National HIV Behavioral Surveillance System:
Men Who Have Sex with Men- Round 3
(NHBS-MSM3)

OPERATIONS MANUAL

Behavioral Surveillance Team
NCHHSTP/DHAP/BCSB

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Appendices

1 Introduction

1.1 Overview

The *NHBS-MSM3 Operations Manual* is designed to guide project staff during the implementation of NHBS-MSM3. All project staff should read the *NHBS-MSM3 Operations Manual* and the *NHBS-MSM3 Model Surveillance Protocol* in order to prepare for NHBS-MSM3 activities. The *NHBS-MSM3 Operations Manual* should also be available during each recruitment event as well as at the project office.

The manual describes in detail procedures needed to conduct NHBS-MSM3 using venue-based sampling. This includes staffing the project, preparing for the project, constructing recruitment calendars, making preparations for and managing recruitment events, implementing recruitment event procedures, closing out recruitment events, conducting HIV testing, reviewing process monitoring reports and conducting ongoing formative research, and conducting data management activities.

1.2 Justification

The primary purpose of an operations manual is to develop and document procedural strategies to be used in conducting NHBS- MSM3 activities. The manual ensures operational standardization of NHBS- MSM3 activities across all project sites.

1.3 Responsibilities

The CDC investigators are principally responsible for writing the *NHBS-MSM3 Operations Manual* and supporting appendices and will provide technical assistance to project sites during implementation. The local NHBS-MSM3 staff will conduct the project using the procedures described and submit necessary data to CDC through the Data Coordinating Center (DCC) Data Portal in a timely manner.

1.4 NHBS-MSM3 Methods

NHBS-MSM3 will be carried out using venue-based sampling (VBS). VBS is used to conduct a cross-sectional survey of men who have sex with men (MSM) who attend venues within the metropolitan statistical area (MSA). VBS sampling activities include constructing an initial "universe" of MSM-identified venues through formative research. Next, project staff will use the identified Venue Universe to construct monthly sampling frames of venues and their associated day-time periods (VDTs) that are expected to produce a sufficient number of eligible men. The final stage is conducting interviews and

HIV testing with eligible men at VDTs that are randomly selected from constructed sampling frames. During recruitment events, project staff count, approach, and interview eligible men who wish to participate in NHBS-MSM3.

1.5 MSM3 Operations Checklist

The MSM3 Operations Checklist is found in **Appendix A**; in prior rounds of NHBS, this document was referred to as the Pre-implementation Checklist. Project sites should complete the checklist and send it to their CDC Project Officer along with the requested attachments at least **two weeks** before planned implementation of NHBS-MSM3 activities. Project sites may also want to send draft sections of the checklist to their CDC Project Officer as they are completed. The CDC Project Officer will set up a conference call to review the checklist prior to implementation to ensure all preparations for the NHBS-MSM3 project have been addressed. Once these materials are reviewed and approved by the CDC Project Officer, project sites will receive confirmation via email that project activities may begin.

Project sites should revise the checklist when there are changes over the course of the NHBS-MSM3 cycle (e.g., new staff), and each revised version of the checklist should be sent to the CDC Project Officer.

2 Staffing, Training and Evaluations

2.1 Overview

Successful staffing, training, and performance evaluations are critical to the success of NHBS-MSM3. Likewise, excellent leadership abilities, a strong understanding of the research methodology, good communication skills, and enthusiasm for the project are essential attributes to ensure successful project delivery and quality data collection.

This chapter will describe the CDC-recommended staffing for NHBS-MSM3, the importance of NHBS skill standardization and quality assurance, staff training, and evaluations.

2.2 Staffing

This section shows the recommended staffing for NHBS-MSM3 and description of each role. CDC assists each project site in identifying the most effective staffing plan per local needs to ensure the successful delivery of NHBS-MSM3.

2.2a Management staff

Every project site should have persons designated to serve as principal investigator, project coordinator, and field supervisor for NHBS-MSM3. These management staff are responsible for administering project activities and for ensuring that NHBS-MSM3 project activities are carried out in compliance with the *NHBS-MSM3 Model Surveillance Protocol*, other NHBS guidance documents (*NHBS-MSM3 Operations Manual, NHBS Round 3 Interviewer Guide)*, and other locally developed procedures. In addition, they are in charge of overseeing successful collection and quality assurance of NHBS-MSM3 data and monitoring project staff performance. The management staff are also responsible for the safety, security and confidentiality of NHBS project staff, participants, and data; as such, they should also ensure that field incidents and adverse events are reported to CDC (within 48 hours of occurrence) and to the IRB(s) per local guidelines and procedures.

Table 2.1 shows in more detail the recommended duties and responsibilities for each management staff role. Project sites should tailor this table to reflect their local staffing plan and attach it the NHBS-MSM3 Operations Checklist (see **Appendix A**). Project sites may want to add columns to this table if more than one individual fulfills a specific role (e.g. a health department principal investigator and a contractor principal investigator).

Principal investigator

The principal investigator provides local scientific oversight for NHBS. The directly funded health department principal investigator is ultimately responsible for the success of NHBS-MSM3. Duties and responsibilities may be shared between the health department principal investigator and the contractor principal investigator; however, the directly funded health department principal investigator is ultimately responsible for matters related to fiscal and data-related issues (analysis, security, confidentiality, etc.) and is the primary contact for CDC regarding these matters.

Principal investigators will spend approximately 10% of their time on the project.

Project coordinator

A successful project coordinator has considerable knowledge of HIV/AIDS and surveillance activities, excellent leadership skills and attention to detail. In addition, the project coordinator should be familiar with computer programs such as word processing, spreadsheets, file management, and have a willingness to learn additional programs, such as the Questionnaire Development System (QDS™) and the VDTS Program.

The project coordinator is responsible for the day-to-day management of the project including support for key administrative functions. A high-level of supervision for all aspects of NHBS-MSM3 is necessary to ensure the success of project activities. Project coordinators will spend up to 100% of their time on NHBS-MSM3. Generally, the project coordinator and field supervisor jobs together comprise 1.5-2.0 FTEs.

Field supervisor

A successful field supervisor has considerable knowledge of the communities in which NHBS-MSM3 is conducted, knowledge of HIV/AIDS and surveillance activities, excellent leadership skills, attention to detail, high motivation, and cultural competence. In addition, a field supervisor should be familiar with computer programs such as word processing, spreadsheets, file management, and have a willingness to learn additional programs, such as the Questionnaire Development System (QDS™) and the VDTS Program.

The field supervisor assists with the day-to-day management of the project, particularly overseeing the field staff and recruitment events. A high-level of supervision for all aspects of NHBS-MSM3 is necessary to ensure the success of data collection. Field supervisors will spend up to 100% of their time on NHBS-MSM3. Generally, the project coordinator and field supervisor jobs together comprise 1.5-2.0 FTEs.

2.2b Field staff

Successful implementation of venue-based sampling and NHBS-MSM3 activities requires interviewers, counters, recruiters, and HIV test counselors. Depending on the staff structure and qualifications, some field staff may assume multiple roles. For example, some recruiters may also conduct interviews or some interviewers may also conduct HIV counseling and testing. In order to maximize flexibility of operations, it is recommended to cross-train field staff to fulfill multiple roles.

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.

Field staff should be outgoing, welcoming, and culturally competent. Prior to implementation and throughout the entirety of the project, field staff should participate in all required trainings and evaluations and demonstrate the ability to carry out their role-related activities.

Field staff are expected to adhere to procedures in accordance with the *NHBS-MSM3 Model Surveillance Protocol*, other NHBS guidance documents (*NHBS-MSM3 Operations Manual, NHBS Round 3 Interviewer Guide)*, and other locally developed procedures. Field staff should comply with guidelines for maintaining safety, data security, and participant confidentiality. In addition, field staff should implement local safety procedures and report field incidents and adverse events to field supervisors within 24 hours of occurrence.

Table 2.2 shows in more detail the recommended duties and responsibilities for each field staff role. Project sites should tailor this table to reflect their local staffing plan and attach it the NHBS-MSM3 Operations Checklist (see **Appendix A**).

Interviewers

A successful interviewer should be an excellent communicator, have considerable knowledge of HIV/AIDS, and have considerable knowledge of the local MSM community. In addition, an interviewer should have excellent interviewing skills, previous experience working with populations at risk for HIV, a thorough understanding of the importance of the informed consent process and the ability to collect data accurately.

Interviewers are responsible for screening participants for eligibility, administering the consent process, conducting interviews using handheld computers, and providing appropriate referrals to participants after the completion of the survey.

Counter

A successful counter has a thorough understanding of, and ideally, previous experience with, venue-based sampling. In addition, the counter should have excellent attention to detail.

The counter is responsible for counting venue attendees and directing recruiters to approach selected attendees for recruitment. There should be one full-time counter at each recruitment event. The field supervisor should not serve as the counter.

Recruiters

A successful recruiter is highly motivated, has considerable knowledge of the local MSM community, has excellent communication skills, and to the extent possible, representative of the major racial/ethnic population segments of MSM. In addition, a recruiter should have a sound understanding of venue-based sampling and the NHBS-MSM3 study.

Recruiters are the face of NHBS-MSM3; they approach potential participants and invite them to participate in the project.

HIV test counselors

HIV test counselors must be trained and certified to conduct the specific type of HIV test being used at the respective project site. A successful HIV test counselor has considerable knowledge of the local MSM community, considerable knowledge of HIV/AIDS, and has excellent communication skills. HIV test counselors should also be able to target prevention messages to specific risks identified during the NHBS-MSM3 interview as well as provide referrals for any additional social support or medical services identified during the counseling session.

HIV test counselors are responsible for conducting the HIV testing component of NHBS-MSM3 with men who agree to participate. Responsibilities include providing men with information about HIV testing, managing the applicable paperwork and data collection, and ensuring local HIV testing guidelines are followed.

2.2c Data manager

A successful data manager has considerable knowledge of the NHBS data system, experience in managing data from multiple sources, excellent organization skills, and attention to detail. The data manager is responsible for consolidating local data files, ensuring data quality, data entry and submission to the Data Coordinating Center (DCC) Data Portal, and communicating data issues to the DCC and other project staff. Data managers should ensure that data are stored in a manner which maintains required security and confidentiality; as such, data managers should report data-related adverse

events to the field supervisor per local protocol. Data managers will spend approximately 15% of their time on NHBS-MSM3.

Table 2.2 shows in more detail the recommended duties and responsibilities for the data manager role; this table should be tailored specifically for each project site and attached to the NHBS-MSM3 Operations Checklist (see **Appendix A**). If the project coordinator, for example, is to fulfill the data manager role, then this should be updated accordingly for Tables 2.1 and 2.2.

2.2d Spanish-speaking staff

NHBS project sites that utilize Spanish language materials will need to have Spanish-speaking project staff available for interviewing and HIV counseling and testing at every recruitment event. A Spanish-speaking project staff member should also be available at every recruitment event for answering general questions about the project. Some project sites have few venues that cater to monolingual Spanish-speaking clientele. Therefore, project sites should talk to their CDC Project Officer if they are only able to schedule Spanish-speaking project staff members for specific recruitment events.

2.3 The Importance of NHBS Skill Standardization and Quality Assurance

The quality of NHBS-MSM3 data is dependent upon each project staff member's ability to perform their job successfully, consistently, and in the same manner as their NHBS counterparts within and across project sites. Standardization of procedures and quality is an important aspect of all data collection efforts. To ensure standardization of NHBS-MSM3 across all project sites, 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.

2.3a What is standardization?

Standardization is important to ensure data quality and, in theory, means participants should have very similar experiences regardless of where they are interviewed. 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 Baltimore, Boston, or Miami. Although a participant will have the same past behaviors and experiences regardless of interviewer or location, *what he chooses* to report during an interview can be very different depending on the interviewer and/or setting.

Such things as interactions with and demeanor of project staff, distractions, feeling uncomfortable, or privacy-related concerns can impact what a participant chooses to report. Since external factors cannot be completely removed, the best way to minimize these effects, which cause measurement error, is to standardize procedures and quality within and across sites.

2.3b What is measurement error?

Measurement error affects the reliability of data and is a primary concern during any data collection effort. There are two types of measurement error, random and non-random. **Random measurement error makes the data less precise**. An example is when an interviewer accidently marks a response option that is different from what the participant said or when a participant's recall of a behavior is not precise. As some participants' recall may not perfect, we can account for random measurement error by giving a range of possible "true" values for the estimate (a confidence interval). So, for instance, we say the estimate is 50% but acknowledge that the "true" value is somewhere between 48 and 52%.

The other type of measurement error is non-random. **Non-random measurement error occurs when 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 affects the mean of the sample and can result in incorrect conclusions and estimates. An example of non-random measurement error is if a handheld computer's date is wrong resulting in miscalculations of time periods for all interviews collected on that handheld. To reduce non-random measurement error, it is critically important that project staff follow procedures as best as possible to reduce potential systematic variation in how data are collected.

Interviewer variation or interviewer effect is another important factor that affects standardization of data collection. Interviewer effect can include such things as an interviewer misreading questions, response options, or instructions; providing non-neutral feedback; or having lack of rapport with a participant. The best way to minimize interviewer effect is the standardization of interviewing within and across sites.

2.4 Project Staff Training

The goal for each project site's staff training is to ensure that staff members have a thorough understanding of the *NHBS-MSM3 Model Surveillance Protocol*, other NHBS-MSM3 guidance documents and their respective duties and responsibilities. The recommended knowledge and trainings for each project staff's role is summarized in **Table 2.3.**

NHBS-MSM3 project staff are to always conduct surveillance activities in ways that adhere to ethical principles and standards by respecting and protecting to the maximum

extent possible the privacy, confidentiality, and autonomy of participants (for more information, see Chapter 9 of the *NHBS-MSM3 Model Surveillance Protocol*).

NHBS-MSM3 project staff are also expected to maintain ethical standards related to professional behavior and demeanor towards fellow staff members, NHBS participants, and the general public at all times. Management staff should ensure that that these standards are incorporated into local trainings and policies for NHBS.

2.4a NHBS-MSM3 required trainings

There are specific trainings that are required for certain NHBS project staff; these trainings are listed below along with the suggested attendees. Trainings that should be completed prior to implementation should be documented on the MSM3 Operations Checklist (**Appendix A)**.

Field Operations Training

The CDC-sponsored Field Operations Training should be attended by the field supervisor and one additional senior project staff member, who in turn, conduct staff training at their project site. Bringing together the field supervisors and senior project staff is another method to ensure standardization and quality assurance within and across sites.

Recommended participants: field supervisor and a senior project staff member

HIV/AIDS surveillance data security and confidentiality

In accordance with the Assurance of Confidentiality requirements, each project site should adhere to the existing standards of its pertinent State or local health department for protecting the security and confidentiality of HIV/AIDS surveillance data, because these are approved by the Overall Responsible Party (ORP) at the health department. Information on training requirements can be found at: www.cdc.gov/hiv/topics/surveillance/resources/guidelines/guidance/training.htm.

Recommended participants: All NHBS-MSM3 staff

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 on the Data Portal.

Recommended participants: data manager, project coordinator, and/or other designated staff

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

NHBS-MSM3 project staff should be trained on how to respond to emergency situations involving participants, such as if a participant expresses suicidal feelings upon receiving a positive HIV test result. Project staff should also be trained in *de-escalation* techniques, and how to respond to emergencies (e.g., fire/police/hospital contact numbers). Along

with training on general field safety procedures, training should also include a communication plan for alerting project staff to a general threat, plans for dealing with these situations, and procedures for identifying and reporting field incidents and adverse events. Field supervisors should periodically review local safety procedures with project staff to ensure they stay current on what to do in case of an emergency.

Recommended participants: All NHBS-MSM3 project staff

HIV counseling and testing certification

All HIV test counselors must be trained according to state/local HIV testing guidelines.

Recommended participants: All HIV test counselors

HIV counseling and testing--NHBS

All HIV test counselors should be trained according to NHBS-MSM3 and local guidelines and standards regarding HIV risk-reduction counseling and testing procedures, specimen collection, giving discrepant tests results for when rapid and confirmatory tests have differing results, safe handling of blood specimens, and, for applicable project sites, giving HIV test results over the phone.

Recommended participants: All HIV test counselors

2.4b NHBS-MSM3 recommended trainings

Cultural competency course

A cultural competency course is recommended for all recruiters and interviewers so that they may learn how to work with diverse sub-populations of MSM. Such courses may be offered at local universities, through state health departments, medical schools, or through companies that specialize in diversity training.

Recommended participants: All NHBS field staff

Human subjects/scientific ethics training

This free online training covers the historical background of behavioral and biomedical research, the ethical principles for human subject research, case studies, and information on the role of the IRB. Depending on your familiarity of the material, completion time can be approximately from 30-90 minutes. Two websites are listed below that provide the course: (1) Collaborative Institutional Training Initiative (CITI) (www.citiprogram.org) or (2) NIH Protecting Human Research Participants (PHRP) (www.phrp.nihtraining.com). Once registered, you can complete the course in multiple sittings.

Recommended participants: All NHBS field staff

2.5 Project Staff Evaluations

2.5a NHBS-MSM3 performance recommendations

To assist health departments with evaluating pre-implementation and ongoing job performance of NHBS-MSM3 project staff, role-specific evaluation forms are provided (**Appendices B-G**) with NHBS performance recommendations denoted by shading. Performance recommendations are the suggested quality standards for each which staff position should obtain prior to working in the field and should maintain throughout the project. This information is summarized by project staff role in **Table 2.4.**

2.5b Evaluators

The principal investigator, project coordinator, or field supervisor is encouraged to complete pre-implementation and ongoing evaluations for all project staff members to ensure thorough job knowledge and successful skill performance.

As the field supervisor will be busy managing the recruitment event, the project coordinator or principal investigator should conduct most ongoing evaluations.

When evaluating, it is important for each evaluator to have an understanding of each job's responsibilities, evaluation form, and performance recommendations. When conducting observations, the evaluator should only interrupt the interviewer or HIV test counselor for major issues (i.e. issues related to consent or miscoding that leads to an entire section of the survey being skipped). When doing so, the evaluator should be discreet and direct communication only to project staff member and not the participant.

Suggestions for evaluators:

- Maintain pre-implementation and ongoing evaluation schedules.
- When evaluating, have a copy of the evaluation form, applicable script(s), and/or handheld computer.
- Never serve as a mock participant and evaluator at the same time.
- Always provide feedback and recommendations for improvement to the project staff member.
- Communicate with the field supervisor regarding staff evaluations and retraining needs.
- Project staff that perform more than one role should be evaluated for each job.

As each evaluation is intended to build upon previous evaluations, it is suggested that pre-implementation and ongoing evaluation forms be kept on file. When kept, all evaluation forms must be stored in a secure and locked location.

2.5c Project staff

Project staff should be familiar with their role-specific evaluation form, performance recommendations, and local requirements prior to being evaluated. Following each evaluation, feedback should be provided, the evaluation reviewed, and recommendations for improvement provided.

Prior to each evaluation, interviewers and HIV test counselors should follow a locally developed script to explain the evaluation process to the participant. Key points to be discussed with the participant are: (1) the evaluator would like to observe the interviewer and/or HIV test counselor and not the participant; (2) it is the participant's choice for an evaluator being present, and (3) the reason for the observation is to ensure quality standards for NHBS.

2.5d The importance of ongoing evaluations

All project staff should be evaluated on a regular basis to ensure that standardization and quality data collection are maintained throughout the project's implementation. **Over time, it can be expected that project staff, even those with much experience, will begin to drift from NHBS procedures resulting in lack of study standardization.** If these changes are not identified and corrected, data quality will be compromised. Through routine evaluations, the principal investigator, project coordinator, and field supervisor can identify when drift has occurred and correct the behavior.

2.5e Recommended ongoing evaluation schedule and retraining procedures

The importance of ongoing evaluations and its positive impact upon the reliability of NHBS data cannot be overstated. Likewise, it is recommended that retraining occur each time a staff member has been identified as not having maintained the performance recommendations. A summary of recommended ongoing evaluation schedules and retraining procedures is presented in **Table 2.4.**

2.5f Interviewer Improvement Reports

To assist project sites with providing feedback to interviewers to improve their techniques, the DCC will produce a report showing the mean, median and range in length of the eligibility screener, the consent process, and the interview itself by each Interviewer ID (**Appendix H**). Project sites should review this report regularly with interviewers to identify and discuss unusually short or long times for any of these components.

Table 2.1: Recommended Management Staff Roles and Responsibilities

Staff member	Principal Investigator (PI)	Project Coordinator	Field Supervisor
Administrative	• Oversee the hiring and supervision of project staff. • Tailor local *NHBS-MSM3 Model Surveillance Protocol* 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 a Federalwide Assurance (FWA) number. (HD) • 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. (HD) • 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. (HD) • Oversee the development of local use questions • Participate in CDC site visits, PI meetings, and monthly calls.	• Manage contracts related to the project (as applicable). (HD) • 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 between the NHBS and 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	• Participate in CDC site visits, trainings, regular conference calls, and, as available, monthly calls.
Safety, security and confidentiality	• Responsible for safety, security, and confidentiality of NHBS project staff, participants, materials, and data, including the development of local procedures and policies.	• Coordinate development of local procedures for incident reporting, local safety procedures, and handling participants known to project staff.	• Assist in the development of local procedures for incident reporting, local safety procedures, and handling participants known to project staff. • Implement all locally developed procedures, including safety, incident reporting and handling participants known to project staff.
Training and ongoing evaluations	• Ensure required trainings have been successfully completed by all project staff. • Conduct project staff evaluations in collaboration with project coordinator and field supervisor.	• Coordinate and conduct pre-implementation and ongoing trainings for NHBS project staff in collaboration with the Field Supervisor. • Conduct project staff evaluations in collaboration with the PI and Field Supervisor.	• Coordinate and conduct pre-implementation and ongoing trainings for NHBS project staff in collaboration with the project coordinator. • Conduct project staff evaluations in collaboration with the PI and project coordinator.
Project management	• Appoint a designee or serve as back-up for project coordinator in event of absence. • Collaborate with local stakeholders and disseminate information and data from the project to garner support for NHBS.	• Provide overall project management. • Maintain inventory of supplies, materials, incentives and equipment. • Oversee ongoing formative research efforts. • Review, on a weekly basis, process monitoring reports provided by the DCC. • Serve as back up for data manager and field supervisor.	• 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 all aspects of planning for and operations of data collection at recruitment events. • If needed, assist with ongoing formative research efforts.
Data collection, management, analysis, and dissemination	• Ensure timely submission and entry of data to the DCC Data Portal. • Responsible for quality control and data integrity. • Oversee development of policies pertaining to analyses and dissemination of data. (HD) • Oversee analyses of site data. (HD) • Ensure data is released in accordance to local policy and data use agreements. (HD) • Present reports and disseminate study findings. • Use study findings for the development, modification, and evaluation of local prevention programs. (HD)	• Ensure daily transfer of data from the handheld computers to desktop computer. • Ensure that QDS™ Warehouse is maintained. • Ensure HIV testing data, data errors and VDTS information are entered into the DCC Data Portal daily. • Ensure that sampling frame and calendar information is maintained in VDTS program. • Coordinate and implement policies pertaining to data analysis and dissemination. • Participate in data analysis and dissemination.	• Schedule monthly recruitment events. • Review, tabulate, and reconcile forms and logs used in the field. Review errors with recruiters, interviewers, and HIV test counselors. • Oversee documentation of data errors. • Supervise entry of HIV testing data, data errors and VDTS information into the DCC Data Portal.
HIV Testing Operations	• Develop local HIV testing protocol and oversee HIV testing activities.	• Oversee maintenance of HIV testing supplies. • Ship HIV test specimens. • Receive and log HIV test results from lab. • Obtain CLIA waiver, if applicable.	• Ensure proper documentation of HIV testing activities, including consent. • Ensure adherence to HIV testing procedures.

