upon arriving at the venue.
- Identify and set up spaces for interviewing and HIV testing.
- Identify area where counting will take place.
- Identify area where recruitment will take place.
- Hold pre-event meeting with project staff to discuss operational plans.
- If applicable, obtain Pre-Event Count immediately before recruitment event is ready to begin and record the Pre-Event Count (from the tally counter or “clicker”) in **Section 5** of *Recruitment Event Information & Outcomes Form*.

4 – Closeout Tasks to Complete at Recruitment Event

- Hold post-event debriefing.
 - Discuss how recruitment event went in general.
 - Discuss any venue-related issues that affected project operations (e.g., problems with management, change in attendee population).
 - Discuss any barriers related to recruitment or participation, as well as strategies for overcoming these barriers.
 - Discuss any unusual events (e.g., participant ended survey early, participant who initially consented to HIV test changed his mind).
 - Discuss problems with portable computers.
 - Discuss possible errors in survey data entry.
 - For rapid testing, discuss if there were any newly diagnosed HIV+

persons and whether results were returned and if participant was anonymously referred to care and follow-up HIV testing.

- Discuss any problems with HIV specimen collection or test kits.
- Record recruitment event notes in **Section 4** of *Recruitment Event Information & Outcomes Form*.
- Record the Entry Count (from the tally counter or “clicker”) in **Section 5** of *Recruitment Event Information & Outcomes Form*.
- Collect and review forms and logs.

With Recruiters:

- Collect Intercept Forms.
- Review Intercept Forms for accuracy.
- Tabulate column sub-totals for the number of venue attendees approached, the responses to the Previous Participation Question, the number of post-event appointments (PEAs) scheduled, and the number of venue attendees who agreed to screening. Record the sub-totals at the bottom of each Intercept Form.
- If applicable, cross-check Intercept Forms and Appointment Log to ensure that all PEAs have been scheduled.
- If applicable, review Recruiter Evaluation Form(s) or note if scheduled evaluation(s) did not occur and need to be re-scheduled.

With Interviewers:

- Collect Participant Tracking Forms.
- Review code numbers, data edits, and other information on Participant Tracking Forms.
- Cross-check Survey ID Log with Participant Tracking Forms and note any errors with Survey IDs.
- If applicable, review Interviewer Evaluation Form(s) or note if scheduled evaluation(s) did not occur and need to be re-scheduled.

With HIV Test Counselors:

- Collect HIV Testing Log.
- Review HIV Testing Log for completeness.
- Cross-check that there is a specimen for each entry on the HIV Testing Log.
- Cross-check that there is a lab slip for each standard/laboratory or

confirmatory test specimen.

- Check for Lab ID accuracy on HIV Testing Log and on lab slip.
- Check HIV Testing Log to ensure that appointments have been scheduled for HIV test results.
- If applicable, collect Appointment Reminder Call Form and check for completeness.
- If applicable, collect Phone Results Log and check for accuracy and completeness.
- If applicable, review HIV Counseling and Testing Evaluation Form(s) or note if scheduled evaluation(s) did not occur and need to be re-scheduled.

5– Closeout Tasks to Complete at Project Office

Test specimens:

- While waiting to ship HIV test specimens, store them at the appropriate temperature indicated by the laboratory.
- Place DBS cards in a location away from direct sunlight to finish drying.
- Package DBS in ziplock bags when drying is completed (not to exceed 24 hours)
- If not completed in the field, complete Specimen Transport/Shipping Log.
- Ship standard/laboratory HIV test specimens to local laboratory.
- Ship DBS cards to CDC on a weekly basis.

Data:

- Upload NHBS core interview files from portable computers into respective QDS™ Warehouse.
- Upload local survey files from portable computers into respective QDS™ Warehouse.
- Charge and lock up portable computers.
- Lock up completed forms and logs.

DCC Data Portal:

- Enter data edits from Participant Tracking Forms into ***online*** Data Error Log.
- Enter data from ***hardcopy*** HIV Testing Log into ***online*** HIV Test Results Log.

- Enter SRP information from Participant Tracking Forms into *online* HIV Test Results Log.
- Indicate the venue(s) where the recruitment event(s) were conducted (**Section 5** of *Recruitment Event Information & Outcomes Form*) in the Outcomes Section of the VDTS Program.
- Enter the Pre-Event Count and the Entry Count (**Section 5** of *Recruitment Event Information & Outcomes Form*) into the Outcomes Section of the VDTS Program.
- Enter the column sub-totals from each Intercept Form into the Outcomes Section of the VDTS Program.
- If applicable, record reason(s) why alternate venue(s) were used (**Section 5** of *Recruitment Event Information & Outcomes Form*) in the Outcomes Section of the VDTS Program.

Appendix J

Recruitment Event Information & Outcomes Form

A model Recruitment Event Information & Outcomes Form is shown below and on the following pages of this appendix. The actual form can be printed or modified using the Word file named **Appendix J - Recruitment Event Information & Outcomes Form**.

1 – Recruitment Event and Calendar Information

Record information in the table below or attach a print-out from the VDTS Program:

Scheduled Recruitment Event	
Day (circle one): Sun Mon Tue Wed Thu Fri Sat	
Date: ___ / ___ / _____	
Start time: ___ : ___ AM PM	
End time: ___ : ___ AM PM	
Primary Venue	
Venue Name:	Venue Code:
Venue Address:	
Venue Contact (name and phone #):	
Alternate 1	
Venue Name:	Venue Code:
Venue Address:	
Venue Contact (name and phone #):	
Alternate 2	
Venue Name:	Venue Code:
Venue Address:	
Venue Contact (name and phone #):	

2 – Project Staff Information

	Evaluation Scheduled?	Portable Computer #	Interviewer ID
Field Supervisor:	<input type="checkbox"/>		
Counter:	<input type="checkbox"/>		
Recruiter(s):			
<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/>	<input type="checkbox"/>		
Interviewers:			
<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
<input type="checkbox"/>	<input type="checkbox"/>	_____	_____

3 – Recruitment Event Code Numbers

Next sequential Survey ID:
Next sequential Event Number:

4 – Post-event Debriefing Notes

5 – Recruitment Event Notes

<p>Describe where counting, recruitment, interviewing, and HIV testing were conducted at the venue.</p>
<p>Describe any barriers to project operations at the venue. Describe any strategies to overcome these barriers.</p>
<p>Describe attendance at the venue (crowded, sparsely attended, etc.). Describe if and how project operations were adjusted based on attendance (e.g., recruitment area moved, interviews conducted outside because too crowded inside).</p>
<p>Were there any significant changes in the demographics of the population at the venue since it was last visited or assessed? If yes, explain:</p>
<p>Should the venue be removed from the sampling frame? If yes, explain:</p>
<p>For the venue where the recruitment event was conducted, were any new day-time periods suggested by venue attendees? If yes, when:</p>
<p>Were any new venues suggested by venue attendees? If yes, where and when:</p>

6 – Recruitment Event Outcomes

Indicate whether recruitment events were conducted at the primary venue or alternate venues. For each event conducted, record the Event Number and count information.

Primary Venue:
Was recruitment event conducted? <input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes: Event Number _____
Was the Pre-Event Count obtained? <input type="checkbox"/> Yes <input type="checkbox"/> No (No entrance) <input type="checkbox"/> No (Other)
If Yes: Pre-Event Count _____
If No (Other): Explain why:
Entry Count _____
Were there additional entrances where venue attendees were not counted? <input type="checkbox"/> Yes <input type="checkbox"/> No
Alternate 1:
Was recruitment event conducted? <input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes: Event Number _____
Was the Pre-Event Count obtained? <input type="checkbox"/> Yes <input type="checkbox"/> No (No entrance) <input type="checkbox"/> No (Other)
If Yes: Pre-Event Count _____
If No (Other): Explain why:
Entry Count _____
Were there additional entrances where venue attendees were not counted? <input type="checkbox"/> Yes <input type="checkbox"/> No
Explain why the recruitment event was conducted at an alternate venue:
Alternate 2:
Was recruitment event conducted? <input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes: Event Number _____
Was the Pre-Event Count obtained? <input type="checkbox"/> Yes <input type="checkbox"/> No (No entrance) <input type="checkbox"/> No (Other)
If Yes: Pre-Event Count _____
If No (Other): Explain why:
Entry Count _____
Were there additional entrances where venue attendees were not counted? <input type="checkbox"/> Yes <input type="checkbox"/> No
Explain why the recruitment event was conducted at an alternate venue:

Appendix K

Participant Tracking Form

A model Participant Tracking Form is shown below. The actual form can be printed or modified using the Word file named **Appendix K - Participant Tracking Form**.