Table 2.2: Recommended Field Staff and Data Manager Roles and Responsibilities

Interviewer	Counter	Recruiter	HIV Test Counselor	Data Manager
• Accurately document participant information for the eligibility screener, consent form(s), questionnaire, and Participant Tracking Form. • Maintain data integrity (i.e., all data collected accurately represents the information provided by a participant). • Assist with ongoing formative research as necessary.	• Maintain counts of men who appear eligible and cross into counting area. • Direct recruiter to approach next man to be intercepted. • Assist with ongoing formative research as necessary.	• Intercept men in accordance with the protocol and as directed by the counter. • Accurately document all intercepts on Intercept Form. • Assist other recruiters will intercepting and recruiting. • Check in with field supervisor if intercepts not successful • Review all completed Intercept Forms. • Assist with ongoing formative research as necessary.	• Conduct HIV counseling and testing. • Have knowledge of information in package insert (for rapid testing). • Document HIV test results. • Accurately document information on lab slips, HIV Test Result Logs, and Specimen Shipping Log. • For sites with non-interviewer HIV test counselors: Document communication between interviewer and HIV counselor to ensure participant consent was provided for HIV testing).	• Ensure upload of data from handheld computers to desktop computer. • Ensure daily receipt forms/logs and review errors and/or concerns with the field supervisor or project coordinator. • Enter information from forms/logs into DCC Data Portal. • Maintain QDS™ Warehouse and submit weekly to CDC via the DCC Data Portal. • Maintain data integrity (i.e., each record in the database represents the data an individual provided the field team). • Review data reports from DCC as soon as received and provide requested data edits and explanations to resolve data issues via the DCC Portal. • Perform data analyses as needed.

Table 2.3 NHBS-MSM3 Pre-implementation Knowledge and tTainings

	NHBS-MSM3 guidance documents							Required trainings					Recommended trainings	
	Model Surveillance Protocol	Operations Manual	Formative Research Guidelines	Round 3 Interviewer Guide	Round 3 Questionnaire	DCC NHBS Data Management Training Manual	Site-specific HIV testing products documentation	Confidentiality for HIV/AIDS surveillance data	Emergency procedures, field safety, adverse events, and field incidents	CDC-sponsored Field Operations Training	Local site and job-specific trainings	DCC Data Management	Cultural competency course	Human Subjects Ethical Training
Project Coordinator	x	x	x	x	x	x	x	x	x		x	x		x
Field Supervisor	x	x	x	x	x	x	x	x	x	x	x		x	x
Interviewers	x	x	If assisting	x	x			x	x		x		x	x
Counters	x	x	If assisting					x	x		x		x	x
Recruiters	x	x	If assisting					x	x		x		x	x
HIV Counselors	x	x	If assisting				x	x	x		x		x	x
Data Manager	x	x	If assisting		x	x		x	x		x	x		x

Table 2.4 NHBS-MSM3 Evaluation Recommendations

Staff member	Evaluators	Pre-implementation Evaluation of Performance Recommendations	Ongoing Evaluations Schedule	Retraining Recommendations	Retraining Evaluation Schedule
Field Supervisor	PI or PC	Successful evaluation of NHBS performance recommendations.	Recruitment Events: For first 3 weeks, once per week, then once per month	Retraining of necessary skills by PI or PC	Successful evaluation of NHBS performance recommendations.
			HIV Operations: Monthly	Retraining of necessary skills by PI or PC	
Counters	PI, PC, or FS	High level of comfort and accuracy counting venue attendees (Note: there is no evaluation form for counters).	For the first 3 events and then once per month, the counter should be evaluated/monitored for 10-15 minutes to ensure all counting procedures are accurately being performed.	Minor errors: Retraining/review of necessary skills by FS or PC prior to any more counting.	Successful evaluation/monitoring of counter for another 10-15 minutes at same event. If evaluation is unsuccessful, additional retraining is recommended.
				Major errors: Complete retraining by FS or PC prior to any more counting.	Successful evaluations of mock counting scenarios.
Recruiters	PI, PC, or FS	Successful evaluation of NHBS performance recommendations. High level of comfort and accuracy in response to Intercept and Participation Barriers (see **Appendices M and N**)	First 5 approaches at first 3 events, then 5 approaches each during at least 2 events per month. Recruiters should also be evaluated at events where 5 consecutive approaches refuse intercept.	Minor errors: Retraining/review of necessary skills by FS or PC prior to any more approaches.	Successful evaluation of 5 approaches. If evaluations are unsuccessful, additional retraining is recommended followed by successful completion of 5 mock intercepts.
				Major errors: Complete retraining by FS or PC prior to any more approaches.	Successful evaluation of 5 mock intercepts.
Interviewers	PI, PC, or FS	Successful evaluation of two consecutive full mock interviews (screening, consent, and interview).	One evaluation during each of the first 3 weeks, then once every 10 interviews, or if a part-time interviewer with fewer interviews completed, at least once a month.	Minor errors: Retraining/review of necessary skills by FS or PC prior to any more interviewers	Successful evaluation of the next two full interviews (screening, consent, and interview). If evaluations are unsuccessful, additional retraining is recommended followed by succession evaluation of two consecutive mock interviews.
				Major errors: Complete retraining by FS or PC prior to any more interviews	Successful evaluation of two consecutive full mock interviews (screening, consent, interview).
HIV Counselors	PI, PC, or FS	Successful evaluation of two consecutive full mock HIV testing sessions. The following counseling scenarios should be practiced prior to data collection: an HIV negative test result, an HIV preliminary positive test result, an HIV confirmed positive test result, and discrepant HIV test results (preliminary and confirmatory).	For evaluation during each of the first 3 weeks, then once every 10 testing sessions or, if a part-time counselor with fewer sessions completed, at least once a month.	Minor errors: Retraining/review of necessary skills by FS or PC prior to any more HIV testing sessions	Successful completions of the next two HIV testing sessions. If evaluations are unsuccessful, then additional retraining is recommended followed by successful evaluation of two consecutive mock HIV testing sessions.
				Major errors: Complete retraining by FS or PC prior to any more HIV testing sessions	Successful evaluation of two consecutive mock HIV testing sessions with skills.
Data Manager	PI or PC	Successful evaluation of NHBS performance recommendations. Successful data upload from handheld computer without any data loss. For new data managers, successful encryption and submission of QDS™ Warehouse containing mock core interviews to the DCC Data Portal	Monthly	Retraining of necessary skills by PC	Successful evaluation of NHBS performance recommendations.

3 Project Preparation

3.1 Overview

The purpose of this chapter is to describe the preparation tasks that should be completed prior to starting NHBS-MSM3. These tasks include but are not limited to the development of a project logo and marketing materials, access to the Data Coordinating Center (DCC) Data Portal, the preparation of project supplies and the establishment of local safety and field incident reporting procedures.

3.2 Project Logo and Marketing Materials

A logo and marketing materials can be created for NHBS-MSM3 project identification and to promote community awareness of the project. Formative research should guide the creation of these materials, and members of the community should be asked about the types of logos and marketing that would be appealing to potential participants. Marketing materials should be culturally appropriate and respectful of the local community. Project sites should have their logo and materials reviewed by their CDC Project Officer before printing and distributing.

3.3 Access to Data Coordinating Center Data Portal

Project sites will need to regularly submit their QDS™ Warehouse containing NHBS-MSM3 core interviews to the DCC Data Portal (**Chapter 10** of this manual). Project sites will also utilize the Data Portal to enter data into the online HIV Test Results Log (**Chapter 8**) and online Data Error Log (see *DCC NHBS Data Management Training Manual*) as well as access the VDTS Program (**Chapter 4**). Project staff that need access to the Data Portal should first receive approval from the principal investigator of the directly funded health department and then apply for access following the instructions provided in the *DCC NHBS Data Management Training Manual.*

3.4 Project Supplies

This section describes the supplies that project staff should acquire before implementing project activities. The Recruitment Event Checklist (**Appendix I)** has a model list of project supplies that are needed to conduct recruitment events; project sites may need to modify the list to meet local needs.

3.4a Handheld computers and survey software

NHBS-MSM3 surveys must be conducted using handheld computers. Therefore, project sites should check that handheld computers are functioning properly and ensure that enough handheld computers are available for use in the field (including at least one backup). Project sites that have experienced problems with handheld computers during past cycles should consult their CDC Project Officer to discuss options to prevent data loss during NHBS-MSM3.

Paper surveys are not allowed for data collection even if the handheld computers are malfunctioning. A recruitment event cannot be conducted if none of the handheld computers are operational.

HAPI™ version 2.4 must be installed on all handheld computers to operate the NHBS-MSM3 survey. The survey control file will not run properly (i.e., skip patterns may not function appropriately) if a later version of HAPI™ is used. To manage the survey data, project sites should have QDS™ Warehouse version or 2.5 (2.6 is NOT recommended).

3.4b Materials

Project sites should ensure that they have an adequate amount of photocopied consent forms, incentives, flashcards and other materials needed to conduct NHBS-MSM3 activities. Flashcards that are laminated and attached to a ring may be easiest for interviewers to use during survey administration.

3.4c Forms and logs for NHBS-MSM3 project management

To ensure successful project management and quality data collection, NHBS project staff should develop procedures for the day-to-day operations of NHBS-MSM3 activities. Several forms and logs described throughout this manual are used to collect, convey and manage/track information for different operational aspects of NHBS-MSM3. The field supervisor and other project staff will be responsible for completing, reviewing, correcting, and updating forms in accordance with their local procedures and the *NHBS-MSM3 Model Surveillance Protocol*. Project sites are encouraged to develop additional forms to manage NHBS-MSM3 project activities as needed. **Table 3.1** summarizes the minimum forms and logs that are recommended.

The forms and logs recommended in this section are intended for project staff to better manage operations of NHBS-MSM3; these forms are not federal data collection systems nor have they received PRA/OMB approval. CDC does not systematically collect information contained in these forms.

Table 3.1 Summary of forms and logs for NHBS-MSM3 project management

Form or Log	Where it's used	Purpose	*NHBS-MSM3 Operations Manual*
Intercept Form	Recruitment events	Record information collected during intercept.	Appendices O and P
	Project office	Enter recruitment event outcomes into VDTS Program.	
Survey ID Log	Recruitment events	Track survey numbers assigned.	Chapter 5
Participant Tracking Form	Recruitment events	Track participant information and record data edits.	Appendix L
	Project office	Enter data edits into the online Data Error Log (see Data Portal).	
Appointment and Phone Results Card	Recruitment events	Make post-event appointments or appointments for returning HIV test results.	Appendix Q
Appointment Log	Recruitment events	Schedule appointments.	Chapter 6
	Project office	Track appointments.	
Quality Assurance Log	Recruitment events	For rapid HIV tests, monitor controls, temperature, lot numbers, and times tests were started and results read.	Chapter 8
Lab slips	Recruitment events	Identify specimens.	Chapter 8
Specimen Shipping Log	Recruitment events	Ship laboratory specimens, if applicable (e.g. from a mobile unit)	Appendix R
	Project office	Ship laboratory specimens.	
Reminder Call Forms	Recruitment events	Record information for optional reminder call for HIV test results appointment (if applicable).	Appendix T
	Project office	Make reminder calls to participants.	
Phone Results Log	Recruitment events and project office	Record information to return HIV test results over phone (if applicable).	Appendix S
HIV Test Results Log	Recruitment events	Record HIV testing data.	Chapter 8 *(Appendix J, NHBS-MSM3 Surveillance Protocol)*
	Project office	Enter HIV testing data into online HIV Test Results Log (DCC Data Portal).	
Recruitment Event Checklist	Recruitment events and project office	Facilitate preparation for, setup and closeout of recruitment events.	Appendix I
Recruitment Event Information & Outcomes Form	Project office	Record information for recruitment events. Enter recruitment event outcomes into VDTS Program.	Appendix K
	Recruitment events	Record recruitment event notes and outcomes information.	
Project staff evaluation forms	Recruitment Events	Observe and evaluate project staff	Appendices B- G

It is recommended that NHBS project staff use a binder to store forms and logs in a central and easily referenced location. Project sites providing HIV test results over the phone should refer to the HIV Phone Results Protocol (see Appendix H of the *NHBS-MSM3 Model Surveillance Protocol*) and develop a Phone Results Log (see **Appendix S** of this manual). Hardcopy forms that contain confidential information (i.e., Reminder Call Forms, HIV Test Results Log, Phone Results Log, and Participant Tracking Forms) should be stored in a locked file cabinet and handled in a manner which complies with the *Technical Guidance for HIV/AIDS Surveillance Programs, Volume III: Security and Confidentiality Guidelines*[1]. In addition to the aforementioned forms and logs, project staff may want to store additional materials and information in the project binder for easy reference, such as:

- Venue Universe
- Monthly sampling frames and calendars
- Memorandums of Understanding

3.4d Prevention and referral materials

All men who complete at least part of the NHBS-MSM3 survey should be provided with HIV prevention and referral materials; project sites should develop and/or compile these materials and have them readily available at recruitment events:

- **Information and education pamphlets** on the following subjects:
    - Statistical data relaying the current state of the HIV, STD, and hepatitis epidemics, especially among MSM.
    - Modes of transmission for HIV, STD, and hepatitis.
    - Strategies for preventing HIV infection through sex and drug use.
    - HIV testing, hepatitis testing, and other testing services.
    - Alcohol and drug treatment.
- **List of referral agencies** and contact persons to provide to participants who are HIV-positive so that they can enter into 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 social service providers in their communities. This list should include HIV and STD clinics, substance abuse treatment centers, mental health service providers, agencies that offer free HIV testing and hepatitis testing, and organizations that serve gay and bisexual men.
- **Supplies** used to reduce HIV risk, such as condoms and lubricants.

Some project sites have found that packing prevention and referral materials in an interesting way potentially increases their appeal to participants.

3.4e Other supplies and materials

Project sites should acquire any additional supplies that are necessary to carry out NHBS-MSM3 project activities. In regards to HIV testing, project sites should have an adequate supply of test kits, specimen collection equipment and devices, protective equipment, and package inserts specific to the type of rapid test being conducted (if applicable).

3.5 Local Safety Procedures

Before conducting NHBS-MSM3 activities, project sites must develop local safety procedures, document these procedures in the MSM3 Operations Checklist **(Appendix A)** and train project staff on these procedures. Local safety procedures should include a communication plan for alerting project staff to a general threat, plans for dealing with these situations, and procedures for reporting field incidents. Field supervisors should periodically review local safety procedures with project staff to ensure they stay current on what to do in case of an emergency.

Generally, the field supervisor is responsible for crowd control and overall safety. As such, field supervisors should have emergency contact information for each project staff member accessible during recruitment events and hours of operation. Project staff must be alert to their own safety and to that of their co-workers at all times. Each of the project staff should have a basic awareness of their surroundings when working at recruitment events and be responsible for maintaining a safe working environment.

Sections 3.5a-3.5d below present model information that can be incorporated into project sites' local field safety procedures.

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 project or health department identification card.
- Plan ahead, be alert, and use common sense.
- Always have at least 2 project staff members and 1 field supervisor at each recruitment event and post-event appointment.
- Have first aid kits available.

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 in the venue.

- During interviews, position yourself closest to the door wherever possible in the event you need to exit quickly.

- Consider developing a code word to call for assistance from a co-worker. You might use something like the phrase "bring the red folder." For example, if you are not comfortable interviewing a participant alone or need help with an uncooperative participant, ask a co-worker to bring the "red folder" to indicate that assistance is needed.

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 matter.
- Use all of your senses to assess a situation. If your sixth sense tells you that the situation is not safe, then seek immediate assistance from a fellow staff member or security staff (if applicable).
- Approach every potential participant as though he is welcoming, but be cautious if you have concerns about an individual.

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 that contain or imply political or culturally sensitive images or characters.
- 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 working at the recruitment event.

- Do not buy or receive merchandise from participants.
- Do not accept gifts from anyone.
- Do not offer rides to or accept rides from participants.

3.5c Techniques for handling dangerous/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 them vent; listen to and acknowledge their 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 them that you are only there to interview them and that you are not interested in any sexual offers. If the participant continues, tell them that you are going to stop the interview if they 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 data for a variety of reasons. He may be unable to give coherent answers to the questions, nod off or appear to be very drowsy 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, then they should be made ineligible during the screener administration or the interview should be stopped during the survey administration (see **Chapter 6** of this manual for instructions).

3.5d Safeguarding handheld computers

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

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

3.6 Field Incident Reporting Procedures

Project sites should create field incident reporting procedures and include them in the MSM3 Operations Checklist (**Appendix A**). A model field incident report is provided in **Appendix J**. In the event that an incident occurs, project staff should notify their field supervisor within 24 hours. The field supervisor or project coordinator should then notify CDC within 48 hours and complete a "Field Incident Report" and send it to the CDC Project Officer. Project sites should work with their CDC Project Officer to determine if a field incident should be reported as an adverse event (see Chapter 9 of the *NHBS-MSM3 Model Surveillance Protocol*). In addition, project sites should check with their principal investigator to find out if there are any other procedures required by the local IRB(s) for field incidents.

4 Monthly Recruitment Calendar

4.1 Overview

The purpose of this chapter is to provide guidance in 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 VDTS Program supplied by the 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 project 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 VDTs that would be suitable for conducting recruitment events. Suitable VDTs must have all the following:

- management who have agreed to allow recruitment events to be held at their venue,
- safe environments,
- spaces where it is logistically feasible to conduct recruitment, interviewing, and HIV testing (alternatively, a mobile unit can be used for interviewing and testing), and
- ≥ 50% of venue attendees who are eligible for NHBS-MSM3 (≥18 years old, MSA residents, and ever had sex with another man).

Once all the suitable VDTs have been identified, they should be uploaded or entered into the VDTS Program to create the first month's sampling frame (see the *VDTS Program User Manual* for instructions on uploading and entering VDTs).

4.2b Constructing subsequent sampling frames

Based on their ongoing formative research, project sites should update the VDTs on the upcoming month's sampling frame using the VDTS Program. As attendance patterns at venues change, day-time periods on the sampling frame should be adjusted accordingly. If new venues or day-time periods are identified, they should be added to the sampling frame. On the other hand, if venues close or certain day-time periods no longer have sufficient levels of attendance to ensure productive recruitment, they should be removed from the sampling frame.

4.2c Reviewing and editing a sampling frame

After project sites create a monthly sampling frame, they should review it for accuracy. The VDTS Program will allow project 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 project sites by sorting and ordering the venues and day-time periods on their monthly sampling frames. The program first randomly sorts all the venues on the sampling frame and lists them by their selection order. The program then randomly sorts all the day-time periods available for each venue and lists them by their selection order. 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 (**Figure 4.1**).

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. Project sites should plan on conducting a minimum of 14 recruitment events each month to reach the target enrollment of 500 eligible MSM. Once project 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 project 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 3 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, project sites may conduct up to 2 additional non-random events for a total of 5 non-random events. Yet, to be able to conduct these extra non-random events, project 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 project site enroll an important sub-population that the project site is having difficulty reaching. Project 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.

The VDT for a planned non-random event, like a gay pride festival, should be entered in the VDTS Program so that it is available for scheduling, but it should not be included on the sampling frame.

Figure 4.1 Sorted sampling frame.

Sorted Frame for July 2011

Venue Pick Order	Venue Code	Venue Name	VDT Pick Order	Day	Start Time	End Time
1	D001	Club 2000	1	SAT	10:00 PM	2:00 AM
2	B002	Amsterdam's	1	FRI	6:00 PM	10:00 PM
			2	THU	6:00 PM	10:00 PM
3	C001	Woodfire Grill	1	TUE	11:00 AM	2:00 PM
			2	FRI	5:00 PM	9:00 PM
			3	MON	11:00 AM	2:00 PM
4	B001	ESPN Zone	1	SAT	1:00 PM	5:00 PM
			2	SUN	6:00 PM	10:00 PM
			3	SUN	2:00 PM	6:00 PM
5	F002	Fitness Factory	1	THU	4:00 PM	8:00 PM
			2	TUE	4:00 PM	8:00 PM
6	S005	Main ST & 2nd AVE	1	WED	10:00 AM	2:00 PM
7	P002	Piedmont Park	1	SUN	10:00 AM	2:00 PM
			2	SAT	2:00 PM	6:00 PM
			3	Fri	4:00 PM	8:00 PM
			4	SAT	10:00 AM	2:00 PM
			5	SUN	2:00 PM	6:00 PM

Figure 4.1 may look different in the VDTS Program.

Project sites will start the VDT selection process by selecting VDTs for any planned non-random events. They will then enter the anticipated number of random events in the VDTS Program (see the *VDTS Program User Manual* for instructions on selecting VDTs). The maximum number of random events a site can choose each month with the VDTS Program is twice the number of venues on the frame to ensure that events are not held at the same venue more than twice in a single month. The VDTS Program will also allow project 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.

After the number of random events and the number of reserve venues are entered in the VDTS Program, the program will display a table of the VDTs selected from the sorted sampling frame. The program will then give project sites the option of selecting any additional VDTs for non-random events. These VDTs may be chosen from among those that were not included on the sampling frame, as well as from among those that were. The latter option allows sites to conduct non-random events at important VDTs that were included on the sampling frame, but were not randomly selected for scheduling on the monthly recruitment calendar. Ordinarily, in a given month, non-random events should not be held at the same venue as a random event or another non-random event. However, under rare circumstances, project sites may repeat a non-random event at a venue if they obtain prior approval from their CDC Project Officer. When project sites have finished choosing non-random events (or if they by-pass this process), the VDTS Program will display a final table of selected VDTs (**Figure 4.2**). The top section of this table 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, project 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 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. Project sites should also block-off other dates and times when recruitment events cannot occur, such as weekly office hours.

Figure 4.2 Table of selected VDTs.

Selected VDTs for July 2011

	Venue Code	Venue Name	# of VDTs	VDT Pick Order	Day	Start Time	End Time
Non-random Events:							
	Z001	Auburn Street Fest	--	--	SUN	12:00 PM	5:00 PM
Random Events:							
	D001	Club 2000	1	1	SAT	10:00 PM	2:00 AM
	B002	Amsterdam's	2	1	FRI	6:00 PM	10:00 PM
				2	THU	6:00 PM	10:00 PM
	C001	Woodfire Grill	3	1	TUE	11:00 AM	2:00 PM
				2	FRI	5:00 PM	9:00 PM
				3	MON	11:00 AM	2:00 PM
	B001	ESPN Zone	3	1	SAT	1:00 PM	5:00 PM
				2	SUN	6:00 PM	10:00 PM
				3	SUN	2:00 PM	6:00 PM
Reserve Venues:							
	F002	Fitness Factory	2	1	THU	4:00 PM	8:00 PM
				2	TUE	4:00 PM	8:00 PM
	S005	Main ST & 2nd AVE	1	1	WED	10:00 AM	2:00 PM

Figure 4.2 may look different in the VDTS Program.

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 project sites may have more than one team of field staff. In these cases, if staff are available and burnout can be avoided, project 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.