Participant Tracking Form

Date

Portable Computer #

Data Manager Use Only:

Interview Start Time

Interviewer ID

Survey ID

Venue Code

Event #

INTERVIEWER	NOTES
1. Passed the eligibility screener? Y N	
2. Consented to the interview? Y N	
3. Consented to the HIV test? Y N	
4. Consented to other tests? Y N	
5. Consented to blood storage? Y N	
6. SRP during interview? Y N	
7. Completed the interview? Y N	

TEST COUNSELOR					
1. Obtained test specimen? Y N					
2. SRP during counseling? Y N D R Not Asked					
<i>If yes, SRP date:</i> _____			D	R	
3. Made necessary care referrals? Y N					

DATA EDITS:

Variable Name	Old Value	New Value

Appendix L

Strategies for Overcoming Recruitment Barriers

Recruitment Barriers	Strategies for Overcoming
<p>1. Avoidance</p> <p>Some men may not initially respond to or acknowledge the recruiter when approached. Others may respond, but continue walking.</p>	<p>Within reason, walk a short distance with men who do not initially stop. Terminate the intercept if they continue to walk and ignore you, or if they explicitly gesture or state that they do not wish to answer your questions.</p>
<p>2. Groups</p> <p>Recruiters may frequently encounter groups of two or more men who could be approached for recruitment. Yet, group intercepts can be difficult to manage because one or more members of the group may negatively influence the others.</p>	<p>In most circumstances, the recruiter should systematically approach and intercept one member of the group. If more than one interviewer is available, the recruiter has the option of intercepting as many members of the group as there are interviewers available. In addition, if there is more than one recruiter, multiple recruiters can approach the group and divide its members into more manageable units. Field supervisors should monitor potential negative peer influences such as some group members trying to dissuade others from completing the intercept. When negative influences are identified, field supervisors should attempt to engage these group members to minimize their impact.</p>

Recruitment Barriers	Strategies for Overcoming
<p>3. Time</p> <p>Some men may try to deter the intercept by disclosing that they do not have time to stop or that they are in a hurry.</p> <p><i>Examples:</i></p> <p>“I’m late.”</p> <p>“I’m in a hurry.”</p> <p>“I don’t have time.”</p> <p>“My friends are waiting for me.”</p> <p>“I’m on my way <somewhere>.”</p>	<p>Prospective participants are not aware of how little time is required to complete the intercept. They may also be unaware of the importance of NHBS-MSM. Tell them that it takes very little time to complete the intercept and that they are helping an important cause.</p> <p><i>Examples:</i></p> <p>“No problem, I’ll walk with you if that is OK.”</p> <p>“This will only take a minute of your time and your help is important.”</p> <p>“This will be quick and it’s for an important cause. This is part of a health survey that can help our community.”</p>
<p>4. Ineligibility</p> <p>Some people may try to deter the intercept by stating that they are ineligible for the survey.</p> <p><i>Examples:</i></p> <p>“I’m too young/old.”</p> <p>“I’m not from around here.”</p>	<p>Don’t assume that the person understands NHBS-MSM eligibility criteria. Again, stay positive and do your best to motivate the person to complete the intercept.</p> <p><i>Examples:</i></p> <p>“No problem, your age/residence doesn’t matter for this question. It would be great if you could help us out; it’s for an important cause.”</p>

Recruitment Barriers	Strategies for Overcoming
<p>5. Previous Participation</p> <p>Some men may try to deter the intercept by stating that they have already participated in the survey.</p> <p>Examples:</p> <p><i>“I’ve already done it.”</i></p> <p><i>“I’ve already been interviewed.”</i></p> <p><i>“You spoke to me last month.”</i></p>	<p>Unless the recruiter is certain that the venue attendee has already participated in NHBS-MSM during the current cycle, they should do their best to complete the intercept. Many men may confuse other research projects or previous NHBS cycles with the current NHBS cycle. Thus, the recruiter should try to verify that the venue attendee has already participated in the current cycle of NHBS-MSM. However, if a venue attendee tells the recruiter that he already participated in the current cycle of NHBS-MSM and the recruiter is certain that he did, the recruiter can end the intercept and just complete the Intercept Form (circle “Y” in the “Previously Participated” field).</p> <p>Examples:</p> <p><i>“Let’s be sure; it may not have been us. Let me ask you a few quick questions; it’s important that I get this right.”</i></p> <p>Ask one or more of the following questions–</p> <p>To confirm if it is an NHBS-MSM VDT: <i>“When and where were you interviewed?”</i></p> <p>If standard clothing is worn: <i>“What was the interviewer wearing?”</i></p> <p><i>“Did the person who interviewed you have an ID badge like this (show ID badge)?”</i></p> <p><i>“What was the interview about?”</i></p> <p><i>“How long did the interview take?”</i></p>

Recruitment Barriers	Strategies for Overcoming
<p>6. Previous Non-participation</p> <p>Some men may try to deter the intercept by stating that they have already declined participation in the survey.</p> <p>Examples:</p> <p><i>“I already said no.”</i></p> <p><i>“I told them last week I didn’t have time.”</i></p>	<p>Attempting to get people to stop and complete the intercept may be difficult if they state that they have previously refused to participate. Again, stay positive and do your best to ensure that he is not confusing NHBS-MSM with other research or outreach efforts. Even if you are sure that the person has previously declined participation, attempt to complete the intercept in a friendly and confident manner (what you are doing is important!). Moreover, men who have previously declined to participate in the survey should be given another opportunity to participate.</p> <p>Examples:</p> <p><i>“Let’s be sure; it may not have been us. Let me ask you a few quick questions; it’s important that I get this right.”</i></p> <p>Ask one or more of the following questions–</p> <p>To confirm if it is an NHBS-MSM VDT: <i>“When and where were you approached?”</i></p> <p>If standard clothing is worn: <i>“What was the person who approached you wearing?”</i></p> <p><i>“Did the person who approached you have an ID badge like this (show ID badge)?”</i></p>

Participation Barriers	Strategies for Overcoming
<p>1. Time</p> <p>One of the most frequently given participation barriers is lack of time.</p> <p>Examples:</p> <p><i>“I’m late.”</i></p> <p><i>“I really don’t have time right now.”</i></p> <p><i>“I’m in a hurry; I’m supposed to be meeting friends.”</i></p> <p><i>“I’m busy.”</i></p>	<p>To encourage an intercepted man to agree to participate in NHBS-MSM, emphasize the relatively brief amount of time needed to complete the survey, its incentive, and its benefits to the community. Lack of time may not be an issue once he considers how long the interview will actually take, the importance of the survey, and the compensation. Keep in mind that lack of time may be used to mask other more important barriers, such as disinterest, concerns about privacy, and distrust. If necessary, explore and address these other potential barriers.</p> <p>Examples:</p> <p><i>“The interview doesn’t take too long for the money you’ll earn. We’ll pay you up to \$50 for your time. It’s anonymous and it’s for a very important cause. We’re trying to make a difference in our community and we could really use your help.”</i></p>

Participation Barriers	Strategies for Overcoming
<p>2. Disinterest</p> <p>Another frequent participation barrier is disinterest. Some men may not be interested in participating in research, while others may not be interested because of existing plans or activities.</p> <p>Examples:</p> <p><i>“I’m not really interested.”</i></p> <p><i>“I’m not interested in participating in research.”</i></p> <p><i>“It’s my only night off.”</i></p> <p><i>“I’m here to have fun/drink/dance/be with friends.”</i></p>	<p>If possible, explore and address the underlying reasons for the intercepted man’s stated or implied disinterest. For example, is his disinterest due to a lack of knowledge about the value of NHBS for HIV prevention, his having plans for the evening, his mistrust of research, or is it due to another reason? To help establish rapport when exploring why an intercepted man is disinterested, begin with one or more motivations (community benefit, incentive, etc.). Avoid directly asking “Why not?” which may be perceived as pushy or coercive.</p> <p>Examples:</p> <p><i>“This survey is important; it may help us get more resources to help our community and improve our HIV prevention programs.”</i></p> <p><i>“This isn’t just being offered in <city>. We’re part of a national effort and our community needs to be fully represented. It would be great if you could take part and help ensure that we are.”</i></p> <p>If the intercepted man is still reluctant to participate (but does not explicitly refuse), attempt to identify specific barriers. Sometimes it is helpful to suggest a possible reason for his reluctance to prompt him to share his concerns.</p> <p>Examples:</p> <p><i>“I understand you’re reluctant to participate. What is it about the survey that concerns you? Is it privacy?”</i></p>

Participation Barriers	Strategies for Overcoming
<p>3. Friends & Partners</p> <p>Recruiters may have a difficult time enrolling men who are meeting others or who have plans for the evening. However, some men who are with friends or partners may not have specific plans and may participate if other enrollment barriers are addressed.</p> <p>Examples:</p> <p><i>“I don’t want to leave my friends/partner.”</i></p> <p><i>“I can’t leave my friend/partner alone.”</i></p> <p><i>“I’m meeting friends/my partner.”</i></p> <p><i>“My friends won’t wait.”</i></p>	<p>Don’t assume that an intercepted man cannot or will not participate just because he is with friends or a partner. First, assess whether or not he wishes to participate in NHBS-MSM. If a man agrees to participate, try to keep his friends or partner occupied. Engage them in conversation, keep them comfortable by giving them a place to sit (folding chairs), provide them with prevention materials, or if it can be arranged with venue management, offer them priority entry to the venue.</p> <p>Examples:</p> <p><i>“Your friend/partner can hang out with us; we’ll take care of him.”</i></p> <p>Try humor: <i>“Your friend/partner will wait for you– tell him with the \$50 you earn you can take him out to dinner!”</i></p>