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. Project 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, project 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, project sites can start scheduling those venues with more than one day-time period. Before project 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, *etc.*). 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, project sites should choose the second day-time period listed. If a date cannot be found for this day-time period either, project 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, project 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**, project 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, project sites should move to the next reserve venue on the list. This process should continue until project sites are able to schedule a replacement venue 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 venue because of unforeseen circumstances like inclement weather or a lack of eligible participants. 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 either at the same time as 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. When choosing possible alternate venues, project sites should also consider potential logistical and weather problems. For example, project 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, project 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, project 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, project 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, project 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 project 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, project 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, project 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, project 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, project 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 project 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. Project 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 preparing for and managing recruitment events. The first part of the chapter describes the forms needed to prepare for and manage recruitment events. The second part of the chapter describes the tasks that take place prior to starting the recruitment event and the tasks to setup the recruitment event at the venue. The last part of the chapter describes guidance for managing recruitment events. Procedures for closing out recruitment events are discussed in **Chapter 7** of this manual.

It is expected that the project coordinator or field supervisor will 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 as safe as possible, and that participants are treated with respect.

5.2 Forms for Tracking and Documenting Recruitment Event Information

To successfully conduct NHBS-MSM3 activities, 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 Recruitment Event Checklist (**Appendix I**) is intended for the field supervisor to use 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. 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 recruitment event, while setting up at the recruitment event, while closing out the recruitment event, and at the project office after the recruitment event. **Sections 5.3- 5.4** provide detailed information about the tasks to prepare for and setup at recruitment events. **Chapter 7** of this manual describes the tasks to closeout recruitment events.

5.2b Recruitment Event Information & Outcomes Form

The Recruitment Event Information & Outcomes Form (**Appendix L**) is intended for the field supervisor to use 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 number codes that will be

used for the recruitment event. The last two sections of the form collect post-event information: notes about the recruitment event as well as the outcomes of the event; the recruitment event outcomes information on this form will be entered into the VDTS Program on the Data Coordinating Center (DCC) Data Portal at a later time by the data manager or other designated project staff

5.2c Participant Tracking Form

The Participant Tracking Form (**Appendix L**) is intended be used by the field supervisor, the interviewer and the HIV test counselor to convey and track data through the interview and HIV counseling and testing processes. Such data include the code numbers assigned by the field supervisor, information about whether the participant self-reported HIV-positive during the interview or HIV counseling session (to be entered into the online HIV Test Results Log), and the data edits that the data manager or other designated project staff will need to enter into the online Data Error Log on the Data Portal at a later time. This form contains the minimum data expected to be tracked and is organized according to flow with the general order of procedures at recruitment events.

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

Each scheduled recruitment event will have one or two alternate venues. Before 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 enter and recruit 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. A field supervisor and a minimum of 2 project staff members with defined roles must be present at each recruitment event. The number of project staff needed for a recruitment event may vary depending on the volume of people attending a venue, the size of a venue (i.e., space available for interviewing), the use of a mobile unit, 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 recruitment 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 schedule to work at venues that cater to monolingual Spanish-speaking patrons. 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 recruitment events at these venues.

5.3d Gather code numbers

At the start of each interview, the interviewers will enter four different code numbers into their handheld 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; it is recommended that the Participant Tracking Form be used for this purpose. The field supervisor can refer to the Recruitment Event Information & Outcomes Form when recording these code numbers on 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 MSM3 Operations Checklist (**Appendix A**) and should not be exchanged or re-used among different interviewers 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 time or date (i.e. 'post-event appointments' or 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 6.3e** of this manual). Project sites may choose whichever method is most suitable to meet their local needs. Assigning Survey ID numbers at the time of recruitment can help project 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 of 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
- Indication as to whether the Survey ID number was assigned for a post-event appointment (PEA), *if a project site plans on assigning Survey ID numbers for appointments at the time of recruitment.*
- Comments

Table 5.1 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*	*6/4/2011*	*1*		
1002	*11*	*6/4/2011*	*1*		
1003	*10*	*6/4/2011*	*1*		
1004	*11*	*6/4/2011*	*1*		
1005	*12*	*6/7/2011*	*2*		
1006			*2*	*YES*	*Appointment- Mon 6/9- 2:00PM*
1007	*10*	*6/7/2011*	*2*		
1008	*10*	*6/7/2011*	*2*		
1009	*12*	*6/7/2011*	*2*		

Venue Code

The Venue Code is a unique 4-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 4, Step 6 of the *NHBS-MSM3 Formative Research Manual*. The Venue Code indicates the primary or alternate venue where participants were recruited during a recruitment event. If a project 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 (i.e., the first recruitment event should be assigned 1, the second recruitment event should be assigned 2, and so on). 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 last Event Number that was entered for the previous recruitment event conducted. The field supervisor should then record the next sequential Event Number on the Recruitment Event Information & Outcomes Form.

Because counting is the first step in the process of counting, recruiting, and interviewing venue attendees, a recruitment event officially starts when counting begins. Therefore, an Event Number should be assigned whenever a counting area has been designated at a venue and counting is ***attempted***, even if no venue attendees are actually counted. On the other hand, if a counting area cannot be designated at a venue or counting cannot be attempted, then a recruitment event has not officially started and an Event Number should not be assigned. The following examples illustrate when Event Numbers should and should not be assigned:

- If the counter attempts to count venue attendees at a scheduled recruitment event, assign an Event Number to that event.

  

  A count of zero is still a count.

- If a scheduled recruitment event is canceled before counting can begin, do not assign an Event Number to that scheduled event.
- If the counter attempts to count venue attendees at a recruitment event scheduled at a primary venue and also attempts to count attendees at the first alternate venue (e.g., the recruitment event was moved to the alternate venue because of unsuccessful recruitment), assign an Event Number to the event at the primary venue and the subsequent event number to the event at the alternate venue.
- If the counter does not attempt to count venue attendees at a recruitment event scheduled at a primary venue (e.g., the venue is closed) but does attempt to count attendees at the first alternate venue, assign an Event Number only to the event at the alternate venue.

5.3e Check handheld computers

Project staff should ensure that all handheld computers are charged and working properly before each recruitment event. It is recommended to have one or two backup handheld computers available if possible. Field supervisors should ensure that all data from the previous recruitment events have been uploaded from the handheld computers. Interviewers should check that the

correct date and time are displayed on the handheld computer before conducting the first survey of each recruitment event; it is also recommended that interviewers check the date and time periodically throughout the recruitment 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 may need to 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 conducting interviews and HIV testing activities. In addition, project staff should determine the size and location of the counting area, where recruitment will occur, and whether a post-event appointment (PEAs) system is appropriate; **Chapter 6** of this manual provides detailed guidance on procedures for counting, recruitment 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 recruitment 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 or cancellation of the recruitment event.

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. Specific circumstances include but are not limited to weather, safety, noise levels, privacy, venue owner preference, foot traffic and available space. The optimum interviewing and HIV testing spaces provide privacy for participants (i.e., the interview must not be overheard), safety and comfort.

Within venues

For most recruitment events, it is optimal to conduct interviews and HIV counseling and testing activities within venues. However, venue owners must approve of the activities and provide appropriate space for interviewing and HIV counseling and testing.

Outside venues

Project staff should consider interviewing outside if the venue itself is located outdoors (i.e. street location or park), if the venue owner is not willing to allow interviewing or HIV testing activities inside the venue, or if the inside space is very limited. 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. Interviewing and HIV testing should be conducted far enough away from other people to ensure the confidentiality of the participants' responses and conversations. Interviewers, HIV test counselors and the field supervisor should also be aware of any persons attempting to interrupt an interview or HIV test in progress and deal with these situations accordingly.

Mobile Units

Project sites that have access to mobile units may find it practical to use the mobile unit in addition to space inside or outside of a venue. For instance, interviews could be conducted within the venue and HIV counseling and testing activities could be conducted inside of the mobile unit. Mobile units can be parked immediately outside of the venue or further away from the venue, if a communication mechanism is in place (i.e. walkie-talkies, cell phones, etc.) and if the field supervisor is able to provide adequate monitoring. As with conducting interviews and HIV testing activities within or outside of the venue, confidentiality must be maintained for participants on the mobile unit at all times. Project sites using a mobile unit must indicate this in the MSM3 Operations Checklist **(Appendix A)**.

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, 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 recruitment. To assist with recruitment, field supervisors may want to assign recruiters who have similar demographic characteristics of the venue attendees. These meetings are also a good time to build enthusiasm and raise the energy level of the staff.

Once the counting area is defined (see **Section 6.2** of this manual), project staff positioning at the venue should be discussed. Project staff should be positioned strategically to maximize recruitment, optimize the efficiency of operations, and ensure safety.

5.5 General Guidance for Managing Recruitment Events

5.5a Assurance of Confidentiality and field operations

NHBS-MSM3 data are covered under the *Assurance of Confidentiality for HIV/AIDS Data* (Appendix K of the *NHBS-MSM3 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 secured as soon as possible after each recruitment event. This includes survey data, HIV testing data, Participant Tracking Forms, and any other participant-level data. If data cannot be secured in the project office right after a recruitment event, plans should be in place to lock up all forms and equipment, and to keep handheld computers charged.
- 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 you are planning to return HIV test results in the field, you must get permission from your CDC Project Officer and document the procedures in the MSM3 Operations Checklist.)
- All data transfers must be conducted in a secure manner.

Each NHBS directly 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.

Interview and HIV testing activities should take place in a quiet area that affords privacy for the participant and the interviewer. Other participants should not be able to hear the conversation.

5.5b Recruiting and interviewing 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 project 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 following recruitment and interviewing guidance:

Recruiters

Recruiters may intercept a man they "know" and invite him to participate in NHBS-MSM3.

Interviewers

Interviewers may ***not*** interview a man they "know." If an interviewer "knows" a prospective participant, they must have another project staff member interview the prospective participant. 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, the prospective participant could be offered post-event appointment to be interviewed by a project 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).

Recruiters/interviewers

If a project staff member is a recruiter and an interviewer, they may intercept a man they "know" and invite him to participate in NHBS-MSM3, but they cannot interview him. Another interviewer who does not "know" the prospective participant must conduct the interview as described above for "Interviewers."

Project sites should develop local procedures for implementing this guidance and training their staff on it.

5.5c Alternate venues

Unless the primary venue is unsafe or closed, project staff should attempt to count and recruit men for at least 30 minutes before moving to an alternate venue. If no interviews are obtained after 30 minutes of counting, project staff can remain at the primary venue if the field supervisor believes that enrollment will improve or they can move the recruitment event to the first alternate venue. The criterion of 30 minutes of unsuccessful enrollment also applies to alternate venues. If the first alternate venue fails to produce any interviews after 30 minutes of counting, project staff can remain at the alternate venue anticipating that enrollment will improve or they can move the recruitment event to the second alternate venue. See **Chapter 4** of this manual for more information on scheduling alternate venues.

Project sites are only allowed to attend the same venue twice in one month even in circumstances where there are a limited number of venues in a project site and the same venue is scheduled as an alternate multiple times on the monthly recruitment calendar.

5.5d Length of recruitment events

Most recruitment events should have a standard length of 4 hours. Standardizing the length of recruitment events helps ensure that a similar number of men are enrolled at each venue. Nevertheless, some recruitment events may be planned for less than 4 hours. For example, a recruitment event held at the meeting of a social organization may only last a couple of hours. Regardless of the length of the recruitment event, project staff should continue to count and recruit venue attendees up until the scheduled end time for the event. 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 event venue. The number of interviews conducted during a recruitment 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 NHBS-MSM3 sample from being dominated by attendees from a few very busy venues, project sites cannot conduct more than 20 completed interviews during a recruitment event.

As described in **Chapter 4** of this manual, project sites may conduct more than 3 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 NHBS-MSM3 sample could be recruited from venues related to a single gay pride festival. In order to prevent project sites from having a disproportionate share of the sample size for NHBS-MSM3 (n=500) come from one large event, project sites may conduct no more than 15 interviews per pride-related recruitment event if more than 3 pride-related recruitment events are scheduled in a month. For example, if a project site conducts 4 separate recruitment events related to their local gay pride festival in June, 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).

5.5f Target sample size

The target sample size for each project site is to have completed interviews with 500 eligible men who report having had sex with another man in the past 12 months. Criteria that make men eligible to participate in NHBS-MSM3 are as follows:

- has not previously participated in NHBS- MSM3;
- is at least18 years of age;
- lives in the participating MSA or Division;
- is male;
- ever had oral or anal sex with another man; and
- is able to complete the interview in English or Spanish;

5.5g Supervision

Strong supervision is crucial during each recruitment event. Knowing what occurs during intercepts, monitoring trends in recruitment (refusals, successes), and realizing each project staff member's strengths and weaknesses are critical components of NHBS-MSM3 field supervision. Other supervisory components are as follows:

- Before going into the field, discuss with the team specific logistical, teamwork, and recruitment strategies needed for the particular event. Plan ahead – don't wing it.

- Check in with project staff members after each intercept. Suggest ways to improve recruitment techniques (responses to recruitment barriers especially) and to enhance participation and troubleshoot difficult intercepts.

- Monitor recruitment and enrollment throughout the event to determine individual as well as team performance. Make changes to the counting area, recruitment techniques, team operations, and appointment systems when necessary.

- Listen in on intercepts. Assess whether standard responses to recruitment barriers are being used appropriately and how well the recruiter engages potential participants. Provide feedback to recruiters.

- Let the project staff learn your recruitment technique and benefit from your expertise.

- Maximize your project staff's strengths. Determine the best recruiters by reviewing recruitment data and by observation. Determine who works best at which venues, and with which populations.

- Know the protocol and operations manual like "the back of your hand." Know when you need to follow exact procedures and when local adaptations are allowed.

- Build team morale. Recognize a job well done and encourage the team to encourage each other.

5.5h Teamwork

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

- When intercepts are being conducted by one recruiter, all staff should remain alert to what is going on. By monitoring what occurs, other staff can lend a hand when necessary.

- Develop communication cues (e.g., hand positioning) to inform team members assistance is needed. Using the cues, develop and practice appropriate segues (e.g., timing, language, positioning) into existing intercepts. Understand how each recruiter develops rapport and "works" the intercept and assess when the appropriate time is to intervene.

- Team members should check-in to discuss what is working and what is not working throughout the events. Continually assess the successes and failures of intercepts and brainstorm ways to improve technique and opportunities for success. Recruiters should learn from one another as well as encourage each other.

- Be alert for indications that the team may be in danger.

5.5i Recruiting technique

Effective communication, strong belief in the value of NHBS, demonstrated motivation and high energy are the keys to successful recruiting. How the team operates as a group as well as how each staff person demonstrates this positive affect should be continually assessed and improved upon. The Field supervisor should work with the project staff to brainstorm new ways to increase completed intercepts and participation; additional information on strategies for overcoming intercept and participation barriers can be found in **Appendices M and N** of this manual. To be successful, recruiters should:

- Incorporate the best style and show enthusiasm for **each** intercept rather than quickly moving onto the next one. The quality of the intercept is more important than the quantity of intercepts.

- Maintain a high level of energy and salesmanship (e.g., introduce yourself with a warm and sincere smile). Men intercepted and offered participation should feel a level of energy, enthusiasm, and commitment commensurate with the importance of NHBS-MSM3 and HIV prevention for MSM living in these areas.

- Spend sufficient time with each person intercepted. It is difficult to build rapport during a 30-60 second intercept but it is absolutely necessary to increase enrollment. When eligible people are engaged, determine and address barriers to participation. All this takes time, but is often worth it.

- Intercept early. The earlier you intercept a potential participant, the more time you have to engage them.

- Anticipate common reasons for refusal and apply classic and innovative responses to recruitment barriers. Brainstorm new responses to refused intercepts and participation.

- Apply the "5Refusal Rule." When a series of 5 refusals to intercepts or to participate in NHBS-MSM3 occurs, the team should stop counting, 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 implemented, counting and recruitment can resume. If the event remains unsuccessful, then the team can terminate the recruitment event and move to the first alternate. However, before doing this, they should first try all possible solutions to address the problem.

6 Counting, Recruitment, and Interviewing

6.1 Overview

Project sites will recruit and interview NHBS-MSM3 participants at the venues and during the day-time periods scheduled on their monthly recruitment calendars. At the scheduled recruitment events, project staff will perform four main duties: 1) count venue attendees, 2) intercept attendees and recruit them to participate in NHBS-MSM3, 3) screen and interview participants, and 4) provide HIV counseling and testing to those who are interviewed. The field supervisor will manage the recruitment event and two or more additional project staff will be needed to perform all the required duties. One staff member will count all men who cross or enter a defined area of the venue. Other project staff members will then consecutively approach the counted men, tell them about NHBS-MSM3, and invite them to participate in the project. Men who wish to participate in NHBS-MSM3 will be screened for eligibility, and if eligible, interviewed, HIV tested, reimbursed 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. Counted attendees will form the pool of men who can be approached and recruited to participate in NHBS-MSM3. In addition, attendance counts are used to weight the NHBS-MSM3 data during analysis. Accordingly, it is extremely important for project sites to obtain accurate attendance counts.

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 counter should also direct recruiters to approach attendees and invite them to participate in NHBS-MSM3. 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 or trying to recruit them more than once.

Usually, an experienced staff member is selected for the critical role of counter. Because counting may interfere with the field supervisor's management and oversight responsibilities, they 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 Who to count

The counter should count all venue attendees who enter or cross the counting area (**Section 6.2d** below) and who appear to be male and at least 18 years of age. These men are potentially eligible to participate in NHBS-MSM3. 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. The counter should ***not*** count venue attendees who are already in the counting area when counting begins (these attendees did not "enter or cross" the counting area after the start of counting). Nevertheless, if any of these attendees leaves the counting area and re-enters it at a later time during the recruitment event, they may be counted. Venue attendees should only be counted once during a recruitment event, even if they enter or cross the counting area multiple times.

The counter should count venue attendees who have previously participated in NHBS-MSM3. 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-MSM3 (**Section 6.3c** 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-MSM3 and have entered or crossed the counting area for the first time. Foremost, the counter should never count self-referrals. Self-referrals are people who purposefully enter or cross the counting area trying to enroll in NHBS-MSM3. Self-referrals may learn about the project from another venue attendee or they may be attracted by the activity generated by recruitment event operations. When the counting area is located outside of the venue, self-referrals are common and are often not venue attendees. Another group that should not be counted is 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. Lastly, the counter should not count venue attendees who could not be approached for recruitment, such as those who are running, biking, or talking on a cell phone.

6.2c When to count

The counter should begin counting when project staff are ready to begin recruiting venue attendees to participate in NHBS-MSM3 and the counter should stop counting when the last attendee is approached for recruitment. 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. The only time counting may stop is if project staff must halt all recruitment event activities to discuss an operational problem, like low NHBS-MSM3 participation rates among venue attendees.

6.2d Counting area

The counting area is a defined space at the venue where venue attendees who enter or cross the space are counted. 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 counting area. The counting area can be of any size and it can be situated in any location of the venue. However, it should be

defined to maximize the counter's ability to effectively count venue attendees and direct recruitment. Most importantly, because a requirement of venue-based sampling is that participants have to be venue attendees, the counting area must be defined to ensure that only men attending the selected venue are counted and recruited to participate in NHBS-MSM3.

Size of counting area

The counting area should be large enough to have a sufficient number of venue attendees who could be recruited to participate in NHBS-MSM3, but it should not be so large that the counter becomes overwhelmed and cannot accurately count or direct recruitment. A simple rule of thumb is smaller counting areas for venues with high traffic flows and larger areas for venues with low traffic flows. During a recruitment event, the size of the counting area can be adjusted to match changing traffic flows. If traffic flows though the counting area are higher than initially anticipated, the size of the counting area can be decreased, and if traffic flows are lower, the size can be increased. When traffic flows are extremely high, like at a busy street corner, it may also be necessary to restrict counting to just those venue attendees who enter or cross the counting area from a single direction.

Location of counting area

The field supervisor should select a location for the counting area based on the logistics of operations at the recruitment event. The location should allow the counter to effectively direct recruitment and it should also be convenient to the spaces used to interview participants and provide HIV tests. To facilitate counting and minimize any potential errors, avoid placing the counting area in a location that venue attendees might cross multiple times, such as near a restroom or a smoking area. The counting area can be located either inside the venue or outside. Usually, the counting area is located inside the venue when interviewing and testing occur inside and it is located outside the venue when interviewing and testing occur outside. Yet, this does not always have to be the case. For example, venue attendees could be counted and recruited inside the venue and then brought outside for interviewing and testing in the project site's mobile unit.

The doorway of a venue is a common location for the counting area whether counting occurs inside the venue or outside. When a doorway is designated as the counting area, it is helpful to count venue attendees in only one direction to avoid duplicate counting. For example, if the counter were inside the venue, he would just count venue attendees who pass through the doorway to enter the venue; and if the counter were outside the venue, he would just count venue attendees who pass through the doorway to exit the venue. At some venues, project staff may encounter long lines of people waiting to enter the venue. In these situations, instead of designating the doorway as the counting area, the end of the line could function as the counting area. The counter would count venue attendees as they joined the line and would direct the recruiters to approach the last attendee who joined. Venue attendees who are already in line when counting begins would not be counted and they could not be recruited to participate in NHBS-MSM3.

6.3 Recruitment

After a venue attendee has been counted, the counter will direct a recruiter to approach the attendee and try to recruit him to participate in NHBS-MSM3. During recruitment, the recruiter will briefly describe NHBS-MSM3 to the prospective participant and determine whether he previously participated in the survey. Venue attendees who have not previously participated in NHBS-MSM3 will be invited to do so.

6.3a Intercept

The process of approaching a venue attendee and attempting to recruit him to participate in NHBS-MSM3 is called the "intercept." After a venue attendee who appears male and at least 18 years of age enters or crosses the counting area, the counter will count him and direct a recruiter to intercept him. The counter always decides who the recruiter should intercept; the recruiter should ***never*** decide who to intercept on his own. As long as recruiters and interviewers are available, recruiters should intercept venue attendees consecutively. That is to say, once the first attendee counted has been intercepted, the second attendee counted should be intercepted, and so on.

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).

Although recruitment may be intermittent during a recruitment event, counting is not. Counting should continue until the last venue attendee has been intercepted and recruited to participate in NHBS-MSM3.

6.3b 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. So that venue attendees immediately recognize that the recruiter is a representative of the local NHBS-MSM3 project, all recruiters should wear a shirt with the project logo or have a clearly visible project ID.

6.3c Intercept methods

Once directed by the counter, 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 6.3d** below):

> *During 2011, 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-MSM3 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 handheld computer. If the attendee already participated in NHBS-MSM3 (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-MSM3 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 upbeat 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-MSM3, 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 M and N** contain strategies for overcoming some common recruitment and participation barriers that project sites have encountered during previous NHBS-MSM cycles.

Participants always have the right to decline participation in NHBS-MSM3. Efforts to encourage men to participate must respect this right.

Men who decline the recruiter's invitation to be screened for consent – after project staff has addressed participation barriers – may not return later to NHBS staff and ask to be screened. Their initial refusal may not be overturned; in other words, "no" means "no" throughout the recruitment event.

If a venue attendee agrees to participate in NHBS-MSM3, 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-MSM3 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 handheld computer so that eligibility statistics and data weights can be calculated.

6.3d 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 **Appendices O and P**. 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 his 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. Project 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.

6.3e Post-event appointments

Ordinarily, a venue attendee is interviewed immediately after he is intercepted and agrees to participate in NHBS-MSM3. Yet, 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-MSM3 protocol does not require project sites to offer appointments; project sites should decide on their own whether or not to offer them. If project sites do choose to offer appointments, they should only use them when absolutely necessary. Project sites should conduct the vast majority of their interviews during recruitment events.

Appointments 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-MSM3. 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, appointments could be used to interview prospective participants on another day.