Participation Barriers	Strategies for Overcoming
<p>4. Intruders</p> <p>Sometimes, friends or others will interrupt the intercept and deter men from participating.</p> <p>Examples:</p> <p>Intruder: <i>“C’mon, we don’t have time for this. We’re going to be late.”</i></p> <p>Intruder: <i>“Give us a break; there are plenty of others you can talk to.”</i></p>	<p>Respond to interruptions from others based on the level of disruption and whether you think it can be safely addressed. If the interruption is minimal, focus on the prospective participant and complete the intercept. If the interruption is deterring enrollment and you feel you can safely address it, suspend the intercept and respond to the intruder. Stay positive, acknowledge and address his questions or concerns, and then return to the prospective participant and complete the intercept. If the interruption is severe and rapport or safety is jeopardized, do not confront the intruder. Simply tell the prospective participant that this does not appear to be the best time and thank him. Field supervisors should do their best to prevent interruptions from others by occupying potential intruders.</p> <p>Examples:</p> <p><i>“I just have a quick question for your friend; it will only take a minute.”</i></p> <p><i>“It’s important that I speak with your friend. Can you just give us a minute?”</i></p> <p>If necessary, use one of the previously mentioned motivations (community benefits, incentive, etc.).</p>

Participation Barriers	Strategies for Overcoming
<p>5. Low Risk Behavior</p> <p>Some men may believe that the survey is only for men at high risk for HIV infection. Others may think that participation is unnecessary if they do not have substantial risks for HIV infection.</p> <p>Examples:</p> <p><i>“You know, I’m not really at risk for HIV.”</i></p> <p><i>“I just got tested and I know I’m negative.”</i></p> <p><i>“I always use a condom.”</i></p> <p><i>“I’m in a long-term relationship; I doubt I would be of much help.”</i></p> <p><i>“I’m not sexually active.”</i></p>	<p>Stress the importance of universal participation and the value of everyone’s contribution. Risk behavior is NOT an eligibility requirement. We need to profile the risk behavior of all men who attend our venues, not just the riskiest ones.</p> <p>Examples:</p> <p><i>“That’s great. We definitely need to talk to you to learn about how you stay safe. We’d also like to know about HIV prevention services you have received and if they worked for you. It’s really important for us to know what works and what doesn’t so that we can improve our prevention efforts.”</i></p> <p><i>“We talk about things other than sex. You’ll be able to give us other important information.”</i></p>

Participation Barriers	Strategies for Overcoming
<p>6. Distrust or Cynicism</p> <p>Some men may have concerns about the underlying intentions of government-sponsored research or may perceive a lack of benefit to the community. Government distrust and cynicism may be particularly prevalent in some racial and ethnic minority communities.</p> <p>Examples:</p> <p><i>“I don’t trust the government.”</i></p> <p><i>“Yeah right, and what has research done for my community?”</i></p> <p><i>“I don’t see how prevention is working with all the risk behavior that’s going on.”</i></p>	<p>To address barriers involving distrust or cynicism about government surveys, explain the steps taken to protect privacy and participant anonymity. Also, cite local funding, policy changes, and prevention initiatives that have been implemented because of findings from HIV surveillance and research (support for nearly all prevention efforts is based on HIV surveillance and research). NHBS-MSM can help explain increasing trends in HIV and STDs among MSM in some areas and it can help identify prevention needs.</p> <p>Examples:</p> <p><i>“<Agency name> has taken special care to make sure that your participation in this survey is not harmful to you or anyone else. No one outside of our staff will know you participated, and that includes anyone from the government.”</i></p> <p><i>“Actually, local organizations like <CBO names> have used what was learned from our survey to request and obtain more resources to fight HIV and to help our community.”</i></p> <p><i>“Actually, because of our efforts, federal and local governments have devoted more resources to fight HIV. Our own HIV prevention organizations like <CBO names> have benefited from the type of data we collect.”</i></p> <p><i>“So that we can improve prevention efforts, we have to do a better job of finding out why rates of HIV infection are going up in some communities. Your thoughts are important to us.”</i></p>

Participation Barriers	Strategies for Overcoming
<p>7. Privacy & Anonymity</p> <p>Some men may be very concerned about their privacy and anonymity. This may be particularly true among non-gay-identified men and those recruited at sex venues (e.g., cruising areas, bathhouses, sex clubs).</p> <p>Examples:</p> <p><i>“I don’t want to give you my name.”</i></p> <p><i>“I’m not comfortable talking here.”</i></p>	<p>Stress that the survey is anonymous and that the names of participants are not collected. Reassure the prospective participant that staff are prohibited from discussing interviews with unauthorized persons. Describe how survey forms have no identifying information and are maintained in locked filing cabinets with limited access.</p> <p>Examples:</p> <p><i>“That’s perfectly OK. This survey is completely anonymous; you don’t need to give your name or any other identifying information.”</i></p> <p><i>“We’ll conduct the interview in a private area so that no one can overhear your answers. Nothing that you tell us will be shared with anyone else.”</i></p>

Participation Barriers	Strategies for Overcoming
<p>8. Incentive Not Enough or Not Important</p> <p>Some men might say that the incentive of \$25 or \$50 is not enough.</p> <p><i>Examples:</i></p> <p>“That’s not enough money.”</p> <p>“Is that all that’s offered?”</p> <p>Other men may say the incentive is not important.</p> <p><i>Examples:</i></p> <p>“I don’t need the money.”</p> <p>“The money really isn’t important to me.”</p>	<p>For those men who think the incentive is insufficient, stress that our interviews are not nearly as long as many other surveys, which provide lower incentives. Also emphasize the importance of NHBS-MSM for helping the community.</p> <p><i>Examples:</i></p> <p>“The interview won’t take too long and we pay much more than other surveys do. It’s for a very important cause. We’re trying to make a difference in our community and we could really use your help.”</p> <p>For those men who say that the money is not important, appeal to their altruism. In addition, explore other potential participation barriers and address those.</p> <p><i>Examples:</i></p> <p>“The money is a small token of our thanks for your time and help. The information you provide can help us improve our prevention efforts and better serve our community.”</p>

Participation Barriers	Strategies for Overcoming
<p>9. HIV Testing</p> <p>Because of HIV stigma, some men may not want to participate in the survey and receive an HIV test. This may be especially true if rapid HIV tests are used.</p> <p>Example:</p> <p><i>“I don’t want everyone knowing my business.”</i></p> <p>Other men may not be concerned with HIV stigma, but are not interested in getting tested while out socializing and having a good time with friends.</p> <p>Example:</p> <p><i>“I’m out having fun. I don’t want to know that.”</i></p>	<p>Assure the participant that his confidentiality will be protected and that the HIV test will be conducted in a private area. If that does not ease his concerns, note that the HIV test is optional.</p> <p>Examples:</p> <p><i>“We won’t ask your name and we won’t tell anyone else your result.”</i></p> <p><i>“You can still take the survey without having a test.”</i></p> <p>Project sites that use rapid HIV tests should also offer standard HIV tests to men who do not want to get their test results while out at the venue. If a man is still unwilling to participate, note that the HIV test is optional.</p> <p>Examples:</p> <p><i>“You don’t have to get your test results tonight. You can come to our office/call us.”</i></p> <p><i>“You can still take the survey without having a test.”</i></p>

Appendix N

Intercept Form and Instructions

Recruiters should record all information collected during an intercept on the Intercept Form (**Figure N.1** on the next page). The actual form can be found in a separate Excel file named **Appendix N- Intercept Form**. Project sites may customize the Intercept Form to meet their own needs, but if they do, they must collect all the data elements that will be entered in the recruitment event outcomes window of the Venue-Day-Time Sampling (VDTS) Program (see **Section N.4**). Instructions for completing the Intercept Form are outlined below.

N.1 Recruitment Event Information

Information needed to identify the recruitment event is collected at the top of the Intercept Form. To help keep track of forms, recruiters should enter the required information on all forms used during the recruitment event, not just on the first form.

N.1a Description of the recruitment event information

Venue Code: The 4-digit venue identification code assigned to the venue where the recruitment event is being conducted.

Event Number: The consecutive number assigned to the recruitment event. Each recruitment event must have its own unique number.

Date: The date of the recruitment event in a month/day/year format. If an event runs over two days (e.g., starts at 10:00 PM one day and ends at 2:00 AM the next), project sites should record the date the event began.

Venue Name: The name of the venue where the recruitment event is being conducted.

Recruiter: The recruiter's name or, if a project site prefers, the recruiter's identification code. Each recruiter working at a recruitment event must have their own Intercept Form(s).

N.2 Recruitment Data

Each numbered line on the Intercept Form represents recruitment data on a different venue attendee approached to participate in NHBS-MSM. To ensure that recruitment data are accurate, recruiters must make an entry on the Intercept Form for every venue attendee they attempt to intercept, even if the attendee ignores them and does not stop.

Figure N.1 –Intercept Form

Intercept Form

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

Venue Name: _____ Recruiter: _____

#	Previously Participated				Agreed to Screening		Post-event Appointment		Comments
	Y	N	D	R	Y	N	Y	N	
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 ____

N.2a Description of the recruitment data

(Number): A running count of the venue attendees approached to participate in NHBS-MSM. The first attendee approached by the recruiter is number 1, the second attendee approached is number 2, and so on. The recruiter should consecutively circle the numbers on the form when they approach venue attendees for recruitment.

Previously Participated: After a recruiter intercepts a venue attendee and greets him, they should ask the previous participation question:

During 2014, did you already complete at least part of the health survey that (project name or sponsoring agency's name) is conducting? It could have been here or at another location.

Based on the venue attendee's response, the recruiter should circle either the "Y" (yes), "N" (no), "D" (don't know), or "R" (refused) in the "Previously Participated" field:

Venue Attendee's Response	Letter to Circle
Indicates that he completed at least part of the survey during the current project cycle. (This includes men who were found to be ineligible or stopped the survey prematurely.)	Y
Indicates that he did not complete any of the survey during the current project cycle.	N
Indicates that he does not know or does not remember whether he completed any of the survey during the current project cycle.	D
Ignores the recruiter, does not stop to talk to the recruiter, is not able to answer the question (e.g., language barrier), or refuses to answer the question.	R

If the venue attendee already completed at least part of the survey ("Y" [yes] response), the recruiter should thank him for helping with the project and the recruiter should end the intercept. On the other hand, if the attendee did not complete any of the survey ("N" [no] response) or if he cannot remember if he completed any of the survey ("D" [don't know] response), the recruiter should invite him to participate in the survey (see **Chapter 6** of this manual). Attendees who refuse to answer the question ("R" [refused] response) should be thanked for their time and the intercept ended.

Agreed to Screening: After the recruiter invites a venue attendee to participate in the survey, the recruiter should indicate whether or not the attendee agreed to be screened for NHBS-MSM eligibility. If the venue attendee agreed to be screened for eligibility, the

recruiter should circle “Y” for yes; and if the venue attendee did not agree to be screened, the recruiter should circle “N” for no.



A response should only be recorded if the venue attendee was invited to participate in the survey (i.e., the venue attendee responded “no” or “don’t know” to the previous participation question).

PEA: Project sites that offer post-event appointments (PEAs) should indicate whether or not the prospective participant will be screened for NHBS-MSM eligibility and interviewed using a PEA. If a prospective participant will be screened and interviewed using a PEA, the recruiter should circle “Y” for yes; whereas, if a prospective participant will not be screened and interviewed using a PEA, the recruiter should circle “N” for no.



A response should only be recorded if the venue attendee agreed to be screened for eligibility.

Comments: The recruiter can use the “Comments” field to record any additional information provided by the venue attendees approached, such as reasons for refusing to accept the intercept or for declining to participate in the survey. Project sites can use this information to identify any potential barriers to recruitment or participation. The “Comments” field can also be used to track at-event appointments (see **Section 6.3g** of this manual).

N.3 Page Numbers

To help keep track of the Intercept Forms, the recruiter should number the forms they have used during a recruitment event. The bottom of the form has a field for the recruiter to circle the page number and indicate the total number of forms used.

N.4 Data Summation

At the end of a recruitment event, the field supervisor should collect all the Intercept Forms used during the event. For each of the forms, the field supervisor should tabulate the number of venue attendees approached, the responses to the previous participation question, the number of venue attendees who agreed to be screened for eligibility, and if applicable, the number of post-event appointments made. The column sub-totals should be recorded in the row at the bottom of the Intercept Form. The field supervisor or data manager should then enter the column sub-totals for each form in the event outcomes section of the VDTS Program.

N.4a Tabulating column sub-totals

Number of Venue Attendees Approached: The highest number circled in the “#” (number) field. For example, if numbers 1 through 12 were circled, the number of venue attendees approached would be 12.

“Yes” Responses to the Previous Participation Question: The number of “Y” (yes) responses circled in the “Previously Participated” field.

“No” Responses to the Previous Participation Question: The number of “N” (no) responses circled in the “Previously Participated” field.

“Don’t know” Responses to the Previous Participation Question: The number of “D” (don’t know) responses circled in the “Previously Participated” field.

“Refused” Responses to the Previous Participation Question: The number of “R” (refused) responses circled in the “Previously Participated” field.

Number of Attendees who Agreed to Screening: The number of “Y” (yes) responses circled in the “Agreed to Screening” field.



Since just the number of men who *agreed* to screening is entered in the VDTS Program, the number of “N” (no) responses circled in the “Agreed to Screening” field does not have to be tabulated.

Number of Post-event Appointments (PEAs): The number of “Y” (yes) responses circled in the “PEA” field.



Since just the number of men who *are* interviewed by appointment is entered in the VDTS Program, the number of “N” (no) responses circled in the “PEA” field does not have to be tabulated.

Appendix O

Post-event Appointment Card

Project sites should provide prospective participants with appointment cards to remind them of their post-event appointments (PEAs). The card should be pre-printed with the project name, phone number, days and hours of operation, address of the project office, and if possible, directions to it. The card should also have fields for the date and time of the appointment and the recruitment event information (Venue Code, Event Number, and date of the recruitment event during which the prospective participant was recruited). Sites that plan on assigning Survey IDs for PEAs at the time of recruitment should include a field for the Survey ID as well.

A model PEA card is shown below. The model card can be printed or modified using the Word file named **Appendix O – Post-event Appointment Card**.

<i>[PROJECT NAME]</i>	
Your appointment is scheduled for:	
_____	_____
day	date
at _____ AM PM	
time	
If you need to reschedule your appointment or have any questions, please call us at <i>[project phone number]</i> .	
Our office is located at:	
<i>[address of project office]</i>	
and is open <i>[days of operation]</i> from <i>[opening time]</i> to <i>[closing time]</i> .	
Venue Code: _____	Survey ID: _____
Event Number: _____	Date of Recruitment Event: _____

Appendix P

Rapid Testing Quality Control Log

A model Rapid Testing Quality Control Log is shown below. The actual log can be printed or modified using the Word file named **Appendix P – Rapid Testing Quality Control Log**.

Rapid Testing Quality Control Log NHBS-MSM4: 2014

Date Controls Ran	Name of Person Running Controls	Date Controls Opened	Reason for Running Controls	Negative Control Result	HIV-1/HIV-2 Positive Control Result(s)	Notes	
				<i>Indicate if Controls Ran Successfully</i>			
			<ul style="list-style-type: none"> ▪ Routine ▪ New Operator ▪ New Shipment 	<ul style="list-style-type: none"> ▪ New Lot Opened ▪ Storage Temp Irregularity ▪ Test Area Temp Irregularity 	<ul style="list-style-type: none"> ▪ Yes ▪ No 	<ul style="list-style-type: none"> ▪ Yes ▪ No 	
			<ul style="list-style-type: none"> ▪ Routine ▪ New Operator ▪ New Shipment 	<ul style="list-style-type: none"> ▪ New Lot Opened ▪ Storage Temp Irregularity ▪ Test Area Temp Irregularity 	<ul style="list-style-type: none"> ▪ Yes ▪ No 	<ul style="list-style-type: none"> ▪ Yes ▪ No 	
			<ul style="list-style-type: none"> ▪ Routine ▪ New Operator ▪ New Shipment 	<ul style="list-style-type: none"> ▪ New Lot Opened ▪ Storage Temp Irregularity ▪ Test Area Temp Irregularity 	<ul style="list-style-type: none"> ▪ Yes ▪ No 	<ul style="list-style-type: none"> ▪ Yes ▪ No 	
			<ul style="list-style-type: none"> ▪ Routine ▪ New Operator ▪ New Shipment 	<ul style="list-style-type: none"> ▪ New Lot Opened ▪ Storage Temp Irregularity ▪ Test Area Temp Irregularity 	<ul style="list-style-type: none"> ▪ Yes ▪ No 	<ul style="list-style-type: none"> ▪ Yes ▪ No 	

Field Supervisor Signature: _____

This appendix provides guidance on testing for hepatitis B virus (HBV) and hepatitis C virus (HCV), as well as information on interpreting HBV and HCV test results.

R.1 Hepatitis B Testing

HBV testing requires laboratory-based testing. Project sites should perform three tests for HBV infection: 1) hepatitis B surface antigen (HBsAg), a protein on the surface of HBV; 2) antibody to HBsAg (anti-HBs); and 3) total antibody to hepatitis B core antigen (anti-HBc), an antibody to HBV core proteins. The presence of each antigen or antibody indicates a different stage of HBV infection. HBsAg indicates current infection, anti-HBs indicates immunity to infection (either from natural infection or vaccination), and anti-HBc indicates past or current infection. If a participant is found to be currently infected with HBV, a test for IgM anti-HBc can be performed to help distinguish between acute and chronic HBV infection. **Table R.1** on the next page describes the interpretation of HBV test results for counseling participants and making any necessary referrals.

R.2 Hepatitis C Testing

HCV testing may be conducted using laboratory-based or rapid testing.

R.2a Laboratory-based hepatitis C testing

The standard laboratory-based screening test for HCV infection is an enzyme immunoassay (EIA) test. A negative EIA test result can be considered a final result. Specimens with a positive EIA test result can be considered antibody positive and indicative of either current or past (resolved) HCV infection. If available, reflex testing with a nucleic acid test (NAT) would allow categorization of infection status as active/current or resolved/past infection. Although counseling messages differ for a positive EIA and a positive NAT, in either case, participants should be referred for medical evaluation for infection status and stage of liver disease if currently infected.

R.2b Rapid hepatitis C testing

Recently, the FDA approved a rapid HCV test for use on blood collected through venipuncture or fingerstick. The test is CLIA-waived for use in field settings by non-laboratory staff, and results are available within 20 minutes. A reactive rapid HCV test can be considered equivalent to a positive EIA; a reactive rapid HCV test indicates current or past (resolved) HCV infection. Project sites may return rapid HCV test results

to participants, and all participants with reactive rapid tests should be referred for medical evaluation for current infection and liver disease.