If a prospective participant is merely waiting for an interviewer to become free, project sites should treat this as a routine intercept and ***not*** consider it an appointment. Similarly, if a prospective participant is going to return to be interviewed at a later time ***during*** a recruitment event, project sites should also treat this as a routine intercept and ***not*** an appointment. In prior NHBS-MSM rounds, when a prospective participant returned to be interviewed at a later time during a recruitment event, project sites regarded this as a same day appointment (SDA); but for NHBS-MSM3, this will no longer be considered an appointment.

Project sites that offer appointments ***cannot*** pre-screen prospective participants for NHBS-MSM3 eligibility. Prospective participants can only be screened for eligibility when they return for their appointments. Project sites must therefore make it clear to men scheduled for appointments that their participation in NHBS-MSM3 is not guaranteed.

Scheduling appointments

When scheduling an appointment, 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

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

To keep track of their appointments, 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 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 identifier 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 appointment is scheduled. They may want to record the information in pencil so that changes can be readily made if an appointment 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 appointments at a local NHBS-MSM3 project office, such as their field office, the health department, or the office of a local collaborator. If absolutely necessary, project sites may conduct an appointment in the field before or after a recruitment event, but they should ***never*** conduct one during an event. When a participant is interviewed via an appointment, at least 3 staff members must be present, including the field supervisor or another senior manager.

6.4 Interviewing

After a venue attendee agrees to participate in NHBS-MSM3 and has been assigned a Survey ID, he should be escorted to a private space to begin the interview process. During interviewing, the interviewer will screen the prospective participant for eligibility, obtain informed consent from him, and ask him the core survey and local questions.

6.4a Screening for eligibility

The interviewer should administer the eligibility screener using a handheld computer. The computer will automatically determine whether the prospective participant is eligible for NHBS-MSM3 based on the following criteria:

- age 18 years or older,
- did not complete any part of the NHBS-MSM3 survey (including the eligibility screener),
- resident of the defined MSA for the project site,
- born male and self-identifies as male, and
- reports ever having had oral or anal sex with a man.

Men who meet all of the above criteria will be consented and invited to participate in NHBS-MSM3. Those who do not meet at least one of the criteria will be told that "the computer has not selected you to participate in the health survey" and should be thanked for their time.

Repeat participants

Some men who already participated in NHBS-MSM3 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 2011, did you already complete at least part of the health survey that <*project name*> is conducting?" the interviewer should ***not*** accept this answer and check "No" in the handheld computer. Instead, the interviewer should check "Known previous participant" and the handheld computer will automatically make the man 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.

Inebriated participants

If an interviewer determines that a man is inebriated with alcohol or drugs and therefore mentally incompetent to consent to participate in NHBS-MSM3 or to complete the survey, the interviewer should check "No" in the handheld computer when asked, "Is this person alert and able to complete the health survey in English or Spanish?" After checking "No," the interviewer will then be asked to specify why the person was not able to complete the survey. For an inebriated participant, the interviewer should check "Not alert." As with a previous participant, the handheld computer will automatically make the man ineligible.

6.4b Obtaining informed consent

The interviewer will read the NHBS-MSM3 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. Consent to participate in NHBS-MSM3 will be obtained orally and recorded in the handheld 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-MSM3 survey or 2) the NHBS-MSM3 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.

If the local IRB requires informed consent to be obtained before a prospective participant is screened for eligibility, project sites must do so.

It is critically important for interviewers to accurately record consent in the handheld computer. If a participant's consent is not recorded in the handheld computer, the participant's survey data and HIV test result are deemed void and cannot be used in NHBS.

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 allow a participant to obtain an HIV test if he initially declines testing but changes his mind during the survey.

6.4c NHBS-MSM3 survey

The interviewer will use a handheld computer to administer the NHBS-MSM3 survey to eligible men who consent to participate. The NHBS-MSM3 survey will take approximately 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 *Round 3 Interviewer Guide* for explanations of the core survey questions and guidance on interviewing. Major areas of focus include:

Reading questions and "Say" boxes as written. To help ensure standard data collection among interviewers and across project sites, interviewers must read survey questions and "Say" boxes as written. Nevertheless, if a participant does not understand a survey question as asked, the interviewer can rephrase the question using colloquial language or local terminology.

Using flashcards. Flashcards help the participant understand the intent of a question or its responses. 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. Most often, participants have trouble remembering dates. When this occurs, the interviewer should try to help the participant remember the date by starting with a broad period and then narrowing the period down. For example, if a participant cannot remember the month that he had his most recent HIV test, the

interviewer could start by asking what season he had the test. Once the interviewer has determined what season the participant was tested, they could try to identify the month by anchoring it to a holiday or a special event (i.e., was it before or after the holiday or special event).

Ending an interview early

If a participant stops an interview early or an interviewer must stop an interview because a participant is behaving inappropriately or is too intoxicated to continue, the interviewer should record the reason for stopping the interview in the data edits section of the Participant Tracking Form (**Appendix L**). When entering this data edit into the online Data Error Log on the Data Corrections 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 Testing

After the NHBS-MSM3 survey is completed, participants who have consented to HIV testing should receive prevention counseling and an HIV test. Project sites must conduct all HIV counseling and testing in accordance with the NHBS-MSM3 protocol and their local testing policies. Most importantly, a participant cannot receive HIV testing or prevention counseling before he finishes the core NHBS-MSM3 survey. If project sites that are not required to provide pre-test counseling prior to specimen collection adhere to these restrictions on counseling, they may collect a specimen for rapid HIV testing before starting the NHBS-MSM3 survey. This will allow these project 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 as well as his rapid test result. Detailed guidance on HIV testing is provided in **Chapter 8** of this manual.

Men who do not consent to take the NHBS-MSM3 survey cannot receive HIV tests at recruitment events or through NHBS-MSM3. Project sites should refer these men to public and private agencies in their communities that provide HIV counseling and testing services.

6.6 Participant Compensation

Participants who complete the entire NHBS-MSM3 survey should be compensated for their time and effort. Those who also test for HIV should receive additional compensation. The NHBS-MSM3 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

All men who complete at least part of the NHBS-MSM3 survey should be provided with HIV prevention materials (informational pamphlets, condoms, lube, etc.). Those in need of health or social services should also receive referrals to the appropriate service providers in the community. Of utmost importance, men who are newly diagnosed with HIV infection must be referred for HIV medical care and case management as described in **Chapter 8** of this manual. So that project sites can readily make any necessary referrals, they should maintain a list of the names and contact information of health and social service providers in their communities. This list should include HIV and STD clinics, substance abuse treatment centers, mental health service providers, agencies that offer free HIV tests, and organizations that serve gay and bisexual men.

7 Recruitment Event Closeout

7.1 Overview

The purpose of this chapter is to provide guidance on closeout of recruitment events. The Recruitment Event Checklist (**Appendix I**) can be used to guide closeout of recruitment events. The first part of the chapter describes the closeout tasks that occur before leaving the recruitment event. The second part of the chapter describes the closeout tasks that take place at the project office.

7.2 Closeout at Recruitment Event

7.2a Hold post-event debriefing

At the end of each recruitment event, it is useful to hold a post-event debriefing for project staff to discuss any issues or circumstances that occurred. This debriefing can take place in the form of a meeting convened with all project staff or one-on-one conversations. Some questions for discussion may include:

- In general, how did the recruitment event go?
- Were there any venue-related issues that affected project activities?
- Were there any barriers to recruitment? What strategies were successful?
- Were there any unusual events (e.g., a participant ended the survey early, a participant initially consented to HIV test but changed his mind)?
- Were there any problems with the handheld computers?
- Were there any possible errors with the survey data?
- Were there any persons newly diagnosed with HIV?
- Were there any problems with HIV test specimen collection or test kits?

As questions are asked and discussion follows, project staff may remember events or information that will be helpful during the next recruitment event; the field supervisor can record this information in the Recruitment Event Information & Outcomes Form (**Appendix K**) and in other relevant forms, such as the HIV Test Results Log or Participant Tracking Form, when appropriate.

7.2b Record recruitment event notes

The field supervisor should record notes about the recruitment event; the Recruitment Event Information & Outcomes Form (**Appendix K**) is provided for this purpose. The purpose of these notes is to document any barriers or changes at the venue where the recruitment event was conducted, to provide information on new venues and day-time periods to update the monthly sampling frame, and if applicable, to explain why the event was moved to an alternate venue. This information is important when interpreting recruitment statistics and provides a framework for improving operations. Field supervisors should consider collecting the following information:

- Description of the counting, recruitment, interviewing, and testing areas at the venue.
- Barriers to project activities at the venue.
- Significant changes in the demographic characteristics of venue attendees since the formative research report was prepared.
- New venues or day-time periods that were suggested during the recruitment event.
- Reasons for removing the venue from the sampling frame.
- Reasons for moving the recruitment event to an alternate venue.
- Information about parking or transportation.

Project sites are required to enter the reason for moving to an alternate venue into the VDTS Program.

7.2c Collect and review forms and logs

At the end of the recruitment event, the field supervisor should collect all forms and logs from project staff, review them for accuracy, make corrections when necessary, and tabulate recruitment outcomes.

Intercept Forms

The field supervisor should collect the completed Intercept Forms (**Appendix O**) from each recruiter. The field supervisor should review the forms for accuracy and completeness, and then following the instructions provided in **Appendix P**, calculate the column sub-totals and record them at the bottom of each Intercept Form. If applicable, the field supervisor should conduct a cross-check of the Intercept Forms and the Appointment Log to ensure that post-event appointments (PEAs) have been scheduled.

Participant Tracking Forms

The field supervisor should collect the Participant Tracking Forms (**Appendix L**) from each interviewer. The purpose of the Participant Tracking Form is described in more detail in **Chapter 5** of this manual. Data entry errors made during an interview should be recorded in the data edit section of the form, including the variable name, the 'old' or incorrectly entered value, and the 'new' or the value to which the variable should be corrected. Interviewers can also note

any unusual events that happened during the interview in the 'comments' section. Interviewers and HIV test counselors should record whether a participant has self-reported as previously testing HIV-positive during the interview and/or HIV counseling session. The field supervisor should collect these forms at the end of each recruitment event, review them with the interviewers and HIV test counselors, and make sure they are complete. If the same data entry errors are made repeatedly, additional training should be conducted with the interviewers to help avoid any more occurrences.

HIV Test Results Log

The field supervisor should collect all hardcopy HIV Test Results Logs from the HIV test counselors and inquire about any inconsistencies. The field supervisor should review the logs to make sure that a specimen was collected for each entry on the form and conversely, that for every specimen collected, there is an entry on the form. In addition, the field supervisor should make a note of any problems with specimens or specimen collection. For standard or confirmatory tests, the field supervisor should check the Lab ID labeled on the specimens against the Lab ID that is written on the HIV Test Results Log. For rapid tests, the field supervisor should make sure that there is either a negative test result or a preliminary positive result recorded, and if applicable, a confirmatory specimen collected. In addition, the field supervisor should check the Appointment Log to ensure that appointments have been scheduled for returning HIV test results.

Project staff evaluation forms

If any project staff were evaluated during a recruitment event (see **Appendices B –G**), the field supervisor should review completed forms with the staff members who were evaluated. If any project staff were scheduled for an evaluation that did not occur, the field supervisor can note this on the Recruitment Event Information & Outcomes Form as a reminder to schedule an evaluation at the next recruitment event.

7.3 Closeout at Project Office

7.3a Manage HIV test specimens

The field supervisor should ensure that all HIV test specimens are transported and stored according to the package insert and in a manner that maintains the integrity of the specimen. As soon as possible after the recruitment event, the field supervisor should complete the Specimen Shipping Log (**Appendix R**) and ship the HIV test specimens using the procedures agreed upon by the laboratory working with the project site.

7.3b Enter data into Data Coordinating Center Data Portal

On a daily basis, the data manager or other designated project staff should enter the data edits recorded on the Participant Tracking Forms into the online Data Error Log on the Data Coordinating Center (DCC) Data Portal. The data from the hardcopy HIV Tests Results Log and

the information regarding whether the participant self-reported as previously testing HIV-positive (SRP) from the Participant Tracking Forms should also be entered daily into the online HIV Test Results Log on the DCC Data Portal. In addition, column totals from each Intercept Form and information from the Recruitment Event Information & Outcomes Form should be entered into the event outcomes section in the VDTS Program; information from the Recruitment Event Information & Outcomes Form include the venue(s) where the recruitment event was conducted, the total counts for the recruitment event, and if applicable, the reasons why alternate venues were used.

7.3c Data handling

The data manager or other designated project staff should upload the NHBS-MSM3 core interview files and the local survey files from the handheld computer into the respective QDS™ Warehouse as soon after the recruitment event as possible. After uploading the data, the handhelds should be charged and locked up in the project office; if the handhelds are not returned to the project office the same day as the recruitment event then they should be charged and stored in a manner which complies with the data security and confidentiality requirements (see **Chapter 5** of this manual). All completed forms and logs should be stored in a locked filing cabinet in the project office when not in immediate use by project staff.

8 HIV and Other Laboratory Testing

8.1 Overview

The purpose of this chapter is to provide information about HIV and other laboratory testing procedures and requirements. For other information about these procedures, refer to Chapter 5 of the *NHBS-MSM3 Model Surveillance Protocol.* Local procedures for conducting HIV testing, returning results, and referrals for care must be documented in the MSM3 Operations Checklist (**Appendix A**) before NHBS-MSM3 activities can begin. Any additional testing forms or logs (e.g., lab slips, risk assessment forms, etc.) other than those suggested in this manual should be included in the checklist. Project sites are responsible for following specific local laws, guidelines, or requirements for laboratory testing and counseling (these topics are outside the scope of this document). It is recommended that project staff meet with local laboratory staff to review testing and specimen handling requirements.

8.2 HIV Testing

Individuals who agree to participate in NHBS-MSM3 will be offered an anonymous HIV test in all project sites. The testing component of NHBS-MSM3 is voluntary—those who choose to participate in the survey are not required to provide a specimen for HIV testing. The purpose of testing is to calculate HIV prevalence among persons participating in NHBS-MSM3; even participants who report that they have previously been diagnosed with HIV will be offered an HIV test. HIV counseling will be conducted only after the survey is completed.

NHBS-MSM3 project sites can choose from a number of options for HIV testing methods. Project sites must develop their local testing protocols, including appropriate tests and specimen types, before NHBS-MSM3 begins. Project sites are responsible for hiring, training, or certifying project staff in specimen collection and HIV counseling procedures. CDC will not conduct a national training that addresses these procedures.

Project sites offering rapid HIV testing must be prepared to collect a confirmatory test specimen at the time that a reactive rapid test result is given. For standard HIV laboratory testing methods, one specimen must be adequate to conduct both the standard EIA and confirmatory (e.g., WB, IFA) tests.

All final HIV test results must be made available to participants and provision of results will be tracked; these procedures must be in place before NHBS-MSM3 activities can begin. After the NHBS-MSM3 survey is completed, project sites offering rapid testing must return negative and reactive rapid test results to participants as soon as possible. To receive standard and confirmatory test results, the participant must return to a designated location or receive the result over the phone. Project sites will need to refer to their state and local policies and procedures to determine if returning test results by phone is allowed.

HIV test results and other testing data should be recorded on a hardcopy of the HIV Test Results Log while in the field (see Appendix J of the *NHBS-MSM3 Model Surveillance Protocol*) and subsequently entered into the online HIV Test Results Log on the Data Coordinating Center (DCC) Data Portal. Any HIV testing forms or logs used in the field must be locked at all times when not in the immediate possession of a project staff member.

As specified in Chapter 5 of the *NHBS-MSM3 Model Surveillance Protocol,* HIV test counselors should target prevention messages to specific risks identified during the NHBS-MSM3 survey. Project sites that have separate project staff conducting HIV testing should develop procedures for incorporating these risks into the counseling interview. For example, HIV test counselors can administer a separate risk assessment or the interviewer can discretely and confidentially pass risk behavior information to the HIV test counselor; the latter should be done in a manner that complies with the Assurance of Confidentiality (see **Chapter 5** of this manual).

All rapid and confirmatory HIV laboratory test specimens and results must be collected, stored, and tested anonymously. Project sites unable to perform anonymous HIV testing will not be allowed to participate in NHBS. Similarly, if HIV test kits are unavailable, data collection should be suspended until the kits are available or an alternate test is identified. For those who are diagnosed with HIV as a result of participating in NHBS-MSM3, an anonymous process must be in place to refer these individuals to care. The facility or physician to whom participants are referred will then be responsible for retesting and reporting the diagnosis to the appropriate health department authority. **NHBS project staff are not permitted to report HIV cases to the state or local health department.**

Project sites that are concerned about participants not returning for their test results should consider the following options:

- Use rapid HIV tests so that those who test negative get their results the same day and those who test positive are given a reactive test result.
- Make specific appointments for participants to get their test results.
- Use reminder phone calls for test result appointments.

- Incorporate the rapid test algorithm so that those who are likely to be HIV-infected are referred to care based on results of the rapid test algorithm (see Appendix G of the *NHBS-MSM3 Model Surveillance Protocol*.)

Information about NHBS-MSM3 methods, including the survey and HIV testing, is provided to individuals during the consent process (see Appendix F of the *NHBS-MSM3 Model Surveillance Protocol*). Consent for participation in each of NHBS-MSM3 activity must be obtained separately and recorded in the handheld computer (see **Section 6.4b** of this manual). If consent is not recorded in the handheld computer for an HIV test that was conducted, that test result will not be included in the NHBS-MSM3 data set. Before the core questionnaire closes out electronically in the handheld computer, the interviewer will be asked to verify if the participant consented to an HIV test. This will allow for a consent response to be recorded in instances in which a participant does not initially consent to an HIV test but changes his mind during the survey, or in which the interviewer erroneously records that a participant declined consent. Details of the process are described further in the *NHBS Round 3 Interviewer Guide*

The verification for HIV test consent at the end of the core questionnaire is the last opportunity for the participant to provide consent for an NHBS HIV test. If the participant decides that he wants an HIV test after the core questionnaire has been completed, project sites may still perform an HIV test, but that test will not be considered to be an NHBS HIV test. Therefore, the HIV test results will not be included in the NHBS-MSM3 data set, and the participant should not receive an incentive for the test. Further, project staff are not allowed to change the consent variable in the online Data Error Log on the DCC Data Portal.

8.3 Other Laboratory Testing

Some project sites may offer other laboratory tests or want to store blood samples. Additional laboratory testing must be conducted anonymously and in accordance with local policies and procedures. Two alternatives for other laboratory testing are specified in the Model NHBS-MSM3 Consent Form (see Appendix F of the *NHBS-MSM3 Model Surveillance Protocol*):

1. Other laboratory tests

Project sites that want to conduct other laboratory tests and return the results to participants must detail procedures for each test in the consent form. Consent for these tests is recorded when the interviewer selects "Yes" to the question "Do you agree to have other lab tests?" in the handheld computer.

If the state or local health department does not allow anonymous testing for a particular laboratory test, that test cannot be offered as part of NHBS. Procedures must be in place to provide other laboratory test results to participants in an anonymous way. Anonymous referral to care procedures for participants who are diagnosed with the condition for which they are tested must be in place before NHBS-MSM3 data collection can begin.

2. Blood sample storage for future testing

Project sites that want to conduct a laboratory test and link it to the participant's survey, but will not return the result to the participant, must obtain consent to do so; this is covered under the section of the model consent form called "Blood storage" and is recorded when the interviewer selects "Yes" to the question "Do you agree to let us store a sample of your blood for future testing?" in the handheld computer. Storage for future testing must be communicated with the laboratory to which the specimen is shipped; it is recommended that this be recorded on a Specimen Shipping Log (**Appendix R**).

Project sites conducting **HIV incidence testing** should also record consent for this activity by having the interviewer select the "Storing a blood sample for future testing" check box in the handheld computer.

8.4 Specimen Collection and Testing in the Field

Projects sites collecting whole blood specimens either for rapid or laboratory testing must adhere to the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard with respect to universal precautions (e.g., personal protective equipment) and appropriate syringe/device disposal: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

In addition, project staff conducting testing should be trained in the safe handling of blood specimens.

8.4a Rapid 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 test results, as 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 results can be immediately referred to care (see **Section 8.6b**). In addition, receiving a preliminary positive test result may increase a person's likelihood of seeking additional testing or care, even if he does not return for the final NHBS test result. Returning preliminary test results in the field is particularly important when sampling populations with a high HIV prevalence, such as MSM.

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
NHBS project sites may operate under an existing waiver already obtained to their organization.

There are 4 rapid tests available that are CLIA-waived for use in field settings by non-laboratory staff. Prior to implementation of NHBS-MSM3, project staff who are administering and overseeing HIV testing must carefully read and understand the package insert for the particular rapid test being used. The package insert has guidance specific for each type of rapid test with respect to materials provided, materials required but not provided in the test kits, sample collection procedures, testing requirements, etc. A package insert should be available for project staff's reference during each event.

Rapid testing must be conducted in an appropriate environment with respect to temperature and lighting. These requirements can be found in the package insert provided with the test kits and should be adhered to at all times. Rapid testing should be conducted in adequate work space. Food or drink consumption has not been found to interfere with the test itself; however, food particles (e.g., gum, pieces of candy) can inhibit the test collection device from being placed flat against the gums for adequate specimen collection. Therefore, if the participant has recently eaten something or is chewing gum/candy it is recommended that test administrators request that these food particles be removed from the mouth before specimen collection. Interviewers for project sites conducting rapid testing on oral fluid specimens should explain to participants how to appropriately swab their mouths and monitor participants to assure that the specimen is collected appropriately. Interviewers for projects sites conducting rapid testing on whole blood should clean the participants' fingers with an alcohol swab before performing finger sticks.

Helpful hints for fingerstick specimen collection[2-6]: 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 and therefore are less likely to have calluses or tough skin. Warm the participant's finger if possible. The finger should be allowed to dry after cleaning it with an alcohol swab. Avoid the tip and center of the finger as well as the edge of the nail bed and the side (where there is less soft tissue). The puncture should be 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. Wipe away the first drop of blood, which tends to contain excess tissue fluid, with a sterile gauze pad or cotton ball. Hold the finger downward. If needed, the finger may be gently massaged at the base or gentle pressure may be applied next to the point of puncture to increase blood flow. Avoid "milking" and/or squeezing the finger as this may dilute the blood with excess tissue fluid. The idea is that the blood should be free flowing and not "forced" to flow. Allow a new drop of blood to form before using the sample collection device.

Each rapid test device should be labeled with the Survey ID of the participant.

During rapid test development, the test face of the device should not be visible by the participant. This is best achieved by conducting testing in a central area separate from the interview. If testing is conducted in the interview area, the test face should be turned away from the participant or the device covered in some way, as having the test face visible to the participant may result in anxiety or misinterpretation of the test result. Shielding the test result from the participants is particularly important for project sites that collect the specimen before beginning the survey and run the test while the survey is being conducted. Running the test in the same room could result in interruption of the survey by the participant, who may ask questions. Because counseling may not be conducted until the survey is completed, it is important that the participant not be able to view the result and that the result not be disclosed until the end of the interview.

Rapid and confirmatory testing for preliminary positives should be conducted in a private area within venues. Therefore, it is important to conduct counseling and testing activities in a manner which maintains the audible and visible privacy of the participant to avoid disclosing or bringing attention to those who undergo a second HIV test (i.e., revealing a preliminary positive status). Venue operations should be set up in such a way as to collect confirmatory specimens from participants with reactive rapid test results in a private and confidential manner. For example, operations could be set up in a way that requires all participants to receive incentives and confirmatory testing in the same private area.