Table R.1 – Interpretation of hepatitis B virus (HBV) test results

Test	Result	Interpretation
HBsAg anti-HBc anti-HBs	negative negative negative	Susceptible
HBsAg anti-HBc anti-HBs	negative positive positive	Immune due to natural infection
HBsAg anti-HBc anti-HBs	negative negative positive	Immune due to hepatitis B vaccination
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	Acutely infected
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	Chronically infected
HBsAg anti-HBc anti-HBs	negative positive negative	Interpretation unclear; four possibilities: 1. Resolved infection (most common) 2. False-positive anti-HBc, thus susceptible 3. “Low level” chronic infection 4. Resolving acute infection

Adapted from: A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. Part I: Immunization of Infants, Children, and Adolescents. MMWR 2005;54(No. RR-16).

Appendix S

DBS Supplies

This appendix contains a list of vendors that sell supplies that project sites will need for creating and shipping dried blood spots (DBS).



The use of trade names is for identification purposes only and does not imply endorsement by the Centers for Disease Control and Prevention or the U.S. Department of Health and Human Services.

DBS Cards

Product: Item # 10534612
Whatman 903® protein saver card

Vendor: GE Healthcare Life Sciences
(800) 526-3593
<http://www.whatman.com/903ProteinSaverCards.aspx>

DBS Drying Clips

Product: Binder clips for attaching DBS cards to drying racks

Vendor: http://www.staples.com/Staples-Small-Metal-Binder-Clips-3-4-size-with-3-8-Capacity/product_831594

DBS Drying Racks

Product: Test tube racks for drying DBS cards

Vendor:
<http://www.fishersci.com/ecommerce/servlet/productimagesview?catalogId=29103&productId=803184&langId=-1&storeId=10652&distype=3&isChemical=false&selectedImage=-1&highlightProductsItemsFlag=Y&fromSearch=1>

or:
<http://www.fishersci.com/ecommerce/servlet/itemdetail?catalogId=29103&productId=2423908&distype=0&highlightProductsItemsFlag=Y&fromSearch=1&storeId=10652&langId=-1>

Desiccant Packs

Product: 1 gram desiccant packs with blue indicator that turns pink in high humidity

Vendor: Poly Lam Products, Corp
(800) 836-9648
<http://www.polylam.com/Desiccant%20Packets%20Dist.pdf>

Envelopes

Product: High-quality bonded, anti-tear/moisture envelopes (e.g., Tyvek)

Vendor: <http://www.staples.com/>
<http://www.officedepot.com/>

Humidity Indicator Cards

Product: Item # MS20003-2, 125 can

Vendor: Poly Lam Products, Corp
(800) 836-9648

Lancets

Product: Item # 366594
BD Microtainer[®] Contact-Activated Lancet (Blue)
Puncture (blade) 1.5mm x 2.0mm
High Flow Blood Volume

Vendor: Beckton-Dickinson
(201) 847-6800
<http://www.bd.com/vacutainer/products/capillary/>

Low-gas Permeable Plastic Zip-lock Bags

Product: Item # 11217-106

Vendor: VWR Scientific
(800) 932-5000

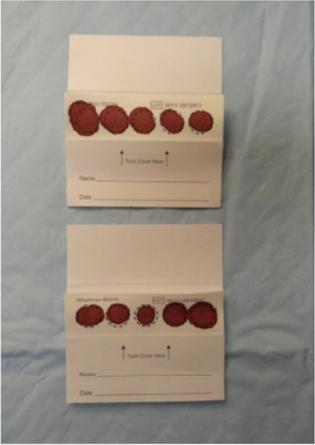
Product: Item # 19240127

Vendor: Fisher Scientific
(866) 884-2019

Appendix T

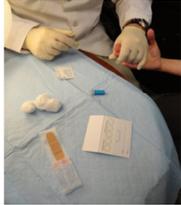
Fingerstick Quick Reference Guide

The Fingerstick Quick Reference Guide is shown below. The actual guide can be two-side printed using the Word file named **Appendix T - Fingerstick Quick Reference Guide**.

<p>Valid DBS Specimens...</p> 	<p>Supply list...</p> <ul style="list-style-type: none">▪ Band aids▪ Cotton balls▪ Alcohol prep pads▪ Lancets▪ Absorbent paper (i.e., “chucks”)▪ DBS cards▪ Biohazard waste containers▪ Gloves▪ Disinfectant cleaner  <p>Biohazard reminders....</p> <ul style="list-style-type: none">▪ Gloves must be worn at all times▪ Gloves should fit appropriately; DO NOT begin collection until you have gloves that fit snug▪ Blood collection should occur over absorbent paper in case of spillage▪ Always have a disinfectant cleaner on hand	<p>POCKET GUIDE TO FINGERSTICK BLOOD COLLECTION FOR DRIED BLOOD SPOTS</p> 
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Before sticking the finger...

- Set out all supplies needed to collect blood; open band aid and alcohol pad
- Ask the participant which is his non-dominant hand
- Assess positioning of you and the participant to decide the easiest way to collect blood for the rapid test and DBS



- Assess which finger is free of callouses and has the softest skin – this is typically the ring finger
- Even if the participant's hands are warm, massage the whole hand to increase circulation; hold participant's hand downward (below the heart) while massaging. Circulation can also be increased by asking the participant to pump his hand or squeeze a stress ball
- Ask participant to flick his hand in a downward motion
- Clean the finger with an alcohol pad



The stick...

- Lay the hand against a hard, flat surface



- Hold the lancet just off from the center of the fingertip pad and perpendicular to the ridges of the fingerprint; **DO NOT STICK THE FINGER ON THE SIDE**
- Massage from the base of the finger using a squeeze-release motion; it works well to wrap your fingers around the stuck finger and the finger next to it
- **DO NOT SQUEEZE** the tip of the finger



- Wipe away the first drop of blood with a cotton ball

If blood is not readily flowing:

- Massage entire hand using both of your hands; one hand should continue with the squeeze-release of the fingers
- If participant is feeling okay, ask him to stand up to allow the hand to be held much lower than the heart
- Be patient and keep massaging; sometimes it takes time for the blood to start flowing

Specimen collection...

- Allow a new drop of blood to form after wiping the first drop with a cotton ball
- Collect specimen for rapid test
- Flip the hand downward toward the DBS card, continue massaging, allow enough time for a very large drop of blood to form before applying to the first circle



- Touch the drop of blood to the card but **DO NOT TOUCH THE FINGER TO THE CARD**; the card will wick the drop of blood away from the finger
- If one drop of blood does not fill the entire circle, immediately apply a second drop of blood to that same circle
- Continue above procedures as you move to next circle



- Upon completion, the circles should be full

Appendix U Specimen Transport/Shipping Log

If the local laboratory does not provide a specimen transport or shipping log, project sites can use the Local Specimen Transport/Shipping Log shown below in **Figure U.1**. In addition, project sites collecting dried blood spots (DBS) for HIV incidence testing should use the CDC DBS Specimen Transport/Shipping Log shown on the next page in **Figure U.2** to send their DBS specimens to CDC.

The Local Specimen Transport/Shipping Log can be printed or modified using the Excel file named **Appendix U - Local Specimen Transport & Shipping Log**, and the CDC DBS Specimen Transport/Shipping Log can be printed using the Excel file named **Appendix U - CDC DBS Specimen Transport & Shipping Log**.

Figure U.1 – Local Specimen Transport/Shipping Log

Local Specimen Transport/Shipping Log

[Project Name] Contact Person: _____ Courier's Name: _____

[Project Name] Phone Number: _____ Lab Signature: _____

[Project Name] Fax Number: _____

Lab ID or Survey ID	Date Collected	Specimen Type (Oral or Blood)	Reactive Rapid Test? (Yes or No)	Self-reported HIV-positive? (Yes or No)	Storage for Future Tests? (Yes or No)	Date Sent to Lab

Lab Staff: Regardless of the results of any screening tests performed, **ALL** persons who are self-reported HIV-positive must have a confirmatory test (e.g., Western Blot, IFA, NAAT, or other tests that are part of a CDC-approved algorithm).

Page _____

Figure U.2 – CDC DBS Specimen Transport/Shipping Log

CDC DBS Specimen Transport/Shipping Log

[Project Name] Contact Person: _____ Project City: _____

[Project Name] Phone Number: _____

[Project Name] Fax Number: _____

2-Letter City Code <i>plus</i> Survey ID	Date Collected	Reactive Rapid Test? (Yes or No)	Self-reported HIV-positive? (Yes or No)	Storage for Future Tests? (Yes or No)	Date Packaged	Date Sent to Lab

Page _____

Appendix W Appointment and Phone Results Cards

Project sites should provide participants with cards to remind them to obtain their laboratory-based test results. **Figure W.1** (below) shows a model Appointment Card to remind participants of their appointments to obtain their test results in-person and **Figure W.2** (on the next page) shows a model Phone Results Card to remind participants to obtain their test results by phone. Both cards should have the project name, phone number, and days and hours of operation pre-printed on them. The Appointment Card should also list the address of the project office and, if possible, directions to it. Since all testing conducted as part of NHBS must be anonymous, survey IDs or laboratory IDs should be used to locate and confirm participants' test results.

The model cards can be printed or modified using the Word file named **Appendix W - Appointment & Phone Results Cards**.

Figure W.1 – Model Appointment Card

<p><i>[PROJECT NAME]</i></p> <p>Your appointment is scheduled for:</p> <p>_____ , _____ at _____ AM PM day date time</p> <p>If you need to reschedule your appointment or have any questions, please call us at <i>[project phone number]</i>.</p> <p>Our office is located at: <i>[address of project office]</i></p> <p>and is open <i>[days of operation]</i> from <i>[opening time]</i> to <i>[closing time]</i>.</p> <p>ID Number: _____</p>

Appendix X

Appointment Reminder Call Form and Procedures

If a participant indicates that he would like to receive a phone call to remind him of his appointment for obtaining his test results, a staff member should help the participant complete an Appointment Reminder Call Form (**Figure X.1** on page X-3) by following the steps outlined below. A model form can be printed or modified using the Word file named **Appendix X – Appointment Reminder Call Form**.

Step 1. Schedule appointment

Schedule an appointment for the participant to obtain his test results and give him an Appointment Card with his appointment information.

Step 2. Complete Appointment Reminder Call Form

Record the day, date and time of the participant's appointment on an Appointment Reminder Call Form and then help him complete the remainder of the form. Ask the participant to write his phone number on the form and indicate the best day(s) and time(s) to call him with his appointment reminder. Be sure that the participant understands what your standard reminder message will be and ask him if he would like a different message.

Step 3. File form

After the participant completes the form, store it in a locked file or file box for later processing. Forms should be ordered by the date when the reminder call will be made.

Step 4. Process reminder calls

Every day, retrieve the forms that are due reminder calls on that date and make the calls at the designated times. Before making each call, review the information provided by the participant to ensure that you follow his instructions exactly (e.g., what name to use, what message to leave); and after the call, record the date, time, and outcome of the call in the "Staff Use" section of the form. When calling, always ask for the name that the participant wrote on the form:

- If the participant answers, provide the reminder message and file the form for later shredding.
- If someone other than the participant answers and the participant is not available, ask when it would be best to call back to reach the participant. Record the call-back date and time in the "Staff Use" section of the form and file it under the new call date. If you are told not to call back, note that in the "Staff Use" section of the form and file it for later shredding. Do not provide

any additional information about NHBS or the participant to the person who answers the phone.

- If voice mail or an answering machine picks up the call, leave the message that the participant agreed to and file the form for later shredding. If the participant did not give permission to leave a message, try calling back one more time at a later time or date.
- If no one answers the phone, try calling back one more time at a later time or date.



Do not try to reach a participant more than two times. Regardless of the outcome of a call, file the form for later shredding after the second call attempt.

Step 5. Re-schedule appointment (optional)

If project sites wish, they may contact participants who miss their appointments to try to schedule a new one. To do this, project sites should review their test results appointment book and note the dates and times of missed appointments. For each missed appointment, they should search their file of Appointment Reminder Call Forms for a form with a matching date and time. Project sites can then call the participants whose forms have matching dates and times to reschedule their missed appointments. Project sites are only allowed one attempt to try to reach the participant for rescheduling; they cannot call back repeatedly.

Figure X.1 – Appointment Reminder Call Form

Appointment Reminder Call Form

I would like a phone call to remind me of my test results appointment on:

_____ , _____ at _____ AM PM
day date time

Please answer the following questions about the call:

1. What is your phone number? (_____) _____ – _____
2. What are the best days and times to call you?
 Days: _____
 Times: _____
3. Who should we ask for when the phone is answered?
 Your first name or nickname: _____
4. Is it okay for us to identify ourselves as **[Project Name]** when we make the appointment reminder call?
 Yes No
5. Unless we are instructed otherwise, our standard appointment reminder message is:
*Hello, this is (staff member's name) from **[Project Name]** calling to remind you of your appointment on (day), (date), and (time). Thank you.*
 If no one answers, is it okay to leave this message on voicemail or an answering machine?
 Yes No
6. Add any additional instructions: _____

STAFF USE ONLY
 << DO NOT record the survey ID or lab ID on this form >>

1st Call:
 Date of Call: _____ Time of Call: _____ AM PM
 Outcome of Call: _____
 Is a 2nd call necessary? Yes No
If Yes: Call-back Date: _____ Call-back Time: _____ AM PM

2nd Call:
 Date of Call: _____ Time of Call: _____ AM PM
 Outcome of Call: _____

Appendix Y

Previous Positive Questions

HIV test counselors should ask the *Previous Positive Questions* to determine whether participants previously tested HIV-positive, and if so, the date they first tested positive. The test counselors should not ask all participants the questions; they should only ask those participants who meet the following criteria based on the type of HIV testing used:

If Using Laboratory-based HIV Testing:	If Using Rapid HIV Testing:
Did not report a previous positive test result during the interview	Did not report a previous positive test result during the interview AND Had a preliminary positive rapid test

To ensure that the *Previous Positive Questions* are asked in a consistent manner among test counselors and across project sites, test counselors should use the following script:

[READ] Sometimes people don't feel comfortable sharing that they previously tested positive for HIV. We understand that this is private information but it is very important and helps us learn more about HIV in your community. We would like to ask two additional questions about your knowledge of your HIV status before testing today. Remember that any information you share is anonymous and will not affect how much you will be compensated.

1. Before today, have you ever tested positive for HIV?
2. *If yes:* When did you first test positive for HIV? Please provide the month and year. If you cannot remember the month, just provide the year.

Project sites conducting laboratory-based HIV tests can print a copy of the script from the Word file named **Appendix Y - Previous Positive Questions for Lab Testing**, and project sites conducting rapid HIV tests can print a copy of the script from the Word file named **Appendix Y - Previous Positive Questions for Rapid Testing**. Spanish versions of these questions are contained in the Word files named **Appendix Y – Spanish Previous Positive Questions for Lab Testing** and **Appendix Y - Spanish Previous Positive Questions for Rapid Testing**.

Responses to the *Previous Positive Questions* should be recorded on the Participant Tracking Form (**Appendix K**). The HIV test counselor should record the participant's answer to the first *Previous Positive Question* under the "SRP during counseling" question (SRP stands for self-reported positive). Responses to the first *Previous Positive Question* should be coded and recorded as described in the table below:

If the participant's response to the first <i>Previous Positive Question</i> is...	Circle this response option for the "SRP during counseling" question...
Yes	Y
No	N
Don't know	D
Refuses to answer	R
If the HIV test counselor does not ask the first <i>Previous Positive Question</i>	Circle "Not Asked" for the "SRP during counseling" question

If the participant responds "yes" to the first *Previous Positive Question*, the HIV test counselor should ask the second *Previous Positive Question* and record the date in the "SRP date" field. If the participant does not know the date of his first positive test, circle "D" for does not know, and if he refuses to provide the date, circle "R" for refuses.

The responses to the *Previous Positive Questions* on the Participant Tracking Form should be entered into the HIV Test Results Log on the NHBS Data Coordinating Center (DCC) data portal after each recruitment event or as soon as possible after each event.

Appendix Z

Data Entry for Laboratory-based HIV Testing

In the HIV Test Record Worksheet window of the HIV Test Results Log on the DCC data portal, project sites should enter the types of laboratory-based HIV tests used by their local laboratories for standard or confirmatory testing. Sites can enter up to four different types of laboratory-based HIV tests using the entry fields for Test 1, Test 2, Test 3, and Test 4. The response options available for these entry fields are:

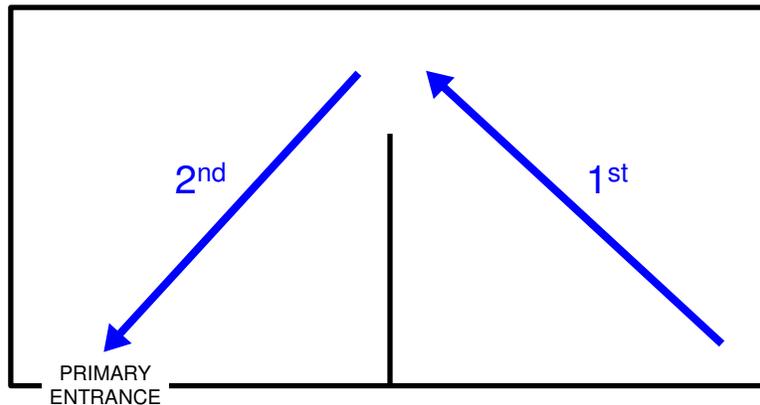
- Immunoassay (4th generation)
- Immunoassay (3rd generation)
- Immunoassay (1st generation)
- Laboratory Rapid Test
- IFA
- Nucleic Acid Test (NAT)/RNA Test
- Western Blot

Table Z.1 on the next page shows which response options project sites should select depending on the trade names of the laboratory-based HIV tests used locally.