It is recommended that project sites maintain a Quality Assurance Log to monitor the run of controls, the temperature at which the tests are run and stored, and the lot numbers for each batch of test kits used. A good reference guide for Rapid Testing Quality Assurance can be found at
http://www.cdc.gov/hiv/topics/testing/resources/guidelines/pdf/qa_guidlines.pdf

Rapid test results must be read within the appropriate timeframe in accordance with the test package insert, as this time may vary for each specific test. Project sites should develop a system for recording the time the test was started and the time the test results were read. For example, these times could be recorded on the HIV Test Results Log, the Participant Tracking Form or the Quality Assurance Log.

8.4b Laboratory testing

Projects sites must collect either an oral or blood specimen for laboratory testing. Oral specimens are collected via the OraSure Oral Mucosal Transudate (OMT) device. The OMT devices should be stored and used in accordance with the package insert. As with the oral rapid test, food or drink consumption has not been found to interfere with the OMT; however, food particles (e.g., gum, pieces of candy) can inhibit the specimen collection device from being placed flat against the gums for adequate specimen collection. Therefore, if the participant has recently eaten something or is chewing

gum/candy it is recommended that test administrators request that these food particles be removed from the mouth before specimen collection. Interviewers should explain to participants how to correctly place the collection device in their mouths and monitor participants to assure that the specimen is collected appropriately. The participant should not speak during the specimen collection. Blood specimens are collected via venipuncture, which should only be performed by project staff trained in phlebotomy. Project staff should speak with laboratory staff to find out what types and tradenames of tests will be performed on each type of specimen as this information is required to be entered in the MSM3 Operations Checklist (see **Appendix A**).

Sometimes participants who already know that they are HIV-positive have a false negative test result. This may occur because the laboratory performs screening tests (EIA) and, per laboratory protocol, does not conduct Western Blot or IFA testing if the EIA testing is non-reactive. However, in this situation (when we suspect a person is HIV- positive because of self-report), having a Western Blot or IFA performed can give additional valuable information. Therefore, for participants who report that they are HIV- positive during the interview, project sites must communicate to the laboratory that the confirmatory test (Western Blot or IFA) MUST be performed on those specimens regardless of the results of the screening tests (EIA) performed as part of the laboratory's HIV testing algorithm. As with storing specimens for future testing, this information can be communicated to the laboratory on a Specimen Shipping Log. It is important that the method of communicating this information to the laboratory be decided before specimen collection begins. Plans for this should be included in the MSM3 Operations Checklist.

8.5 Rapid Test and Specimen Storage, Specimen Processing and Transport/Shipping Procedures

All rapid test devices should be stored in accordance with the package insert provided with the test kits. Project staff should always check the date on the test kits before usage to ensure that they have not expired.

Project sites will need to work closely with their designated laboratory facility to identify any special requirements related to specimen type and storage, specimen processing, and transport/shipping. A model Specimen Shipping Log is provided in **Appendix R**; this model log can be used if the local laboratory does not provide one. Project sites may modify this log to include other tracking information required by the laboratory and other tests being conducted; it will not be sent to CDC. **Specimens sent to the laboratory for testing should be labeled with either the Lab and/or Survey ID**. The link between the Lab ID and the Survey ID must be documented on the hardcopy HIV Test Results Log along with other field logs, if applicable.

Project sites should create a clear plan in consultation with laboratory staff to ensure that specimen storage, processing, and transport/shipping is accomplished to allow for good specimen quality and a timely return of test results to participants, and staff should be trained for the tasks to which they are assigned. It is important to consider specimen handling requirements when planning HIV testing procedures. These requirements can differ with respect to the type of specimen collected (e.g., whole blood collection tube or oral fluid collection device). Examples of situations to consider are the time of day a specimen collection takes place as it pertains to how long before the specimens can be processed by the laboratory (hours of operation) and the time of year the specimens are collected as it pertains to the conditions (e.g., heat, humidity) under which the specimens are stored and transported prior to processing. All precautions should be taken to ensure the quality of the specimens collected. All specimens should be stored and transported or shipped in containers appropriately labeled according to OSHA guidelines. The NHBS-MSM3 specimen storage, processing, and transport/shipping procedures developed in conjunction with laboratory staff should be approved by the CDC Project Officer.

8.6 Anonymity, Test Results and Referral to Care

Anonymous HIV testing and referral for care procedures must be in place and documented in the MSM3 Operations Checklist (**Appendix A**) before NHBS-MSM3 data collection can begin. Participants must not be required nor asked to provide a name or any other identifier to receive test results or a referral. All specimens collected for NHBS are not to be used for HIV/AIDS case reporting or any other name-based or confidential system.

8.6a Providing laboratory test results

Plans for provision of test results must be in place and documented in the MSM3 Operations Checklist before project activities can begin. Project sites conducting rapid HIV testing must be prepared to 1) provide negative results in the field and 2) counsel for a reactive rapid result, obtain a confirmatory laboratory testing specimen, and have a means of providing the final test result (either through an appointment at a location with specified hours or by telephone). Project sites conducting only laboratory HIV testing must be prepared to obtain a specimen that is appropriate for both standard EIA and confirmatory (e.g., WB, IFA) testing and to provide a means for returning the final test result (either through an appointment at a location with specified hours or by telephone). All local policies and procedures for counseling and testing should be followed. Project staff should check with the laboratory performing the test about test turnaround time and keep this in mind when determining appointment scheduling. Appointments for returning test results should be made using the Appointment and Phone Results Cards located in **Appendix Q.** Project sites can also decide to provide appointment reminders for returning test results (see **Section 8.8** for more information).

Project staff should use caution when returning rapid test results to ensure the privacy of each participant. No conversation regarding testing should occur outside the interview rooms.

Participants have the right to refuse receipt of their rapid test results; however, it is still important to collect a confirmatory specimen from participants with preliminary positive results, as 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 prior to rapid specimen collection, it is recommended that a confirmatory specimen be collected at the same time as the rapid test specimen. In situations where the participant refuses the rapid test result after the rapid test has been run, it is recommended that project staff request that the participant provide a confirmatory specimen (without disclosing his preliminary positive result) to fulfill the activities to which he consented. Project sites should consult their local IRB guidance to determine if an incentive should be given to a participant who refuses to provide a confirmatory specimen. Document any inconsistencies in the data error log.

During past NHBS cycles, some participants have disclosed a previous positive test result during post-test counseling despite not reporting a previous positive test result during the survey. To capture this information, CDC has added a variable to the HIV Test Results Log (Appendix J of the *NHBS-MSM3 Model Surveillance Protocol*) which records whether a participant with a positive NHBS test result disclosed a previous positive HIV test during the counseling session. In order to standardize collection of this information for participants who test positive but did not report a previous positive test result during the survey, NHBS staff are encouraged to probe during post-test counseling to assess whether this was truly a new diagnosis or whether the participant had previously tested positive.

Project sites planning to provide test results over the phone should refer to the *Model HIV Phone Result Protocol* in Appendix H of the *NHBS-MSM3 Model Surveillance Protocol*. Tracking of results given over the phone should be conducted using a Phone Results Log (**Appendix S**).

8.6b Anonymous referrals

NHBS project staff must make all referrals to care or partner notification services anonymously. Project sites must have a relationship with an agency which accepts anonymous referrals before data collection can begin. Generally, referral in this context means referral for HIV-related care, but the same policies must be used for referrals to other programs that participants may need.

It is expected that agencies to which participants are referred will require that participants provide their name to receive care and that the participant will receive a confidential HIV diagnostic test along with the baseline viral load and CD4 tests. These activities are not

the responsibility of the NHBS project staff: they must be separate from NHBS. Furthermore, no outside agency shall have access to any NHBS code number (Survey ID or Lab ID) that could link the name of a person (provided to their agency) to the NHBS survey data.

NHBS project staff cannot provide any documentation of the NHBS anonymous test result to any other agency or individual. The participant can choose to report to the referred agency that he had a HIV-positive result from a test done through NHBS if he wishes.

An anonymous referral to care from NHBS can include more than simply telling a participant where to go to receive HIV-related care. For example, project staff may offer to call an agency to schedule a medical appointment for a participant if he wishes. These types of efforts may improve linkage to care among HIV-positive participants and are acceptable as long as project staff adhere to the limitations described above with respect to anonymity.

Project sites performing rapid testing may make an immediate referral to care for participants with preliminary positive results in the manner described above.

Participants in NHBS-MSM3 have the right to decline anonymous referral to care.

8.6c Referral to care and counseling and testing by outside agencies

Several project sites collaborate with outside agencies to provide HIV counseling and testing for NHBS-MSM3. This collaboration creates special circumstances with regard to referral and returning HIV-positive test results.

Agencies that provide HIV counseling and testing services for NHBS-MSM3 may make referrals to their own agency or to another agency for services (e.g., diagnosis, care and treatment, prevention case management, partner counseling and referral, etc.). There are two scenarios for referrals when an NHBS-MSM3 participant tests positive:

The agency providing the test result does not provide services

The HIV test counselor provides the final test result to the NHBS-MSM3 participant and offers the participant a referral for services to another agency. If the participant accepts the referral to the other agency, the counselor should follow NHBS policy on providing referrals. In no case shall the NHBS Survey ID, Lab ID or any other NHBS identifier be associated with the referral. The NHBS-MSM3 HIV test result must also not be associated with the referral. To get into care, a **confidential** HIV test that is completely separate from NHBS-MSM3 activities may be performed by the agency to which the NHBS-MSM3 participant is referred even though that person tested HIV positive in NHBS. The **confidential** HIV test result is the result that will follow him through care – NOT the NHBS HIV test result.

The agency providing the test result also provides services

The HIV test counselor provides the final test result to the participant and offers to provide services to the participant. If the participant accepts the referral to the counselor's agency, the counselor sends the participant to another staff member of the agency to provide services. The counselor must make it clear to participants that they are moving from activities included within NHBS (providing HIV testing and test results) to activities provided by the agency (providing services). In no case shall the NHBS Survey ID, Lab ID, HIV test result or any other NHBS identifier be recorded in the participant's new agency file, nor shall the procedures overlap. To get into care, a **confidential** HIV test that is completely separate from NHBS-MSM3 activities may be performed by the agency to which the NHBS-MSM3 participant is referred even though that person tested HIV-positive in NHBS. The **confidential** HIV test result is the result that will follow him through care – NOT the NHBS HIV test result.

8.7 HIV Test Results Log Data Entry

HIV testing data for NHBS-MSM3 should be entered into the online HIV Test Result Log on the Data Portal on a **daily basis.** It is important for these data to be entered on a daily basis so that reports generated by the DCC will reflect project sites' current numbers. Projects sites should refer to the *DCC NHBS Data Management Training Manual* for specific data entry guidance including variables required, a data dictionary, and hardcopy logs for recording test results in the field. Any additional data (e.g., other local tests) collected for local use are not required to be entered into the online HIV Test Result Log on the Data Portal.

Detailed HIV testing results (i.e., Western Blot bands) will be required for self-reported positives whose NHBS-MSM3 HIV test result is either negative or indeterminate. This guidance is included in the *DCC NHBS Data Management Training Manual.*

8.8 Optional Appointment Reminder Procedures

Project sites have the option of offering a phone appointment reminder for provision of the final HIV (or other) test results to NHBS-MSM3 participants. Because of the sensitive nature of the information being collected, implementation of appointment reminder procedures must be approved by the CDC Project Officer.
The optional procedures described in this section involve the collection of the participant's phone number to remind him of the day and time of an appointment, but neither the participant's Survey ID nor Lab ID is linked to the phone number. Project sites can choose to offer this service but cannot require that participants use it. A special folder or box for storing the appointment reminder forms must be created, and a project

calendar must be available in the office and in the field to track appointments. The file box must have a lock in order to keep confidential information secure.

If the participant indicates that he is interested in this service, follow the appropriate steps below. If the participant declines the reminder service, fill out the appointment card as usual and remind the participant that he can call to change or reschedule his appointment as needed.

Step 1– Make an appointment for returning test result.

Create an appointment card to obtain the HIV test results (**Appendix Q**)

Step 2– Fill out reminder phone card.

Give the appointment reminder call form (**Appendix T**) to the participant and assist him with filling it out. Ask the participant to record his phone number and indicate the best day and time to call him. Be sure the participant understands what your standard reminder message will be. File the appointment reminder call form in a reminder calls file or box.

Step 3– Process reminder calls.

Following each recruitment event, lock the reminder system file box in the project office. On a daily basis, project staff will process the reminder calls according to the following system:

Reminder phone calls before the appointment date

The appointment reminder forms should be pulled from the file or box every day and the designated project staff should make that day's reminder calls at the times indicated. The following are instructions that project staff should follow when conducting reminder phone calls before the appointment date:

- Before making the call, review the information provided by the participant, and be sure to follow the participant's instructions for what name to use, what message to leave, etc.
- Do not give out any additional information about NHBS or the participant to anyone.
- If a person answers, ask for the name that the participant wrote on the phone card.
- Do not leave a message on voice mail unless the participant has agreed.
- If a person other than the participant answers, say thank you and end the call.
- If the reminder call is successful, record the date and time on the card and place it in the "reminder calls completed" file (to be locked in the file cabinet).

- If the call is unsuccessful, record the date and time the attempt was made, and replace the card in the file or box for the next day (when a second attempt will be made).
- After the second attempt to call the participant, place the card in the "reminder calls completed" file regardless of whether the call was successful or not. Do not make more than two reminder call attempts before the appointment.

Reminder phone calls after the appointment date

The following are instructions that project staff should follow when conducting reminder phone calls:

- Each day, review the appointment book and note the times for missed appointments on the previous day.
- Then search the "reminder calls completed file" for a matching date and time (there is no link to the NHBS-MSM3 Survey ID).
- If a match is found, call the participant to reschedule his missed appointment. If no contact is made, try the next day.
- After a new appointment is made (or after two unsuccessful attempts), shred the appointment reminder call form (no later than one week after the initial appointment date).

9 Process Monitoring and Ongoing Formative Research

9.1 Overview

Process monitoring and ongoing formative research are conducted to help NHBS project staff ensure quality data collection. Both are intended to complement information gained through the formative research conducted prior to conducting NHBS-MSM3 project activities.

9.2 Process Goals

Process goals have been established for NHBS-MSM3 to help project sites monitor and evaluate recruitment and enrollment. The following target goals were established for the NHBS-MSM3 cycle:

- 75% of the men approached accept the intercept (i.e., answer the question about being a previous participant);
- 70% of those who accept the intercept agree to be screened for eligibility;
- 90% of eligible men agree to participate in the survey;
- 90% of survey participants consent to an HIV test;
- a minimum of 500 eligible men who reported having sex with a man in the previous year complete an interview;
- Sites conduct a minimum of 14 recruitment events per month with at one field supervisor and least 2 interviewers; and
- No more than 3 non-random recruitment events are conducted within a month (except in months when the main gay pride festival is held, then 2 additional non-random events can be conducted at venues that are part of the main gay pride festival, for a total of 5 non-random events- see **Chapter 6** of this manual).

Achieving recruitment and enrollment goals is critical. Not meeting these goals may jeopardize the external validity of findings and undermine the strength of future recommendations resulting from NHBS-MSM3 data. Project sites should monitor their process figures and compare each with the corresponding target goal above. If the recruitment and enrollment rates are below the established goal, then project staff should critically evaluate what factors are contributing to the low percentage (e.g., logistical barriers, participation barriers, etc.). Project staff should also assess whether low percentages are associated with participant demographics (age, race/ethnicity, etc.), specific recruitment events, or interviewer. When necessary, project sites should hold team meetings and consult with persons knowledgeable of the community (e.g., outreach-based research/prevention workers, venue owners/gate keepers, key informants, etc.) to identify possible causes and solutions for low recruitment and enrollment rates (see **Section 9.4** for more information).

9.3 Process Monitoring

Process monitoring involves monitoring recruitment, eligibility, enrollment, HIV testing, and sample characteristics to identify possible participation barriers or recruitment schemes that may be undermining the quality of the resulting data. The Data Coordinating Center (DCC) will generate the process monitoring reports using data submitted by project sites. The generated reports will be available on the DCC Data Portal for review by project sites and CDC Project Officers. Project sites should review these reports weekly.

Process monitoring reports generated by the DCC will present information on recruitment monitoring, eligibility characteristics, sample characteristics, HIV testing characteristics, and possible previous participants. Some project sites may wish to generate their own additional reports to monitor other aspects based on their unique circumstances.

CDC Project Officers will discuss the process monitoring reports with project sites at least every two weeks. During these discussions, it may be determined that the project site should conduct additional staff training or collect additional information (e.g. ongoing formative research) to address the problems identified in the reports.

9.3a Recruitment Monitoring Report

The Recruitment Monitoring Report (**Appendix U**) will provide information about enrollment and eligibility statistics, including the number of people who accepted the intercept, were screened for eligibility, were eligible, completed interviews, met the MSM definition, and consented to an HIV test. This report should be reviewed to identify possible problems with recruitment including:

- Low or decreased proportion of people agreeing to be screened for eligibility;
- Low or decreased enrollment;
- Large proportion of ineligible participants;
- Low proportion of participants meeting the MSM definition;
- Low proportion of participants consenting to the HIV test; and
- Low proportion of participants returning for post-event appointments.

Participants who have met the 'MSM definition' are those who have reported having sex with a man in the past 12 months during the NHBS-MSM3 survey; this is an inclusion criterion applied during data analysis as opposed to an eligibility criterion for enrollment into the project (e.g., men who have had sex with a man ever).

9.3b Sample Characteristics Reports

The Sample Characteristics Reports (**Appendix V**) will provide information about important characteristics of 1) persons screened for eligibility; 2) participants who completed the NHBS-MSM3 survey; and 3) the HIV test results. The formative research reports compiled at the beginning of the cycle should provide information about the expected characteristics of local MSM. These reports should be consulted when reviewing the Sample Characteristics Reports. The cross tables in these reports should be reviewed to monitor:

- The percentage of persons screened who were determined to be ineligible on each eligibility criterion;
- Whether the sample is representative of the demographics reported in the formative research reports;
- The productivity of certain types of venues for reaching MSM;
- The percentage of participants who met the MSM definition criteria;
- The percentage of participants who did not report being HIV-positive, but were confirmed positive by the HIV test (undiagnosed infection); and
- The percentage of possible false-negative HIV test results (where the participant reported being HIV- positive during the survey, but whose HIV test result was negative or indeterminate).

9.3c Venue-Based Sampling Report

Each project site should monitor certain aspects of venue-based sampling that could influence recruitment or the sample characteristics. The Venue-Based Sampling Report (**Appendix W**) will provide information on which venues or types of venues are productive at reaching MSM. In addition to reviewing this report, it is recommended that project sites review data about each month's recruitment events in the VDTS Program to ensure that about 14 recruitment events were scheduled and that no more than 3 of the events were non-random except in months when the main gay pride festival is held (see **Chapter 6** of this manual).

9.3d Previous Participant Report

Each project site should monitor whether persons are attempting to participate in the survey more than once. The Previous Participant Report (**Appendix X**) provides a summary of participants who may have re-entered the survey.

9.4 Ongoing Formative Research

Ongoing formative research involves gathering additional information to address concerns identified either from reviewing the process monitoring reports or via feedback from the field staff.

Information collected during ongoing formative research activities will help project staff better understand participation barriers and recruitment schemes so that local procedures can be developed and implemented to improve project activities.

Ongoing formative research starts with reviewing the process monitoring reports described in **Section 9.3**. If specific problems are consistently identified in these reports, project staff should consider conducting additional formative research to further investigate these problems. This additional formative research may involve examining existing survey data, observing attendance at venues, conducting street intercept surveys, adding questions about participation barriers or potential venues for recruitment to the local use survey, or discussing issues with key informants and focus groups. The *NHBS-MSM3 Formative Research Guidelines* has more information on conducting street intercept surveys, key informant interviews, and focus groups.

When conducting ongoing formative research, project sites should begin with the quickest and least invasive methods (i.e., review of existing survey data, observations and street intercept surveys) and proceed to more invasive and time consuming methods (i.e. key informant interviews and focus groups) when initial, less invasive methods do not yield results to solve the problem.

Project sites should keep in mind that the qualitative methods used to conduct ongoing formative research should be done with the intention of investigating a problem identified. Ongoing formative research should not be used to conduct a sub-study or to evaluate new research questions. The CDC Project Officer and local principal investigator(s) should be aware of the purpose and type of methods used for ongoing formative research before conducting the work in the field.

9.4a Ongoing formative research example

The first month of recruitment recently ended; the field staff has interviewed about 100 MSM. Recruitment has been going great. About 80% of the men screened were eligible; over 90% of the eligible men agreed to participate in the survey.

The project coordinator reviews the process monitoring reports on the DCC Data Portal to assess the racial characteristics of the sample in the resulting dataset. She hopes the team's attempt to identify more venues attended by black MSM has paid off. In reviewing the Sample Characteristics Report of those screened, she learns that the percentage of eligible men does not appear to vary much by race. However, the Sample Characteristics Report of eligible participants shows that only about 10% of black men in the overall sample report having had sex with a man in the past 12 months.

What ongoing formative research activities should the project coordinator conduct to explore this issue?

First, the project coordinator should examine the existing survey data to determine the number of black MSM that have been screened and have completed the interview. This information is also available on the Sample Characteristics Report; however reports on the Data Portal may reflect a lag of a few weeks since data submission. The project coordinator should also to determine which venues have been successful for recruiting eligible black MSM; the Venue-based Sampling Report available on the Data Portal will provide this information by venue. If none of the venues which were expected to yield black MSM were selected for sampling, the project coordinator may consider conducting non-random events at these venues to boost the number of black MSM in the sample.

If a venue which was expected to yield black MSM failed to do so, the project coordinator may want to speak with the venue owner or other gatekeepers to investigate potential reasons why the field staff was unable to recruit black MSM. For example, if black MSM only attend a venue on certain nights of the week, the project coordinator should consider splitting the venue into two venues; i.e. a separate Venue Code for the day-time periods at this venue when black MSM are mostly in attendance and a separate Venue Code for the day-time periods at this venue when attendance is more mixed. Creating two distinct venues will increase the odds that the day-time periods when black MSM are more likely to attend the venue are randomly selected.

Based on the findings from her ongoing formative research activities, the project coordinator may determine that she needs to identify additional venues where black MSM socialize. An efficient strategy might be to ask NHBS participants to identify venues or social events (that are not on the current sampling frame) where other black MSM congregate. These questions may be added to the local survey or may be asked separately as an exit interview. If asking NHBS participants does not yield much information about additional venues, the project coordinator should consider interviewing key informants who may have information about where black MSM socialize.

In addition to asking NHBS participants or key informants about additional venues, the project coordinator should also ask how black MSM in the local area learn about social events. For example, black MSM in the local area may be more likely to attend organized social events in less traditional venues, and the timing and location of these social events may vary. If the project coordinator has information about these types of social events, she may be able to work with the event's organizers to gain permission to conduct NHBS-MSM3 activities.

10 Data Submissions and Management

10.1 Overview

The purpose of this chapter is to briefly describe the data submissions process and present performance goals for NHBS-MSM3. Project sites will receive a detailed, in-person training on managing and submitting data through the Data Coordinating Center (DCC) Data Portal. The training should be attended by at least one NHBS-MSM3 project staff member from each of the projects sites.

10.2 Data Submissions

Project site data for NHBS-MSM3 is managed by the DCC, including data editing. The DCC will also generate the process monitoring reports described in **Chapter 9** of this manual**.** To produce these reports the DCC will use data from the following sources that are submitted to or entered via the DCC Data Portal on a regular basis:

- QDS™ Warehouse containing interview files (eligibility screener and core questionnaire),
- Recruitment Event Information & Outcomes Form
- Participant Tracking Form, and
- HIV Test Results Log.