Table Z.1 – Trade names of laboratory-based HIV tests and the corresponding response options in the HIV Test Results Log

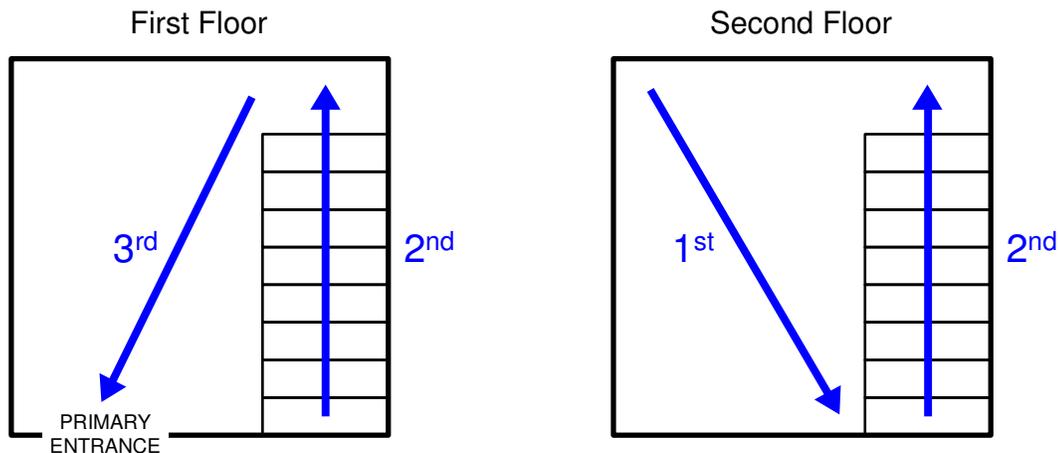
Trade Name of Laboratory-based HIV Test	Response Option
Abbott Architect HIV Ag/Ab Combo Bio-Rad Genetic Systems HIV Combo Ag/Ab EIA	Immunoassay (4 th generation)
Bio-Rad Genetic Systems HIV-1/HIV-2 Plus O EIA ADVIA Centaur HIV 1/O/2 Enhanced Ortho VITROS Anti-HIV 1+2 Immunoassay	Immunoassay (3 rd generation)
Avioq HIV-1 Microelisa	Immunoassay (1 st generation)
Multispot HIV-1/HIV-2 Rapid Test Determine Reveal Rapid HIV-1 Antibody Test <i>Any point-of-care rapid HIV tests</i>	Laboratory Rapid Test
Sanochemia Flourognost IFA HIV-1	IFA
Gen-Probe APTIMA HIV-1 RNA Qualitative Assay Roche Amplicor HIV-1 Monitor Test (PCR) NucliSens HIV-1 QT (NASBA) Versant HIV-1 RNA 3.0 (bDNA) Gen-Probe APTIMA HIV-1 RNA Qualitative Assay (TMA) Abbott RealTime HIV-1 Amplification Kit (PCR) COBAS Ampli-Prep/COBAS TaqMan HIV-1 Test (PCR) <i>Any NAT assay developed and validated in house</i>	Nucleic Acid Test (NAT) or RNA Test
OraSure HIV-1 Western blot Bio-Rad Genetic Systems HIV-1 Western Blot	Western Blot

AA.3 Venues with Multiple Rooms



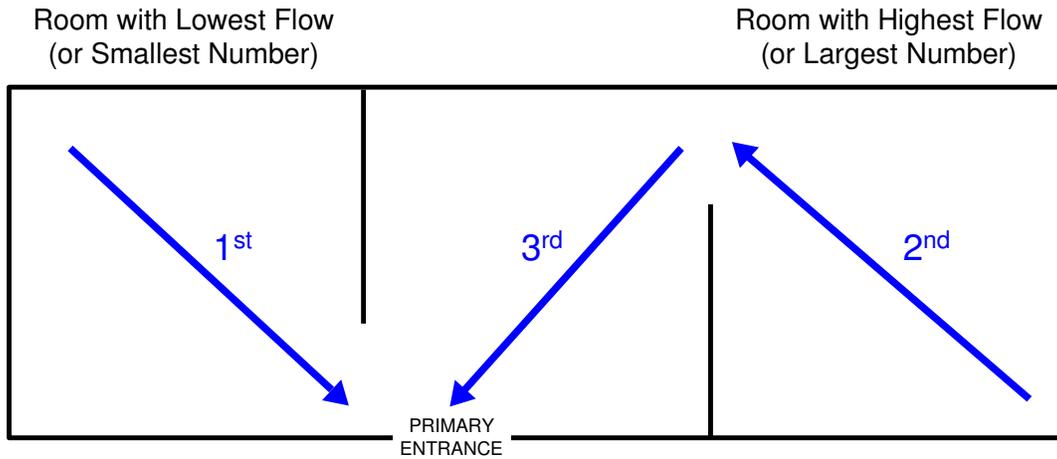
- a) If there are multiple rooms in a venue, the counter should begin counting in the room farthest away from the room with the primary entrance and end counting in the room with the primary entrance.

AA.4 Venues with Multiple Floors



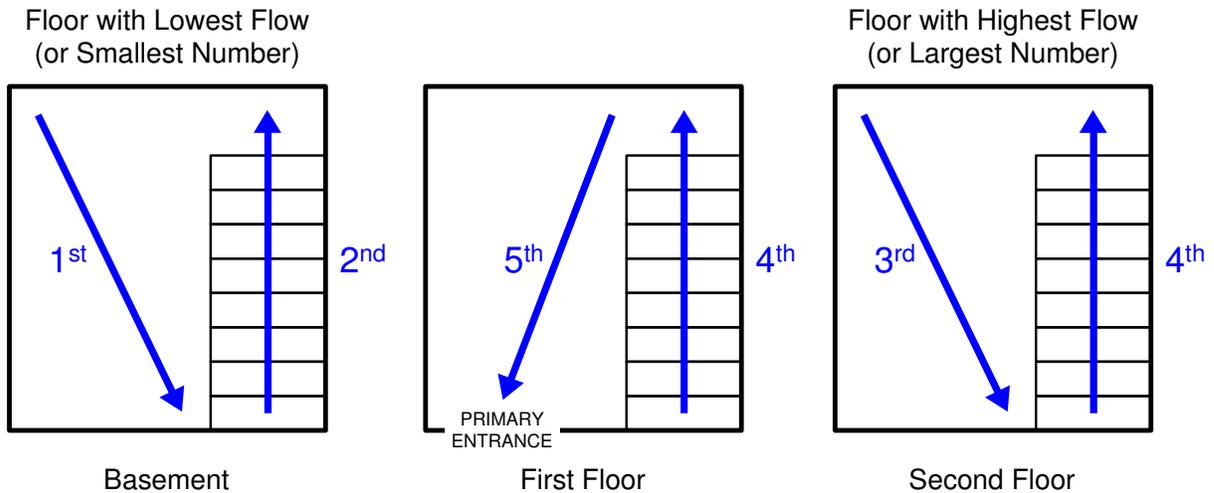
- a) If there are multiple floors in a venue, the counter should begin counting on the floor farthest away from the floor with the primary entrance and end counting on the floor with the primary entrance. In this example, first, count on the second floor while moving toward the staircase; second, count on the staircase while moving down it; and third, count on the first floor while moving toward the primary entrance.

AA.5 Venues with Multiple Rooms Not in Sequence



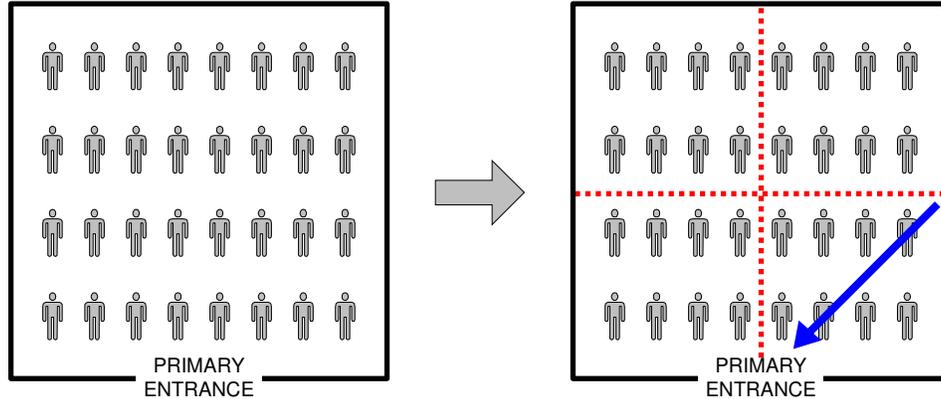
- a) If the rooms in a venue are not arranged in a sequence that ends in the room with the primary entrance, the counter should decide where to start counting based on the flow of men in and out of each room. The counter should begin counting in the room with the lowest flow of men, progressively move to the room with the highest flow, and then end in the room with the primary entrance. If there is no clear pattern to the flow of men in the venue, the counter should decide where to start counting based on the number of men in each room.

AA.6 Venues with Multiple Floors Not in Sequence



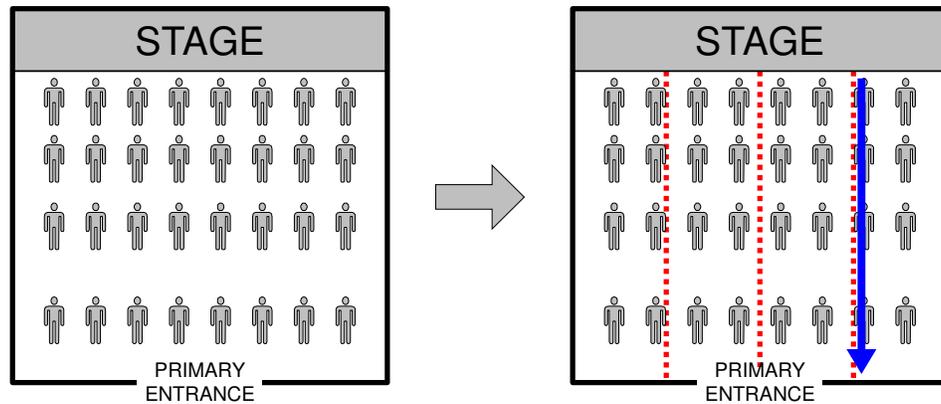
- a) If the floors in a venue are not arranged in a sequence that ends on the floor with the primary entrance, the counter should decide where to start counting based on the flow of men on and off each floor. The counter should begin counting on the floor with the lowest flow of men (the basement in this example), progressively move to the floor with the highest flow (the second floor in this example), and then end on the floor with the primary entrance. If there is no clear pattern to the flow of men in the venue, the counter should decide where to start counting based on the number of men on each floor.

AA.7 Crowded Venues That Have Equally Distributed Attendees



- a) If a venue is so crowded that it would be difficult to obtain an accurate count, the counter may divide the venue into equally-sized sections, count all the men in one of the sections, and then multiply this count by the number of sections to estimate the total count. When the men attending the venue are equally distributed throughout the venue, the counter just needs to ensure that the sections selected are the same size. In this example, the counter divides the venue into quadrants, counts the men in one quadrant, and then multiplies this count by four to estimate the total count for the venue.

AA.8 Crowded Venues That Do Not Have Equally Distributed Attendees



- a) If the counter decides to divide a crowded venue into sections, but the men attending the venue are not equally distributed throughout the venue, the counter must take this into consideration. In addition to ensuring that the sections the venue is divided into are the same size, the counter must also ensure that the distribution of men is the same in each section. In this example, the men attending the venue are concentrated by a stage with performers. The counter therefore divides the venue into four sections that are perpendicular to the stage to ensure that the distribution of men is the same in each section. The counter counts the men in one of the sections and then multiplies this count by four to estimate the total count for the venue. Note that the counter moves toward the primary entrance along the line that divides the section. This allows the counter to keep track of the boundary of the section and makes it easier for him to count since he just has to count the men between himself and the wall.

Appendix BB

Process Monitoring Reports

The NHBS Data Coordinating Center (DCC) will produce the process monitoring reports and post them on the DCC data portal. Project sites should review the reports each week to assess recruitment and enrollment, sample characteristics, HIV and hepatitis testing, previous participants, and interviewer skills. Examples of each report are provided in the tables below.

BB.1 Outcomes Monitoring Report

The *Outcomes Monitoring Report* appears on one line on the DCC data portal, but because of space limitations, it is shown on two lines below:

Event #	Date	Conducted Venue				Recruiter ID 1			Recruiter ID 2		
		Venue Code	Venue Name	Venue Type	Non-Random	No. Approached	No. Agreed to Screen	% Agreed to Screen	No. Approached	No. Agreed to Screen	% Agreed to Screen
TOTAL											

Recruiter ID 3			Counts		Totals			
No. Approached	No. Agreed to Screen	% Agreed to Screen	Pre-Event Count	Entry Count	No. Counted	No. Approached	No. Agreed to Screen	% Agreed to Screen

BB.2 Recruitment Monitoring Report

Event #	Date	Venue Code	Venue Name	Screened		Eligible		Completed Interview		Sex w/ Man Past 12		Consented to HIV Test		Consented to Other Test		Agreed to Blood Storage	
				No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
TOTAL																	

BB.3 Sample Characteristics – Screened Report

1. ELIGIBLE

Eligible	N	%
Yes		
No		
Total		

2. AGE

Age	Eligible		Not Eligible		Total
	N	%	N	%	N
< 18					
18 – 29					
30 – 39					
40 – 49					
≥ 50					
Unknown					
Total					

3. GENDER

Sex at birth/Gender	Eligible		Not Eligible		Total
	N	%	N	%	N
Male/Male					
Male/Female					
Female/Female					
Female/Male					
Other					
Unknown					
Total					

4. RACE/ETHNICITY

Race/Ethnicity	Eligible		Not Eligible		Total
	N	%	N	%	N
American Indian or Alaska Native					
Asian					
Black or African American					
Hispanic					
Native Hawaiian or Other Pacific Islander					
White					
Multiple Races					
Unknown					
Total					

5. MSA RESIDENT

MSA Resident	Eligible		Not Eligible		Total
	N	%	N	%	N
Yes					
No					
Unknown					
Total					

6. KNOWN PREVIOUS PARTICIPANT

Known Previous Participant	Eligible		Not Eligible		Total
	N	%	N	%	N
Yes					
No					
Unknown					
Total					

7. ABLE TO PARTICIPATE

	Eligible		Not Eligible		Total
	N	%	N	%	N
Able to Participate					
Yes					
No					
Total					

8. SEXUAL BEHAVIOR (EVER)

	Eligible		Not Eligible		Total
	N	%	N	%	N
Sexual behavior (ever)					
Sex with men only					
Sex with men and women					
Sex with women only					
No sex					
Unknown					
Total					

BB.4 Sample Characteristics – Interviewed Report

1. AGE

Age	Sex with man past 12 months		No sex with man past 12 months		TOTAL	
	N	%	N	%	N	%
18 – 29						
30 – 39						
40 – 49						
≥ 50						
Unknown						
Total						

2. SEXUAL IDENTITY

Sexual Identity	Sex with man past 12 months		No sex with man past 12 months		TOTAL	
	N	%	N	%	N	%
Homosexual						
Bisexual						
Heterosexual						
Unknown						
Total						

3. RACE / ETHNICITY

Race/Ethnicity	Sex with man past 12 months		No sex with man past 12 months		TOTAL	
	N	%	N	%	N	%
American Indian or Alaska Native						
Asian						
Black or African American						
Hispanic						
Native Hawaiian or Other Pacific Islander						
White						
Multiple Races						
Unknown						
Total						

4. EDUCATION

Education	Sex with man past 12 months		No sex with man past 12 months		TOTAL	
	N	%	N	%	N	%
Less Than High School						
High School						
Vocational/Tech School or Some College						
College Graduate or Graduate School						
Unknown						
Total						

5. INCOME

Income	Sex with man past 12 months		No sex with man past 12 months		TOTAL	
	N	%	N	%	N	%
0 – \$4,999						
\$5,000 – \$9,999						
\$10,000 – \$14,999						
\$15,000 – \$19,999						
\$20,000 – \$29,999						
\$30,000 – \$39,999						
\$40,000 – \$49,999						
≥ \$50,000						
Total						

6. RECRUITMENT VENUE

Recruitment Venue	Sex with man past 12 months		No sex with man past 12 months		TOTAL	
	N	%	N	%	N	%
Bar						
Cafes/Restaurants						
Dance clubs						
Fitness club or gymnasium						
Gay pride or similar event						
House ball events						
Parks/Beaches						
Rave or circuit parties						
Retail businesses						
Sex establishment or environment						
Social organizations						
Street locations						
Other						
Total						

7. GEOGRAPHIC AREA

Geographic Area	Sex with man past 12 months		No sex with man past 12 months		TOTAL	
	N	%	N	%	N	%
Total						

Note: The geographic area is the last 4-digits of the zip code.

BB.5 Test Results Report

1. HIV RAPID TEST RESULT

Rapid HIV Test Result	Final HIV Test Results								Total N
	Positive		Negative		Indeterminate		Unknown		
	N	%	N	%	N	%	N	%	
Preliminary Positive									
Negative									
Invalid									
Not Done									
Unknown									
Total									

2. HIV SELF-REPORTED TEST RESULT

Self-Reported HIV Status	Final HIV Test Results								Total N
	Positive		Negative		Indeterminate		Unknown		
	N	%	N	%	N	%	N	%	
Self-reported Positive									
Interview									
Counseling									
Not Self-reported Positive									
Total									

3. HEPATITIS B TEST RESULT

	Interpretation of HBV Tests by DCC										Total	
	Susceptible		Immune due to natural infection		Immune due to vaccination		Infected		Unknown			
Interpretation of HBV Tests by Project Staff	N	%	N	%	N	%	N	%	N	%	N	%
Susceptible												
Immune due to natural infection												
Immune due to vaccination												
Infected												
Unknown												
Not done												
Total												

4. HCV RAPID TEST RESULT

	EIA Test RESULT						Total
	Reactive		Non-reactive		Unknown		
Rapid HCV Test Result	N	%	N	%	N	%	N
Reactive							
Non-reactive							
Invalid							
Unknown							
Not Done							
Total							

BB.6 Possible Previous Participant Report

Survey ID	Venue Code	Interview Date	Start Time	Interviewer Code	Previous Participant	Eligibility	Validity	Date of Birth	Race / Ethnicity	Education	ZIP Code

BB.7 Interviewer Report

1. INTERVIEWER CAPACITY

Interviewer ID	No. of Completed Interviews	Length of Eligibility Screener					Length of Consent Process					Length of Interview				
		Med	Mean	Min	Max	No.	Med	Mean	Min	Max	No.	Med	Mean	Min	Max	No.
TOTAL																

2. RESPONSE VALIDITY

Interviewer ID	Confident		Some Doubts		Not Confident at All		Total
	N	%	N	%	N	%	N

3. CODING OF OTHER INSURANCE

Interviewer ID	Survey ID	Private	Medicaid	Medicare	Other Government	Tricare (Champus)	VA Coverage	Text for Other Insurance Specified