Each project site will be responsible for submitting the QDS™ Warehouse containing the NHBS-MSM3 core interview files to the Data Portal **on a weekly basis.** HIV test results should be entered into the online HIV Test Results Log on the Data Portal **on a daily basis** and recruitment event outcome information should be entered into the VDTS Program **just after each event**. If data in the QDS™ Warehouse needs to be changed, the project site will need to add the edits to the online Data Error Log on the Data Portal. Edits should be added to the online Data Error Log as soon as the data manager is aware of them. Project sites should refer to the *DCC NHBS Data Management Training Manual* for more information on how to submit data files to the Data Portal and to enter data into these online databases.

Project staff should review and update their data in accordance with their local plan and the *NHBS-MSM3 Model Surveillance Protocol.* Each project site should develop a local plan that identifies specific project staff and activities necessary for ensuring routine, accurate, and complete data submission to the Data Portal. The local plan should include a project staff member responsible for submitting data to the Data Portal, entering HIV test results and recruitment outcome, and serving as the DCC's point-of-contact, as well as someone who can assume each of these responsibilities if needed due to illness or leave. The activities in the local plan should at a minimum include a system of tracking

surveys and data edits; the Participant Tracking Form (**Appendix L**) described in **Chapter 5** of this manual provides a mechanism for tracking these key aspects of interviews (e.g., Survey ID, date of the recruitment event, eligibility status, etc.).

Appendix A MSM3 Operations Checklist

Version Date: ____/____/_____
mm / dd / yyyy

Please send the FINAL completed checklist to your CDC Project Officer at least <u>two weeks</u> before planned data collection. Project sites may want to send a draft of the checklist to their CDC Project Officer earlier so that revisions can be made. Project sites can also send draft sections of the checklist as they complete them.

Be sure to fill out all sections, but adapt certain responses as needed for your project site. Please contact your CDC Project Officer if you have questions about the checklist.

A change to any section of this document (e.g., new staff) needs to be communicated to your CDC Project Officer. Please modify the appropriate section of this checklist and resubmit the checklist to your CDC Project Officer.

Once your CDC Project Officer has approved this checklist, you will receive an email stating you are approved to begin implementation. Project sites are not approved to implement NHBS-MSM3 project activities until receipt of the email.

I – IRB Review

a. Was formative research submitted as a separate package to your local IRB(s)?

❑ Yes ❑ No

a1. If Yes: Please complete the following table about IRB determination for formative research:

	Funded HD IRB	**Other local IRB** *(if applicable)*	**Other local IRB** *(if applicable)*
Name of IRB			
Date FR IRB package submitted			
Date FR IRB approval received			

Name of IRB: List the name of each Institutional Review Board providing a determination for the formative research (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.
Date FR IRB approval received: For each applicable IRB, list the date you received approval to conduct formative research.

b. Please complete the following table about local IRB determination for NHBS-MSM3:

	Funded HD IRB	**Other local IRB** *(if applicable)*	**Other local IRB** *(if applicable)*
Name of IRB			
Date IRB package submitted			
Expedited or full IRB review			
Date IRB approval received			
Date amendment approval received *(if applicable)*			

Name of IRB: List the name of each Institutional Review Board providing a determination for NHBS-MSM3 (do not list an IRB that is deferring to another one).
Date IRB package submitted: For each applicable IRB, list the date you sent the NHBS-MSM3 application or sent an amended package from a previous NHBS cycle.
Expedited or full IRB review: List whether the NHBS-MSM3 application underwent an expedited or full IRB review.
Date IRB approval received: For each applicable IRB, list the date you received approval for NHBS-MSM3 as research.
Date amendment approval received: If you submitted an amendment to any of your applicable IRBs, list the date when approval was received for NHBS-MSM3.

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

❑ Yes ❑ No

c1. If Yes, please specify:

d. Attach your letter(s) of approval.

e. Attach your local consent form and procedures (e.g. oral, written), including Spanish versions if being used.

f. How will interviewers deliver informed consent to participants, as allowed by your IRB(s)? (Please select all that apply)

❑ Read consent form verbatim

❑ Read summary of consent form (*please attach summary*)

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

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

II – Project Identification

a. Record the name of your NHBS-MSM3 project:

_____

b. Insert your NHBS-MSM3 project logo:

III – Use of Mobile Unit

a. Will your project staff be using a mobile unit for the NHBS-MSM3 cycle?

❑ Yes ❑ No

a1. If Yes: Is the mobile unit owned or leased?

❑ Owned (by what agency):_____

❑ Leased (indicate duration): _____

a2. Describe the set up of the mobile unit (rooms for interviewing, HIV testing, participant flow, etc.):

b. For which of the following activities will the mobile unit be used?
(Please select all that apply)

❑ Interviews

❑ HIV tests

❑ Mobile unit/van is only occasionally used for interviews when space is not available in venues

❑ Other (*specify*): _____

IV – Phone

a. Please list the phone number(s) for your NHBS-MSM3 project (write *pending* if a phone number has not yet been acquired):

Phone # _____
Phone # _____
Phone # _____

b. Is voicemail activated on the phone being used for your project?

❑ Yes ❑ No

b1. If Yes, please explain:

V – Post-event Appointments

a. Will your project site be using post-event appointments (PEAs)?

❑ Yes ❑ No

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

a2. If Yes: Please describe circumstances in which PEAs will be utilized:

a3. Please list all locations where PEAs will take place (including any locations using a mobile unit):

Location	**Project Staff**	**Days & Hours**
e.g., DOH *7081 Spring Street, Decatur*	*Field supervisor & 2 interviewers*	*Mon: 12pm-3pm*

Location: Street address or name of location where PEAs will take place.
Project staff: Indicate staff at each location (*at least 1 field supervisor and 2 project staff members are needed to conduct PEAs*).
Days & Hours: Indicate the days and hours PEAs will be conducted.

VI – Project Staff and Trainings

a. Attach a revised, tailored copy of **Tables 2.1 and 2.2 of Chapter 2** of the *NHBS-MSM3 Operations Manual*. This will include the names and specific responsibilities of each project staff member. Add any additional project staff roles and names that are not listed in Tables 2.1 and 2.2 of Chapter 2.

b. List the name of the field supervisor(s):_____
_____

c. Please fill out the table below about project staff trainings:

- *Record each project staff member's name*
- *Record the 1- or 2-digit ID code for each project staff member (if applicable).*
- *All project staff must have had confidentiality training and signed a confidentiality agreement prior to implementation. Please indicate for each project staff member whether they have completed the training (yes/no) and the date they signed the confidentiality agreement.*
- *All project staff must read the NHBS-MSM3 Operations Manual. Please indicate for each project staff member whether they have read this document (yes/no).*
- *All interviewers and field supervisors must read the NHBS Round 3 Interviewer Guide. Please indicate for each project staff member whether they have read this document (yes/no).*
- *All HIV test counselors conducting rapid HIV tests must have read the information in the package insert for the test being utilized. For each HIV test counselor, indicated whether they have read the test package insert (yes/no).*
- *All HIV test counselors must have valid certification. For each HIV test counselor, please indicate the date their certification will expire.*
- *Using a separate row, list each local or CDC-sponsored training that project staff have completed.*

Name of project staff	*e.g., John Doe*				
Job	*Interviewer*				
2-Digit ID Code	*02*				
Received Confidentiality Training?	*Yes*				
Date Signed Confidentiality Agreement	*4/15/11*				
Read *NHBS-MSM3 Operations Manual*?	*Yes*				
Read *NHBS Round 3 Interviewer Guide*?	*Yes*				
Read package insert for HIV test method (*for HIV test counselors conducting rapid HIV tests*)	*Yes*				
Date counseling and testing certification expires (*for HIV test counselors*)	*10/21/12*				
Other training (*specify name and dates*):	*NHBS-MSM3 Field Operations Training 5/17/11- 5/19/11*				
Other training (*specify name and dates*):	*HIV Counseling and Testing 2/7/11-2/8/11*				
Other training (*specify name and dates*):					
Other training (*specify name and dates*):					
Other training (specify name and dates):					

VII – Incentives

a. Please indicate compensation participants will receive for:

a1. NHBS-MSM3 Survey: Amount: _____ Type: _____

a2. HIV testing: Amount: _____ Type: _____

b. Local policy (optional):

b1. Will a participant be compensated if he passes the screener but completes a partial interview?

❑ Yes ❑ No

If Yes: Amount: _____ Type: _____

b2. Will minor (<$5) incentives be given to persons who are found to be ineligible?

❑ Yes ❑ No

If Yes: Amount: _____ Type: _____

b3. Will a participant be compensated if he returns to receive his HIV test result (for project sites with IRB approval and non-NHBS funds)?

❑ Yes ❑ No

If Yes: Amount: _____ Type: _____

VIII – VBS Code Numbers

a. At each recruitment event, the field supervisor should provide the interviewers with a written copy of four code numbers: Interviewer ID, Survey ID, Venue Code and Event Number.

Will your project site be using the Participant Tracking Form for this purpose?

❑ Yes ❑ No

a1. If No: please describe the system the field supervisor will use to provide a written copy of the 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. If a Survey ID Log will be used, please attach an example:

VIX– HIV Testing

a. Will your project site be conducting rapid testing?

❑ Yes ❑ No

If Yes:

a1. Type of specimen collected (i.e., oral, whole blood): _____

a2. Tradename of rapid test: _____
(e.g., OraQuick Advance, Unigold, etc.)

a3. Will your project site be implementing a Rapid Test Algorithm?

❑ Yes ❑ No

If Yes: Indicate the tradename of the 2nd and/or 3rd test used:

2nd rapid test: _____

3rd rapid test: _____

a4. Does your project site have a CLIA certificate of waiver?

❑ Yes ❑ No

a5. Describe the system your project site will use to ensure that test results are read during the appropriate time window as indicated in the test(s) package insert(s):

a6. Will rapid test specimens be run in a room apart from where the participant is being interviewed?

❑ Yes ❑ No

If No: Provide justification for running the rapid test specimen in same room where the participant is being interviewed:

If No: Describe the steps your site will take to minimize bias to the interview:

b. Standard testing (if applicable) and confirmatory testing:

b1. Type of specimen collected (i.e, oral, whole blood, dried blood spots): _____

b2. Tradename of standard screening assay: _____ (e.g., GS HIV-1/HIV-2 Plus O EIA, Avioq HIV-1 Microelisa, Abott Architect Ag/Ab Combo, etc.)

b3. Tradename of confirmatory test: _____ (e.g., GS HIV-1/HIV-2 Plus O EIA, Avioq HIV-1 Microelisa, Abott Architect Ag/Ab Combo, etc.)

b4. Name and contact information of laboratory performing testing:

b5. Attach laboratory specimen intake slip.

b6. Is consent for specimen storage (if applicable) included on consent form?

❑ Yes ❑ No

b7. Does your project site have plans to conduct incidence testing (i.e., BED)?

❑ Yes ❑ No

c. Have specimen/test type handling requirements been discussed with laboratory staff?

❑ Yes ❑ No

c1. Describe where the collected specimens will be stored before sending to the laboratory:

c2. Describe when the specimens will be sent to the laboratory:

c3. Describe how the specimens will be sent (i.e., courier, NHBS staff delivers, etc.):

c4. Describe how project staff will communicate to the lab which specimens are from persons who are self-reported HIV-positive. *These specimens must receive confirmatory testing (e.g. GS HIV-1 Western Blot, OraSure Western Blot Kit) regardless of the results of any screening tests performed:*

c5. If storing specimens for any future testing, describe how project staff will communicate to the lab which specimens have consent for storage and which are to be destroyed (i.e., participant did not give consent for storage):

d. Describe your stepwise HIV counseling and testing procedures at recruitment events:

e. Describe NHBS project site procedures for returning standard and confirmatory laboratory test results:

f. Does your site have plans to use a mobile unit to return test results?

❑ Yes ❑ No

g. List all locations for returning HIV test results (including any locations using a mobile unit):

Location	**Project Staff**	**Days & Hours**
e.g., DOH *7081 Spring Street Decatur*	*Field supervisor &* *1 HIV counselor*	*Mon: 12pm-3pm*

Location: Street address or name of location for returning HIV test results
Project staff: Indicate project staff at each location (i.e. field supervisor, number of HIV test counselors)
Days & Hours: Indicate the days and hours staff will be available for test results.

h. Does your site plan to use the optional phone reminder system (described in Chapter 8 of the *NHBS-MSM3 Operations Manual*)?

❑ Yes ❑ No

If Yes: please attach Appointment Reminder Call Form and script.

i. Describe procedures for referring HIV-positive NHBS participants to care:

j. Please attach any other testing forms or logs that your project site plans to use (e.g., risk assessment forms).

k. Please specify any other (non-HIV) tests conducted:

Test : _____ Returning result? ❑ Yes ❑No
Test : _____ Returning result? ❑ Yes ❑No
Test : _____ Returning result? ❑ Yes ❑No

k1. Please describe how other (non-HIV) tests will be incorporated into NHBS-MSM3 activities:

X– Local Questions

Will participants be asked local use questions after the NHBS-MSM3 core questionnaire has been completed?

❑ Yes ❑ No

If Yes: please attach the MS Word version of the local use questionnaire created in QDS™, including Spanish version if being used (this will require building an interviewer administered questionnaire in the QDS™ Design Studio program).

XI — Data Management

a. Please list the name of your data manager(s) and their contact information:

Name	Phone	E-mail
e.g., Kim Walker	*555-221-1234*	*KW@NET.com*

b. Please attach the following:

- ❑ Data security policy
- ❑ Data confidentiality policy
- ❑ Data transfer protocol (from venue to office)

c. Please list name of individuals responsible for submitting NHBS-MSM3 data to the DCC Data Portal:

Name	Phone	E-mail
e.g., Kim Walker	*555-221-1234*	*KW@NET.com*

XII— Local Safety Procedures/Field Incident Reporting Procedures

Please indicate that your project site has developed the following and attach copies:

- ❑ Local safety protocol
- ❑ Field incident reporting procedures

XIII – Other Supporting Materials

Please attach any other prevention materials or supporting information concerning NHBS-MSM3 implementation.

XIV–Public Health Insurance Plans

Please list your local public health insurance plans and indigent care programs. This might be a local name for a national plan (e.g. Medicaid is called MediCal in California) or might be a plan administered by your state, city, or county (e.g., Texas Gold Card or Healthy San Francisco). Please include plans that are administered or subsidized by local, state, or federal governments and have income, age, or disability as an eligibility criterion or HIV-related care, like Ryan White.

This information will be used to classify health insurance collected during the NHBS core questionnaire as public, private or other.

Name of insurance plan/ Indigent care program	Administered by:	Eligibility criteria:	Comments/notes

Name of insurance plan/Indigent care program: Specify the name of the local insurance plan.
Administered by: Indicate whether plan is run by *federal*, *state*, *local* government or *other entity.*
Eligibility criteria: Indicate what general criteria are used to determine eligibility for the plan, such as *income*, *age*, or *disability*. There is no need to provide detailed eligibility criteria, such as income cutoffs.

Appendix B Field Supervisor— Project Management Evaluation Form

General Instructions:

- 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.
Evaluation Date:	☐ **Pre-implementation Evaluation**
Evaluator:	☐ **Ongoing Evaluation**

Management of Staff	**Rating**				
1. Project coordinator or other staff member is trained as field supervisor back-up.	1 No				5 Yes
2. Evaluation schedule for counters has been maintained.	1 No				5 Yes
3. Evaluation schedule for recruiters has been maintained.	1 No				5 Yes
4. Evaluation schedule for interviewers has been maintained.	1 No				5 Yes
5. Evaluation schedule for HIV test counselors has been maintained.	1 No				5 Yes
Recruitment Event Setup					
6. All supplies were gathered 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. Event was adequately staffed (a minimum of 2 additional project staff).	1 No				5 Yes
9. Checked-in with venue owner/manager upon arrival. ☐ N/A	1 No				5 Yes
10. Conducted a pre-event briefing with staff.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
11. Identified and set up spaces for interviewing and HIV testing.	1 No				5 Yes
12. Identified and set up counting area and where recruitment will take place.	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) prior to each interview started.	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. ☐ N/A	1 No				5 Yes

16. Monitored the flow of participants and, if applicable, adjusted counting area accordingly.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
17. Managed recruitment by monitoring interviewers' availability.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
18. Ensured each interviewer and HIV test counselor worked in an area that protected participants' privacy.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
19. Remained aware of each team member's whereabouts throughout event.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
20. Maintained security of staff and study materials throughout event.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
21. Successfully handled people's attempts to interrupt a participant's session. ☐N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
22. Monitored staff interactions with participants, venue staff, and the public.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
23. Checked in with recruiters periodically to assess recruitment success and, if necessary, made adjustments.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
24. Met with recruiter when five consecutive intercepts were unsuccessful. ☐ N/A	1 No			5 Yes	
25. Checked in with interviewers after each interview.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
26. Assisted field staff when necessary. ☐ N/A	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
27. Met each potential participant prior to the interview.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
28. Treated all participants 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	
Post- Recruitment Event Management					
31. Held post- event debriefing and, if applicable, discussed field incidents, etc.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
32. Completed Recruitment Event Information & Outcome Form: recorded recruitment event notes and outcomes.	1 No			5 Yes	
33. Collected and reviewed HIV Test Results Log.	1 No			5 Yes	
34. Collected, reviewed, and tabulated Intercept Forms.	1 No			5 Yes	
35. Collected and reviewed staff evaluation forms if PC or PI were evaluators. ☐ N/A	1 No			5 Yes	
36. Collected and reviewed Participant Tracking Forms and, if applicable, consent forms for each participant.	1 No			5 Yes	
37. Verified that all participants documented to have provided consent for HIV testing per the Participant Tracking Form had either an HIV rapid test result or documentation of specimen collection.	1 No			5 Yes	

38. Forms that contain confidential information (i.e., Reminder Call Forms, HIV Test Results Log, and Phone Results Log, Participant Tracking Forms), handhelds, and laptops were kept in a locked file cabinet.	1 No			5 Yes	
39. Demonstrated adherence to *NHBS-MSM3 Model Surveillance Protocol* including VBS methods throughout recruitment event.	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

☐ Reviewed evaluation form with the field supervisor.

☐ Provided time for field supervisor to ask questions.

☐ Provided the field supervisor with recommendations for improvement.

☐ Provided a brief description of how each skill was below standard (i.e. what was observed) and the recommendations for improvement shared with the field supervisor in the section below entitled “Skill Description, Recommendations, Accolades, and Additional Comments”.

Appendix C Recruiter Evaluation Form

General Instructions:

- To be conducted by the principal investigator, project coordinator, or, if necessary, the field supervisor
- Shaded areas are NHBS performance recommendations.

Recruiter:	**Rating instructions: Rating instructions:** Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the 'N/A' box.
Evaluation Date:	☐ **Pre-implementation Evaluation**
Evaluator:	☐ **Ongoing Evaluation**

Introduction	**Rating**				
1. Approached counted venue attendees ONLY when directed by the counter.	1 No				5 Yes
2. Approached attendees in a calm and friendly manner.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
3. Introduced self appropriately.	1 Not at all	2 Poorly	3 Okay	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 for the intercept.	1 No				5 Yes
6. Asked the *Previous Participation Question*.	1 No				5 Yes
7. For each approach, recorded a response on the Intercept Form to the *Previous Participation Question*, even for those who did not stop for the intercept.	1 No				5 Yes
8. Did not pre-screen participants based upon eligibility criteria.	1 Pre-screened				5 Did not pre-screen
Invitation to Participate ☐ N/A					
9. Invited all participants not answering YES to the *Previous Participation Question* to participate in the project.	1 No				5 Yes
10. Clearly explained purpose and benefits of the project.	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 participants' barriers to recruitment in an appropriate and effective manner. ☐ N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
13. Addressed participants' barriers to participation in an appropriate and effective manner. ☐ 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, etc.).	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

☐ Reviewed evaluation form with the recruiter.

☐ Provided time for recruiter to ask questions.

☐ Provided the recruiter with recommendations for improvement.

☐ Provided a brief description of how each skill was below standard (i.e. what was observed) and the recommendations for improvement shared with the recruiter in the section below entitled “Skill Description, Recommendations, Accolades, and Additional Comments”.

Appendix D Interviewer Evaluation Form

General Instructions

- To be conducted by the principal investigator, project coordinator, or, if necessary, field supervisor.
- It is recommended that the Evaluator have a handheld or copy of the questionnaire to follow along during the interview.
- **Permission from the potential participant must be received 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.
Evaluation Date:	☐ **Pre-implementation Evaluation**
Evaluator:	☐ **Ongoing Evaluation**

Time						
1. Eligibility screener	**Start:** _____ **End:** _____					
2. Consent process	**Start:** _____ **End:** _____					
3. NHBS-MSM3 Core Questionnaire	**Start:** _____ **End:** _____					
4. Local questionnaire	**Start:** _____ **End:** _____					
Set-up	**Rating**					
5. All necessary materials were prepared prior to starting (flashcards, consent forms, pens, checked day and time on handheld, prevention materials and referral information, etc.).	1 Not at all	2	3 Some	4	5 Fully	
6. Explained evaluation process to participant and received permission for evaluator to sit-in on session.	1 No				5 Yes	
Consent Process						
7. No personal identifiers (i.e. name, address) were recorded.	1 Recorded				5 Not recorded	
8. <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	
9. Provided the participant a copy of consent form to follow along. ☐ N/A	1 No				5 Yes	
10. Interviewer offered the participant a copy of the consent form to keep. ☐ N/A	1 No				5 Yes	
11. Provided an opportunity for questions about the project/consent process.	1 No				5 Yes	
12. Obtained a <u>separate</u> consent for the questionnaire.	1 No				5 Yes	
13. Obtained a <u>separate</u> consent for HIV testing.	1 No				5 Yes	
14. Obtained a <u>separate</u> consent for sample storage and/or additional testing. ☐ N/A	1 No				5 Yes	
15. Pace of reading the consent was…	1 Too slow		1 Too fast		5 Just right	

Eligibility and Questionnaire Administration					
16. Oriented the participant by reading each introductory statement ("Say' box).	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
17. Read each question as written.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
18. Read definitions as written (e.g., partner types, "sharing," etc.).	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
19. Read response options as written when instructed ("READ choices").	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
20. Omitted response options when instructed ("DO NOT read choices").	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
21. Reread and clarified instructions, questions, and responses. ☐ N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
22. Recognized inconsistent responses, clarified with respondent, and corrected data in the handheld computer or on Participant Tracking Form. ☐ N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
23. Probed incomplete, implausible, unclear, and, as appropriate, 'don't know' responses. ☐ N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
24. Used neutral probes (i.e., probed without influencing response).	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
25. The amount of time given for responses was…	1 Too short		1 Too long		5 Just right
26. Pace of reading the screener was…	1 Too slow		1 Too fast		5 Just right
27. Pace of reading the questionnaire was…	1 Too slow		1 Too fast		5 Just right
Flashcards					
28. Used flashcards when instructed.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
29. 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
30. Read the flashcards as written.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
Establishing and Maintaining Rapport					
31. 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
32. Maintained eye contact with participant throughout interview.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
33. Provided neutral feedback throughout the interview.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
34. Remained engaged with participant and his responses throughout the survey.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
35. 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 unclear responses were entered into the handheld.

☐ Reviewed how the interviewer coded the question regarding the validity of answers and agreed with the selection.

☐ Reviewed evaluation form with the interviewer.

☐ Provided time for interviewer to ask questions.

☐ Provided the interviewer with recommendations for improvement.

☐ Provided a brief description of how each skill was below standard (i.e. what was observed) and the recommendations for improvement shared with the interviewer in the section below entitled "Skill Description, Recommendations, Accolades, and Additional Comments".

Appendix E HIV Counseling and Testing Evaluation Form

General Instructions

- To be conducted by the principal investigator, project coordinator, or, if necessary, the field supervisor.
- **Permission from the participant must be received 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 section 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.
Evaluation Date:	☐ **Pre-implementation Evaluation**
Evaluator:	☐ **Ongoing Evaluation**

Counseling and Testing Process	**Rating**				
1. Verified on Participant Tracking Form that consent for HIV testing was provided.	1 No				5 Yes
2. Verified with participant that he is interested in getting tested and has provided appropriate consent(s).	1 No				5 Yes
3. Discreetly obtained relative risk information from interviewer. ☐ N/A	1 No				5 Yes
4. All necessary materials were prepared prior to starting (HIV testing kit/ phlebotomy, HIV Test Results Log, referrals, information handouts, personal protective equipment, etc.)	1 Not at all	2	3 Some	4	5 Fully
5. Explained evaluation process to participant and received permission for evaluator to sit-in on session.	1 No				5 Yes
6. Pre-test counseling was conducted *after* the survey was completed. ☐ N/A	1 No				5 Yes
7. Provided HIV information regarding transmission, risk factors, etc.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
8. Clarified misconceptions of HIV and corrected false information. ☐ N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
9. Asked open-ended questions.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
10. Allowed participant to ask questions and raise concerns.	1 No				5 Yes
11. Answered questions and addressed participant's concerns. ☐ N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
12. Returned test results in a manner that preserved participant's privacy. ☐ N/A	1 No				5 Yes
13. Ensured participant fully understood his HIV test result. ☐ N/A	1 No				5 Yes
14. Conducted a risk assessment specific to the participant.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well

15. Developed a risk reduction plan with the participant.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
16. Discussed disclosure of HIV status to partner(s). ☐ N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
17. Provided information of where partner(s) can be tested.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
18. Provided and explained referral and informational resources.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
19. Provided a phone number/scheduled an appointment to obtain HIV results. ☐ N/A	1 No			5 Yes	
20. Offered an appointment reminder to the participant. ☐ N/A	1 No			5 Yes	
21. Remained engaged with the participant throughout the counseling session.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
HIV Testing Procedures					
22. Test was conducted in an appropriate environment (temperature, lighting, adequate work space, etc.).	1 No			5 Yes	
23. All specimens/test devices were labeled with survey ID or lab ID.	1 No			5 Yes	
24. No personal identifiers were recorded other than for reminder call.	1 Collected identifiable information			5 Did not collect identifiable information	
25. Adequately counseled participant on what to expect during specimen collection.	1 No			5 Yes	
26. OSHA regulations were adhered to with respect to universal precautions (gloves) and syringe/device disposal in approved biohazard/sharps containers.	1 No			5 Yes	
27. Appointment card was provided and participant counseled that card must be presented to obtain HIV test results. ☐ N/A	1 No			5 Yes	
28. Spoke at the participant's level of understanding.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
Rapid Testing ☐ N/A					
29. Oral specimen was collected per MSM3 Operations Manual (e.g., HIV test counselor requested food particles be removed from the mouth before specimen collection). ☐ N/A	1 No			5 Yes	
30. Appropriate instructions for oral specimen collection were provided (note: collection is different for Oraquick and Orasure). ☐ N/A	1 No			5 Yes	
31. Ensured participant followed specimen collection instructions. ☐ N/A	1 No			5 Yes	
32. Fingerstick specimen was collected per MSM3 Operations Manual. ☐ N/A	1 No			5 Yes	
33. Rapid test(s) could not be viewed by participant during test development.	1 No			5 Yes	
34. Rapid test results were read within the appropriate time frame for the test performed (Unigold: 10-20 min, Clearview 15-20 min, Oraquick 20-40 min).	1 No			5 Yes	
35. Recorded start time for test development and time when results were read.	1 No			5 Yes	

36. Confirmatory specimen was obtained if rapid test result was reactive. ☐ N/A	1 No	5 Yes

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

Evaluator: Please ensure that the following steps are completed with the HIV test counselor

☐ Reviewed evaluation form with the HIV test counselor.

☐ Provided time for HIV test counselor to ask questions.

☐ Provided the HIV test counselor with recommendations for improvement.

☐ Provided a brief description of how each skill was below standard (i.e. what was observed) and the recommendations for improvement shared with the HIV test counselor in the section below entitled "Skill Description, Recommendations, Accolades, and Additional Comments".

Appendix F Field Supervisor—HIV Testing Operations Evaluation

General Instructions

- To be conducted by the principal investigator or project coordinator.
- Shaded areas are NHBS performance recommendations.

Field Supervisor: **Evaluation Date:** **Evaluator:**	**Rating instructions:** Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the 'N/A' box. ☐ **Pre-implementation Evaluation** ☐ **Monthly Evaluation**	
Specimen Collection and Storage and Disposal		
1. Maintained a paper log (e.g. HIV Test Results Log) with no personal identifying information that links the Survey ID and the Lab ID.	1 No	5 Yes
2. Site only uses forms that were approved as part of the MSM3 Operations Checklist for processing and tracking specimens.	1 No	5 Yes
3. Specimens are stored in and transported by coolers that are appropriately labeled according to OSHA regulations.	1 No	5 Yes
4. All blood collection devices are disposed of in appropriate biohazard containers. ☐ N/A	1 No	5 Yes
5. Site collects all required HIV testing variables per HIV Test Results Log, Specimen Shipping Log, etc.	1 No	5 Yes
6. Site tracks whether participants have returned for their results.	1 No	5 Yes
7. Site monitors which specimens can be stored and, for the specimens of participants' who don't provide consent to for storage, are disposed of properly. ☐ N/A	1 No	5 Yes
Security and Confidentiality		
8. 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
9. Site uses the DCC Data Portal to enter HIV Test Results Log data.	1 No	5 Yes
10. Sensitive information, such as reminder call forms, are stored and shredded according to NHBS protocol.	1 No	5 Yes
Rapid Testing ☐ N/A		
11. HIV testing package inserts are available for reference at -recruitment event.	1 No	5 Yes
12. Site monitors and records on Quality Assurance Log temperature at which test kits are stored.	1 No	5 Yes
13. Site monitors and records on Quality Assurance Log temperature at which testing is conducted per package insert.	1 No	5 Yes
14. Site runs controls for each new batch of test kits and records the results in a quality assurance log.	1 No	5 Yes

15. Site runs external controls at least once per week.	1 No	5 Yes
16. Site monitors data for discordant test results (i.e., reactive rapid test and non-reactive confirmatory test).	1 No	5 Yes

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

Evaluator: Please ensure that the following steps are completed with the field supervisor

☐ Reviewed evaluation form with the Field Supervisor.

☐ Provided time for the Field Supervisor to ask questions.

☐ Provided the Field Supervisor with recommendations for improvement.

☐ Provided a brief description of how each skill was below standard (i.e. what was observed) and the recommendations for improvement shared with the Field Supervisor in the section below entitled “Skill Description, Recommendations, Accolades, and Additional Comments”.

Appendix G Data Manager Evaluation Form

General Instructions

- 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.
Evaluation Date:	☐ **Pre-implementation Evaluation**
Evaluator:	☐ **First Week of Data Collection Evaluation**
	☐ **As Needed Evaluation**

Data Management		
1. Ensures daily receipt of Participant Tracking Form, HIV Test Results Log or Specimen Shipping Log, Recruitment Event Information & Outcomes Form, and other logs, if applicable.	1 No	5 Yes
2. Successfully uploads data from each handheld to the desktop computer.	1 No	5 Yes
3. Reviews each handheld's QDS™ data files and compares the Survey IDs with the Survey IDs noted on the interviewer's Participant Tracking Forms.	1 No	5 Yes
4. Transfers records from QDS™ data files (e.g., files with *.QAD extension) to the QDS™ Warehouse successfully.	1 No	5 Yes
5. Does not delete data files on the handheld until after confirming the records were added to the QDS™ Warehouse.	1 No	5 Yes
6. Reviews data discrepancies and concerns with the field supervisor or project coordinator to determine resolutions.	1 No	5 Yes
7. Documents data discrepancies and their resolution on the Participant Tracking Form (or other log, if applicable). ☐ N/A	1 No	5 Yes
8. Enters data edits from the Participant Tracking Form (or other log, if applicable). into the online Data Error Log on the DCC Data Portal daily. ☐ N/A	1 No	5 Yes
9. Successfully enters HIV testing data into the online HIV Test Results Log on the DCC Data Portal daily.	1 No	5 Yes
10. Successfully enters recruitment event outcomes, into VDTS Program on the DCC Data Portal after each event. ☐ N/A	1 No	5 Yes
11. Successfully encrypts NHBS data using PGP software.	1 No	5 Yes
12. Submits QDS™ Warehouse containing core interview files to the DCC Data Portal each week. (Note: Please contact the DCC before sending a mock data warehouse to test this procedure.)	1 No	5 Yes
13. Knowledgeable of how to ask questions via the DCC Knowledge Base.	1 No	5 Yes
12. Reviews DCC data reports and responds to inquiries on a timely basis. ☐ N/A	1 No	5 Yes

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

Evaluator: Please ensure that the following steps are completed with the data manager

☐ Reviewed evaluation form with the data manager.

☐ Provided time for the data manager to ask questions.

☐ Provided the data manager with recommendations for improvement.

☐ Provided a brief description of how each skill was below standard (i.e. what was observed) and the recommendations for improvement shared with the data manager in the section below entitled “Skill Description, Recommendations, Accolades, and Additional Comments”.

Appendix H Interviewer Improvement Report

With the data files provided by project sites, the Data Coordinating Center (DCC) will create a report to help improve interviewer skills. The report is designed to identify interviewers who may need additional training. There are several tables comprising this report.

Table H.1: Length of eligibility screener, consent process, and interviews

A table is generated to indicate the length of the eligibility screener, the consent process, and the survey (see **Figure H.1**). The median, mean, minimum, and maximum value for elapsed time will be reported in this table. The table will include aggregate data from eligible participants who consented and completed the survey and who the interviewer feels provided at least somewhat valid responses. Persons who were ineligible, did not consent, did not complete the interview, or did not provide valid responses during the interview are excluded from these reports.

Figure H.1: An example of the interviewer improvement report: length of eligibility screener, consent process, and interview.

INTERVIEWER IMPROVEMENT REPORT: LENGTH OF ELIGIBILITY SCREENER, CONSENT PROCESS & INTERVIEWS

INTERVIEWER ID	No. Completed Interviews	Length of Eligibility Screenings				Length of Consent Process				Length of Interviews			
		Median	Mean	Min	Max	Median	Mean	Min	Max	Median	Mean	Min	Max
1	20	5:13	5:13	2:10	7:45	5:13	5:13	2:10	7:45	15:13	15:02	12:10	17:45
3	12	4:57	4:30	2:12	7:50	4:57	4:30	2:12	7:50	14:57	14:54	12:12	17:50
4	18	6:12	6:05	3:15	8:15	6:12	6:05	3:15	8:15	16:30	16:05	13:15	18:15
5	22	5:59	6:25	3:15	7:15	5:59	6:25	3:15	7:15	15:59	16:25	13:15	17:15
TOTAL	72	5:12	2:45	2:10	8:15	5:12	2:45	2:10	8:15	15:35	16:00	12:10	18:15

Table H.2: Number of questions marked "Don't know" or "Refused" within an interview

A table is generated to indicate the number of questions within an interview marked "Don't know" or "Refused" by an interviewer (see **Figure H.2**). Two variables were created to generate this report. Each variable in the interview that allowed a "don't know" or "refused" response were reviewed. The created variables are basically a score indicating how many of these variables in the interview were coded as either "Don't Know" or "Refused." Persons who were ineligible, did not consent, did not complete the interview, or did not provide valid responses during the interview are excluded from this table.

Figure H.2: An example of the interviewer improvement report: Number of questions marked "Don't know" or "Refused" within an interview.

INTERVIEWER IMPROVEMENT REPORT: Number of questions marked "Don't Know" or "Refused" within an interview										
	No.	Don't Know				Refused				
INTERVIEWER ID	Completed	Median	Mean	Min	Max	Median	Mean	Min	Max	
1	20	3	5	0	35	0	0	1	4	
3	12	2	1	1	3	2	7	1	65	
4	18	0	2	0	5	0	2	0	6	
5	22	0	1	0	2	0	1	1	3	
TOTAL	72	0	3	1	35	0	3	1	65	

Table H.3: Coding of other insurance

A table is generated to indicate the coding of other insurance by each interviewer (see **Figure H.3**). This table will include aggregate data from eligible participants who consented and completed the survey and who the interviewer feels provided at least somewhat valid responses. Persons who were ineligible, did not consent, did not complete, or did not provide valid responses during the interview are excluded from these reports.

Figure H.3: An example of the interviewer improvement report: Coding of other insurance.

INTERVIEWER IMPROVEMENT REPORT: Coding of other insurance									
INTERVIEWER ID	Survey ID	Private	Medicaid	Medicare	Other Government	Tricare (Champus)	VA Coverage	Other Health Insurance	Text for other Insurance
1	1004	0	1	0	0	0	0	1	care source thinks it is medicaid
1	1023	1	0	0	0	0	0	1	cobra
1	1105	0	0	0	0	0	0	1	County Hospital card
3	1067	0	0	1	0	0	0	1	County Hospital card
3	1075	0	0	0	0	0	0	1	County Hospital Service
4	1105	0	0	0	0	0	0	1	ryan white
5	1008	0	0	0	0	0	0	1	adapt primary healthcare
5	1027	0	0	0	0	0	0	1	amerigroup
5	1089	0	0	0	0	0	0	1	Physician coverage
5	1104	0	0	0	0	0	0	1	Blue cross
5	1134	0	1	0	0	0	0	1	aarp

Table H.4: Frequency of validity by interviewer

A table is generated to indicate how each interviewer has coded validity (see **Figure H.4**). This table will include aggregate data from eligible participants who consented and completed the survey, regardless of how the interviewer coded eligibility.

Figure H.4: An example of the interviewer improvement report: validity coding

INTERVIEWER IMPROVEMENT REPORT: Frequency of validity							
Interviewer ID	No. Completed	Validity					
		1		2		3	
		No.	%	No.	%	No.	%
1	21	18	86.00%	2	9.50%	1	4.50%
3	12	8	67.00%	4	33.00%	0	0.00%
4	18	16	89.00%	1	5.50%	1	5.50%
5	22	16	73.00%	2	9.00%	4	18.00%
TOTAL	73	58	78.75%	9	14.25%	6	7.00%

Appendix I Recruitment Event Checklist

A model Recruitment Event Checklist is provided to facilitate the preparation for, setup, documentation and closeout of recruitment events. The checklist should be used in conjunction with the *Recruitment Event Information & Outcomes Form* (see **Appendix K**). The actual checklist can be found in a separate Word file named **Appendix I- Recruitment Event Checklist.doc**. Each site should tailor this checklist to incorporate local information.

I – 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 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 (*use local discretion whether or not to contact owner*).
- ☐ *If mobile unit is used,* obtain permit to block off parking space near the venue from the appropriate local office (if necessary).
- ☐ Schedule project staff (*record in Section II of Recruitment Event Information & Outcomes Form*).
- ☐ If applicable, schedule evaluations for project staff (*record in Section II of Recruitment Event Information & Outcomes Form).*
- ☐ Record Interviewer IDs in *Section II of the Recruitment Event Information & Outcomes Form*.

II – Tasks to Complete Right before Recruitment Event

- ☐ Check that batteries for the handheld computers are fully charged and that handhelds are working properly.
- ☐ Check that data from the previous recruitment event have been uploaded from the handheld computer to the QDS™ Warehouse.
- ☐ Check that correct date and time are displayed on handheld computer.
- ☐ *If mobile unit is used*, make sure the vehicle has a full tank of gas and when appropriate, 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 (*record in Section III of Recruitment Event Information & Outcomes Form).*
- ☐ Gather supplies for recruitment event:

Equipment

- ☐ Handheld computers (1 for each interviewer and backups)
- ☐ AC adaptors for handheld computers
- ☐ Tally counter (i.e., "clickers")
- ☐ Communication equipment (e.g., 2-way radios or cell phones)

Materials

- ☐ Consent forms for each interviewer and participant
- ☐ Flashcards (Appendix E of *NHBS-MSM3 Model Surveillance Protocol*)
- ☐ Enough incentives to cover the expected number of participants

Blank forms/logs

- ☐ Survey ID Log
- ☐ Intercept Form
- ☐ Participant Tracking Form
- ☐ Appointment and Phone Results Cards
- ☐ Appointment Log
- ☐ Quality Assurance Log (for rapid HIV tests)
- ☐ Lab slips
- ☐ Reminder Call Form (if applicable)
- ☐ Specimen Shipping Log (if applicable)
- ☐ Phone Results Log (if applicable)
- ☐ HIV Test Results Log (Appendix J of *NHBS-MSM3 Surveillance Protocol*)
- ☐ Field Supervisor- Project Management Evaluation Form
- ☐ Recruiter Evaluation Form
- ☐ Interviewer Evaluation Form
- ☐ HIV Counseling and Testing Evaluation Form
- ☐ Field Supervisor- HIV Testing Operations Evaluation Form

Prevention and referral materials

- ☐ Information and education pamphlets
- ☐ List of referral agencies and contact persons
- ☐ HIV risk reduction supplies (condoms, lube)

Guidance documents

- ☐ *NHBS-MSM3Model Surveillance Protocol*
- ☐ *NHBS-MSM3 Operations Manual*
- ☐ *NHBS Round 3 Interviewer Guide*

Other materials

- ☐ The current month's recruitment calendar
- ☐ Signed Memorandums of Understanding (if necessary)
- ☐ Incentive log, receipt book, or other forms of incentive tracking
- ☐ Other item: _____

☐ Gather HIV testing supplies:

Rapid testing (differs depending on which rapid test is used)
- ☐ Tests
- ☐ Lancets
- ☐ Fingerstick blood collection devices (i.e., pipettes, loops)
- ☐ Test reagents (i.e., developer solution, wash solution, running buffer)
- ☐ Package inserts (for the specific rapid test being used)

Standard testing
- ☐ Lab slips
- ☐ Oral fluid collection devices (if applicable)
- ☐ Whole blood specimen collection tubes
- ☐ Phlebotomy equipment (i.e., butterfly needles, tube stopper, tourniquet)

General
- ☐ Alcohol swabs
- ☐ Dry sterile gauze
- ☐ Band-aids
- ☐ Biohazard ("sharps") container
- ☐ Personal protective equipment (i.e., latex gloves, eye protection, lab coat)

III – 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 counting area and where recruitment will take place.

☐ Hold pre-event meeting with project staff.

IV– 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 activities (e.g. problems with management, change in attendee population, etc.).
- ☐ Discuss any barriers related to recruitment/participation and 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 handheld 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 IV 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 **Previous Participation Question Responses**, and the **Number of Post-event Appointments (PEAs)** and record at the bottom of each Intercept Form.
- ☐ If applicable, cross-check Intercept Forms and Appointment Log to ensure 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 data edits, code numbers and other information on Participant Tracking Forms.
- ☐ Cross-check Survey ID Log with Participant Tracking Forms and note any errors with Survey ID.
- ☐ If applicable, review Interviewer Evaluation Forms or note if scheduled evaluation(s) did not occur and need to be re-scheduled.

With HIV Test Counselors

- ☐ Collect HIV Test Results Log.
- ☐ Review HIV Test Results Log for completeness.
- ☐ Cross-check that there is a specimen for each entry in the HIV Test Results Log.
- ☐ Cross-check that there is a lab slip for each standard or confirmatory test specimen.
- ☐ Check for Lab ID accuracy in HIV Test Results Log and on lab slip.
- ☐ Check Appointment Log to ensure that appointments have been scheduled for HIV test results.
- ☐ If applicable, collect 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 Forms or note if scheduled evaluations did not occur and need to be re-scheduled.

☐ Record the total **NUMBER COUNTED** (from the tally counter or 'clicker') *in Section V of Recruitment Event Information & Outcomes Form.*

V– Closeout Tasks to Complete at Project Office

Test specimens

- ☐ Store HIV test specimens according to package insert (while waiting to be shipped).
- ☐ Complete Specimen Shipping Log (if not completed in the field).
- ☐ Ship HIV test specimens.

Data Coordinating Center (DCC) Data Portal

- ☐ Enter data edits from Participant Tracking Forms into **online** Data Error Log
- ☐ Enter data from **hardcopy** HIV Test Results 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) was conducted (*Section V of Recruitment Event Information & Outcomes Form)* in the event outcomes section of the VDTS Program.
- ☐ Enter the total **number counted** (*Section V of Recruitment Event Information & Outcomes Form)* into the event outcomes section of the VDTS Program.
- ☐ Enter the column totals from each Intercept Form into the event outcomes section of the VDTS Program.
- ☐ If applicable, record reason(s) why alternate venues were used (*Section IV of Recruitment Event Information & Outcomes Form)* in the event outcomes section of the VDTS Program.

Data handling

- ☐ Upload NHBS core interview files from handheld computers into respective QDS™ Warehouse on project computer.
- ☐ Upload local survey files from handheld computer into respective QDS™ Warehouse on project computer.
- ☐ Charge and lock up handhelds.
- ☐ Lock up completed forms and logs.

Appendix J Field Incident Report

NHBS-MSM3
Field Incident Report

Project Site: _____

Name of Person Filing Report: _____

Position (check all that apply):

__ Interviewer

__ Field Supervisor

__ Project Coordinator

__ Other (Specify): _____

Location of Incident (name and address)

_____

_____

Date of Incident: ____ / ____ / _____

Time of Incident: ____ / ____ am pm (circle one)

Description of Incident and Actions Taken:

_____

_____

_____

_____

_____

_____

_____

Incident Reported locally to (check all that apply)

__ Supervisor Date: ____ / ____ / ____ Time: ____ / ____ am pm (circle one)

__ Police Date: ____ / ____ / ____ Time: ____ / ____ am pm (circle one)

__ IRB Date: ____ / ____ / ____ (Attach report)

__ Other (specify): _____

Date: ____ / ____ / ____ Time: ____ / ____ am pm (circle one)

Incident Report to CDC: Date: ____ / ____ / ____ Time: ____ / ____ am pm (circle one)

Name of Contact at CDC _____

Comments (other information relevant to the incident):

_____

_____

_____

_____

_____

_____

_____

Appendix K Recruitment Event Information & Outcomes Form

A model Recruitment Event and Outcomes Form is provided to record information about recruitment events; this form can be used in conjunction with the Recruitment Event Checklist (**Appendix I**). The first three sections of the form collect pre-event information needed for setup. The last two sections of the form collect post-event information. The recruitment event outcomes information on this form will be entered into the VDTS Program on the Data Coordinating Center (DCC) Data Portal by the data manager or other designated project staff. The actual form can be found in a separate Word file named **Appendix K-Recruitment Event Information & Outcomes Form.doc**.

I – Recruitment Event and Calendar Information

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

Scheduled Recruitment Event	
Day (circle one): Su M T W Th F Sa	
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 #):	

II – Project Staff Information

	Evaluation Scheduled?	Handheld #	Interviewer ID
Field Supervisor:	☐		
Recruiter(s):			
☐	☐		
☐	☐		
Interviewers:			
☐	☐	__ __	__ __
☐	☐	__ __	__ __
☐	☐	__ __	__ __
☐	☐	__ __	__ __
☐	☐	__ __	__ __
☐	☐	__ __	__ __
☐	☐	__ __	__ __
☐	☐	__ __	__ __

III – Recruitment Event Code Numbers

Next sequential Survey ID:
Next sequential Event Number:

IV– Recruitment Event Notes

Actual start time: ___ : ___ AM PM **Actual end time: ___ : ___ AM PM**
Describe any barriers to project activities at the venue. Describe any strategies to overcome these barriers.
Describe attendance at the venue (crowded, sparsely attended, etc.). Describe if and how project activities were adjusted based on attendance (e.g. counting area moved, interviews conducted outside because too crowded inside, etc.).
Was there any significant change in the demographics of the population at the venue from when last attended or assessed? If yes, explain:
Should the venue be removed from the frame? If yes, explain:
For the venue where the recruitment event occurred, what new day-time periods were suggested by venue attendees?
What new venues were suggested by venue attendees? For each new venue, what day-time periods were suggested?
If the recruitment event was moved to an alternate, explain why:

V – Recruitment Event Outcomes

Indicate whether a recruitment event was conducted at the primary venue or alternate venues. For each recruitment event conducted, record the total **Number Counted** from the tally counter or 'clicker':

Primary Venue:	**Alternate 1:**	**Alternate 2:**
Recruitment event conducted? ❑ Yes ❑ No	Recruitment event conducted? ❑ Yes ❑ No	Recruitment event conducted? ❑ Yes ❑ No
Number Counted ____	Number Counted ____	Number Counted ____

Appendix L Participant Tracking Form

A model Participant Tracking Form is provided to give project sites a method of tracking key data points through the interview process. This form replaces the data error log or data corrections log used in previous cycles for recording data edits. Besides being a record of the interview should handheld data be lost, the form serves as a means of communicating information to other project staff. Such information includes whether the participant disclosed they had previously tested positive for HIV to either the interviewer or the counselor and any data edits. The data manager or other designated project staff will need to enter these data points into the Data Coordinating Center (DCC) Data Portal at a later time. Depending on how the project site prefers to track these data, two models are provided (see **Figures L.1 and L.2**). Both contain the minimum data expected to be tracked and are set up to flow with the general interview process. Project sites may modify the form to add fields that are relevant to their local needs. The forms are to be maintained locally; not be submitted to the DCC or CDC. The actual forms can be found in a separate Excel file named **Appendix L- Participant Tracking Form.xls**.

The following fields are included on the model form:

Interviewer: The field supervisor should record the 2-digit Interviewer ID.

Survey ID: The field supervisor, who assigns Survey ID, should record the Survey ID on the form.

Date: The field supervisor should record the date of the interview.

State time: The data manager should record the start time, which is the value for the variable START in the database.

The value of START is only required if an edit needs to be entered into the online Data Error Log on the DCC Data Portal.

Handheld computer #: The field supervisor should record the handheld computer ID. This information can be used to investigate corrupt or lost data files on the handheld. It is recommended that interviewers use designated handheld computers during each recruitment event.

Event #: The field supervisor should record the event number. This information is needed by the interviewer who will enter it into the handheld computer.

Venue Code: The field supervisor should record the Venue Code. This information is needed by the interviewer who will enter it into the handheld computer.

Passed the eligibility screener: The interviewer should record whether or not the person passed the eligibility screener.

Consented to the survey: The interviewer should record whether or not the person consented to the survey. Participants who consent to the survey should be provided an incentive for participating in the survey.

Consented to the HIV test: The interviewer should record whether or not the person consented to the HIV test. If the person consented to the HIV test, they should be provided an additional incentive for testing and have a specimen for HIV testing.

Self-reported positive during the Interview (SRP Interview): The interviewer should record whether or not the person self-reported previously testing HIV-positive during the interview. To minimize disclosure, this variable is represented as "SRP Interview" on the model forms. The data manager will need this information to enter it into the Data Portal's online HIV Test Results Log.

Completed the survey: The interviewer should record whether or not the person completed the survey.

Obtained HIV specimen: The interviewer should record whether or not a specimen was obtained from the person. For various reasons, a person may consent to HIV testing and then not provide a specimen. If a specimen is not obtained, the interviewer should provide comments as to why. The field supervisor may need this information when discussing problems with data collection to the project coordinator or principal investigator.

Self-reported positive during the HIV counseling session (SRP counseling): The HIV test counselor should record whether or not the person self-reported previously testing HIV-positive during the counseling session. To minimize disclosure, this variable is represented as "SRP Counseling" on the model forms. Discrepancies between what is reported during the interview and the counseling session should be resolved prior to providing the form to the data manager. If the information provided during the interview is incorrect, the variable's correct values should be added to the fields on the form as well. The data manager will need this information to enter it into the Data Portal's online HIV Test Results Log.

Data edits: These fields are provided so the data manager will know what edits need to be entered into the Data Portal's online Data Error Log.

Figure L.1. Model Participant Tracking Form for single participant

NHBS-MSM3: PARTICIPANT TRACKING FORM

Interviewer	
Survey ID	
Date	
(Data Manager Use) **Start Time**	
Handheld computer#	
Event #	
Venue Code	

1	**Passed Eligibility Screener?**	Y	N
2	**Consented to the survey?**	Y	N
3	**Consented to HIV test?**	Y	N
4	**SRP Interview?**	Y	N
5	**Completed the survey?**	Y	N
6	**Obtained HIV specimen?**	Y	N
7	**SRP Counseling?**	Y	N

Data edits: Variable Name	**Old Value**	**New Value**

Comments:

Figure L.2. Model Participant Tracking Form for multiple participants.

NHBS-MSM3: PARTICIPANT TRACKING FORM

Interviewer		**Event #**	
Date		**Venue Code**	
Handheld computer#			

Survey ID	Passed Eligibility Screener?	Consented to Survey?	Consented to HIV test?	SRP Interview?	Completed the Survey?	Obtained Specimen?	SRP Counseling?	Variable Name	Old Value	New Value	Variable Name	Old Value	New Value	Variable Name	Old Value	New Value	(Data Mgr Use) Start Time
	Y N	Y N	Y N	Y N	Y N	Y N	Y N										
	Y N	Y N	Y N	Y N	Y N	Y N	Y N										
	Y N	Y N	Y N	Y N	Y N	Y N	Y N										
	Y N	Y N	Y N	Y N	Y N	Y N	Y N										
	Y N	Y N	Y N	Y N	Y N	Y N	Y N										
	Y N	Y N	Y N	Y N	Y N	Y N	Y N										
	Y N	Y N	Y N	Y N	Y N	Y N	Y N										
	Y N	Y N	Y N	Y N	Y N	Y N	Y N										
	Y N	Y N	Y N	Y N	Y N	Y N	Y N										
	Y N	Y N	Y N	Y N	Y N	Y N	Y N										

Comments:

Page (circle one): **1 2 3 of**

Appendix M Strategies for Overcoming Intercept Barriers

Intercept Barriers	Strategies for Overcoming
1. Avoidance Some men may not initially respond to or acknowledge the recruiter when approached. Others may respond, but continue walking.	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.
2. Groups Recruiters may frequently encounter groups of two or more men who have been counted and 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.	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.

Intercept Barriers	Strategies for Overcoming
3. Time 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. ***Examples:*** *"I'm late."* *"I'm in a hurry."* *"I don't have time."* *"My friends are waiting for me."* *"I'm on my way <somewhere>."*	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-MSM3. Tell them that it takes very little time to complete the intercept and that they are helping an important cause. ***Examples:*** *"No problem, I'll walk with you if that is OK."* *"This will only take a minute of your time and your help is important."* *"This will be quick and it's for an important cause. This is part of a health survey that can help our community."*
4. Ineligibility Some people may try to deter the intercept by stating that they are ineligible for the survey. ***Examples:*** *"I'm too young/old."* *"I'm not from around here."*	Don't assume that the person understands NHBS-MSM3 eligibility criteria. Again, stay positive and do your best to motivate the person to complete the intercept. ***Examples:*** *"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."*

Intercept Barriers	Strategies for Overcoming
5. Previous Participation Some men may try to deter the intercept by stating that they have already participated in the survey. ***Examples:*** *"I've already done it."* *"I've already been interviewed."* *"You spoke to me last month."*	Unless the recruiter is certain that the venue attendee has already participated in NHBS during the current project cycle, they should do their best to complete the intercept. Many men may confuse other research projects or NHBS cycles with NHBS-MSM3. Thus, the recruiter should try to verify that the venue attendee has already participated in NHBS-MSM3. However, if a venue attendee tells the recruiter that he already participated in NHBS-MSM3 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). ***Examples:*** *"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."* Ask one or more of the following questions-- To confirm if it is an NHBS-MSM3 VDT: *"When and where were you interviewed?"* If standard clothing is worn: *"What was the interviewer wearing?"* *"Did the person who interviewed you have an ID badge like this (show ID badge)?"* *"What was the interview about?"* *"How long did the interview take?"*

Intercept Barriers	Strategies for Overcoming
6. Previous Non-participation Some men may try to deter the intercept by stating that they have already declined participation in the survey. ***Examples:*** *"I already said no."* *"I told them last week I didn't have time."*	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-MSM3 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. ***Examples:*** *"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."* Ask one or more of the following questions-- To confirm if it is an NHBS-MSM3 VDT: *"When and where were you approached?"* If standard clothing is worn: *"What was the person who approached you wearing?"* *"Did the person who approached you have an ID badge like this (show ID badge)?"*

Appendix N Strategies for Overcoming Participation Barriers

Participants always have the right to decline participation in NHBS-MSM3. Efforts to encourage men to participate must respect this right.

Men who decline the recruiter's invitation to be screened for consent – after project staff has addressed participation barriers – may not return later to NHBS staff and ask to be screened. Their initial refusal may not be overturned; in other words, "no" means "no" throughout the recruitment event.

Participation Barriers	Strategies for Overcoming
1. Time One of the most frequently given participation barriers is lack of time. ***Examples:*** *"I'm late."* *"I really don't have time right now."* *"I'm in a hurry; I'm supposed to be meeting friends."* *"I'm busy."*	To encourage an intercepted man to agree to participate in NHBS-MSM3, emphasize the relatively brief amount of time needed to complete the survey, its benefits to the community, and its stipend. 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, distrust, *etc*. If necessary, explore and address these other potential barriers. ***Examples:*** *"The interview won't take long-- most men finish in only about 25 minutes. It's anonymous and we'll pay you up to $50 for your time. It's for a very important cause. We're trying to make a difference in our community and we could really use your help."*

Participation Barriers	Strategies for Overcoming
2. Disinterest 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. ***Examples:*** *"I'm not really interested."* *"I'm not interested in participating in research."* *"It's my only night off."* *"I'm here to have fun/drink/dance/be with friends."*	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, stipend, *etc*.). Avoid directly asking, "Why not?," which may be perceived as pushy or coercive. ***Examples:*** *"This survey is important; it may help us get more resources to help our community and improve our HIV prevention programs."* *"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."* 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. ***Examples:*** *"I understand you're reluctant to participate. What is it about the survey that concerns you? Is it privacy?"*

Participation Barriers	Strategies for Overcoming
3. Friends & Partners 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. ***Examples:*** *"I don't want to leave my friends/partner."* *"I can't leave my friend/partner alone."* *"I'm meeting friends/my partner."* *"My friends won't wait."*	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-MSM3. 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. ***Examples:*** *"Your friend/partner can hang out with us; we'll take care of him."* Try humor: *"Your friend/partner will wait for you-- tell him with the $50 you earn you can take him out to dinner!*

Participation Barriers	Strategies for Overcoming
4. Intruders Sometimes, friends or others will interrupt the intercept and deter men from participating. ***Examples:*** Intruder: *"C'mon, we don't' have time for this. We're going to be late."* Intruder: *"Give us a break; there are plenty of others you can talk to."*	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. ***Examples:*** *"I just have a quick question for your friend; it will only take a minute."* *"It's important that I speak with your friend. Can you just give us a minute?"* If necessary, use one of the previously mentioned motivations (community benefits, stipend, *etc*.).

Participation Barriers	Strategies for Overcoming
5. Low Risk Behavior 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. ***Examples:*** *"You know, I'm not really at risk for HIV."* *"I just got tested and I know I'm negative."* *"I always use a condom."* *"I'm in a long-term relationship; I doubt I would be of much help."* *"I'm not sexually active."*	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. ***Examples:*** *"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."* *"We talk about things other than sex. You'll be able to give us other important information."*

Participation Barriers	Strategies for Overcoming
6. Distrust or Cynicism 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 communities of color. ***Examples:*** *"I don't trust the government."* *"Yeah right, and what has research done for my community?"* *"I don't see how prevention is working with all the risk behavior that's going on."*	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-MSM3 can help explain increasing trends in HIV and STDs among MSM in some areas and it can help identify prevention needs. ***Examples:*** *"<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."* *"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."* *"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."* *"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."*

Participation Barriers	Strategies for Overcoming
7. Privacy & Anonymity Some men may be very concerned about their privacy and anonymity. This may be particularly true among closeted men and those recruited at sex venues (*e.g*., cruising areas, bathhouses, sex clubs, *etc*.). ***Examples:*** *"I don't want to give you my name."* *"I'm not comfortable talking here."*	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. ***Examples:*** *"That's perfectly OK. This survey is completely anonymous; you don't need to give your name or any other identifying information."* *"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."*

Participation Barriers	Strategies for Overcoming
8. Stipend Not Enough or Not Important Some men might say that the stipend of $25 or $50 is not enough. ***Examples:*** *"That's not enough money."* *"Is that all that's offered?"* Other men may say the stipend is not important. ***Examples:*** *"I don't need the money."* *"The money really isn't important to me."*	For those men who think the stipend is insufficient, stress that our interviews average just 25 minutes, in contrast to many other extremely long surveys. Also emphasize the importance of NHBS-MSM3 for helping the community. ***Examples:*** *"Our interview only averages about 25 minutes. That works out to about 1 dollar for each minute you participate. That's not bad, and we could really use your help."* 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. ***Examples:*** *"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.*

Appendix O Intercept Form

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

Intercept Form

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

Venue Name: _____ Recruiter: _____

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

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

Appendix P Intercept Form Instructions

Recruiters should record all information collected during an intercept on the Intercept Form (**Appendix O**). Project sites may customize the Intercept Form to meet their own needs, but if they do, they must collect the data elements that will be entered in the recruitment event outcomes window of the VDTS Program (**Section P.4** of this appendix). Instructions for completing the Intercept Form are outlined below.

P.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.

P.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.

Venue Name: The name of 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.

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).

P.2 Recruitment Data

Each numbered line on the Intercept Form represents recruitment data on a different venue attendee approached to participate in NHBS-MSM3. 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.

P.2a Description of the recruitment data

 # (Number): A running count of the venue attendees approached to participate in NHBS-

MSM3. 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 first recruiter question:

> *During 2011, 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 (**Chapter 6** of this manual).

PEA: Project sites that offer post-event appointments (PEAs) should indicate whether or not the prospective participant will be screened for NHBS-MSM3 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 or if a venue attendee does not agree to be screened, the recruiter should circle "N" for no.

Comments: The recruiter can use the "Comments" field to record any additional information provided by the venue attendees he approaches, 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.

P.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 they used.

P.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, he should tabulate the number of venue attendees approached, the responses to the previous participation question, and if applicable, the number of post-event appointments. 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.

P.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 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 tabulated.

Appendix Q Model Appointment & Phone Results Cards

Project sites that choose to make post-event appointments (PEAs) and/or appointments for returning laboratory test results in-person or over the phone may use the templates below to create appointment cards. The address, phone number, office hours, and directions to the location should be pre-printed on the card. HIV and other test results must remain anonymous. Therefore, test results can only be returned to participants using a code such as the Survey ID or Lab ID.

Model Appointment Card for PEAs or Returning Laboratory Test Results

PROJECT NAME

Your return visit is scheduled for: *<date>* at *<time>*

Our office is located at _____

_____

If you need to reschedule or have any questions, please call us at:

_____

Our office hours are: _____

ID Number: *<enter Survey ID or Lab ID>*

Event Date: *<PEAs only>*

Event Number: *<PEAs only>*

Venue Code: *<PEAs only>*

Model Phone Results Card

PROJECT NAME

Please call us a week from: *<today's date>* at: *<time>*

Our office hours are: _____

ID Number: *<enter Survey ID or Lab ID>*

Venue Code: _____

Person you spoke to: _____

Appendix R Specimen Shipping Log

Most laboratories will provide a shipping or testing log. This model specimen shipping log is to be modified and used in the case where the laboratory does not require a specific format.

Lab ID	Date Specimen Collected	Specimen Type (Oral or Blood)	Confirming preliminary positive? (Yes or No)	HIV Test	Other Tests (specify)	Storage for future testing? (Yes or No)	Self-reported HIV positive? (Yes or No)	Date Sent to Lab

To Lab: All persons who are self-reported HIV- positive should have the confirmatory test (e.g., Western Blot or IFA) performed regardless of the results of any screening tests performed.

Supervisor Initials _____ Courier Initials _____

Lab Signature _____

Project Office Number:_____

Project Office Fax Number _____

Appendix S Phone Results Log

Project sites planning to return test results over the phone should refer to the HIV Phone Results Protocol (see *Appendix H of the NHBS-MSM3 Model Surveillance Protocol*)

Make sure participant: 1) agrees to return within 48 hours of receiving their result for counseling and referrals if test result is positive; 2) has a password to confirm with their Survey ID; and 3) can identify one person they can call for support.

Test date	Call date	Lab ID	Survey ID	Define Password	Password	Date	Notes

Appendix T Appointment Reminder Call Form

This form is to be filled out by the participant if he chooses to have an optional reminder call to keep his appointment for HIV test results. Participants should receive an appointment card with the date and time (see **Appendix Q** of this manual).

NHBS-MSM3 Appointment reminder call form

This form is kept separate from survey records. Do not write any survey or laboratory identifiers on this form. This form must be destroyed (shredded) at the scheduled appointment time prior to results being returned.

****DO NOT put any Survey ID or Lab ID on this form****

I would appreciate a phone call to remind me of my post-test

appointment on (day of week)_____, ___/___/___ at _____.

My phone number is ( ) _____-_____

The best day/time to call is: _____ at _____ € AM € PM

Please answer the following questions about the call:

1. Is it okay for us to identify ourselves as [*Project Name*] when we make the reminder call?

   €YES €NO

2. We should ask for a person named _____ when the phone is answered.

3. If no one answers, is it okay to leave the reminder on voicemail or answering machine?

   €YES €NO

Unless we are instructed otherwise below, our standard reminder message will be:

Hello, this is [*project staff member's name]* from [*Project Name*], calling to remind you of your appointment on (***date***) at (***time***). Thank you.

Staff ID: _____ Date:_____ Date of Call: _____

Appendix U Recruitment Monitoring Report

The purpose of the Recruitment Monitoring Report (see **Figure U.1**) is to monitor eligibility and recruitment data on participants overall and by recruitment event. This report will be produced by the Data Coordinating Center (DCC). **Table U.1** indicates the description and definition for each column in the report.

Table U.1 Column description and definition, Recruitment Monitoring Report.

Column Name	Description	Definition
Event #	The recruitment event number (see **Chapter 5** of this manual for information on how this assigned).	This information is extracted from the VDTS Program, but should be the same as the value for VBS_EVNT
Date	The date the recruitment event starts.	This information is extracted from the VDTS Program, but should be the same as the value for RDATE
Scheduled VDT: Venue Code	The Venue Code of the scheduled venue for the recruitment event.	This information is extracted from the VDTS Program.
Scheduled VDT: Day:	The scheduled day of the recruitment event.	This information is extracted from the VDTS Program.
Scheduled VDT: Start time	The start time of the scheduled recruitment event.	This information is extracted from the VDTS Program.
Conducted VDT: Venue Code	The Venue Code of the conducted venue.	This information is extracted from the VDTS Program, but should be the same as the value for VENUE
Conducted VDT: Selection type	The selection type of the conducted venue.	This information is extracted from the VDTS Program.
Counted	The number of individuals counted during the recruitment event.	This information is extracted from the VDTS Program.
Approached	The number of men approached during the recruitment event.	This information is extracted from the VDTS Program.
Accepted Intercept	The number of men who accept the intercept (i.e., answer the previous participant question). This information is extracted from the online VDTS database.	This information is extracted from the VDTS Program.
Screened	The number of individuals screened for eligibility.	Sum of interviews for the event where El_MSM=0 or EL_MSM=1

Eligible	The number of individuals screened who were eligible for the survey.	Sum of interviews for the event where EL_MSM=1
Completed Interview	The number of individuals eligible for the survey who completed an interview. Total interviewed cannot be more than the number of people eligible.	Sum of interviews for the event where COMPLETE=1
Met MSM Definition	The number of men who met the MSM definition (Y/N). Men meeting this definition have had sex with a man in the past 12 months.	Sum of interviews for the event where M_MSX12≤1
Consented to HIV Test	The number of individuals who consented to the HIV test.	Sum of interviews for the event where CONSENTB=1 or HIVCNSTA=1
PEAs	The number of post-event appointments scheduled during the recruitment event (see **Chapter 6** of this manual for information on how this assigned).	This information is extracted from the VDTS Program.
PEAs Interviewed	The number and percent of post-event appointments that returned and completed an interview.	Sum of interviews for the event where PEA=1

Figure U.1 An example of the Recruitment Monitoring Report

Event #	Date	Scheduled VDT				Conducted VDT		Counted	Approached	Accepted Intercept		Screened		Eligible		Completed Interview		Met MSM Definition*		Consented to HIV Test		PEAs	PEAs Interviewed		Comments
		Venue Code	Day	Start Time	Random (Y/N)	Venue Code	Selection Type	No.	No.	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	No.	%	
1	6/9/2011	R005	Thu	7:00pm	Y	R005	Primary	18	15	13	87%	12	92%	9	75%	8	89%	6	75%	8	100%	0	0	-	
2	6/10/2011	D008	Fri	10:00 PM	Y	D008	Primary	115	35	16	46%	14	88%	11	79%	11	100%	11	100%	10	91%	0	0	-	
3	6/11/2011	D012	Sat	9:30 PM	Y	D012	Primary	105	46	28	61%	23	82%	20	87%	19	95%	17	89%	18	95%	0	0	-	
4	6/17/2011	B007	Fri	7:30 PM	Y	B007	Primary	58	18	17	94%	15	88%	14	93%	13	93%	16	123%	12	92%	0	0	-	
5	6/17/2011	O008	Thu	8:00 PM	Y	O008	Primary	98	55	38	69%	32	84%	30	94%	28	93%	14	50%	28	100%	0	0	-	
6	6/18/2011	G002	Sat	10:00 PM	N	G002	Primary	165	42	28	67%	26	93%	22	85%	22	100%	21	95%	22	100%	2	1	50%	
7	6/19/2011	G001	Sun	1:00 PM	N	G001	Primary	172	39	22	56%	18	82%	17	94%	17	100%	16	94%	17	100%	0	0	-	
8	6/24/2011	B008	Fri	10:00 PM	Y	B008	Primary	75	32	16	50%	12	75%	9	75%	9	100%	9	100%	9	100%	0	0	-	
9	6/25/2011	E001	Sat	6:00 PM	N	E001	Primary	174	52	38	73%	32	84%	26	81%	25	96%	25	100%	25	100%				
10	7/7/2011	R005	Thu	7:00 PM	Y	D007	Alternate 1	12	10	7	70%	8	114%	7	88%	7	100%	7	100%	7	100%	0	0	-	
11	7/8/2011	B007	Fri	7:30 PM	Y	S001	Other	18	16	10	63%	8	80%	8	100%	8	100%	6	75%	7	88%	0	0	-	Primary venue was closed and neither scheduled alternate was available. Selected another alternate (Alternate 3).
12	7/9/2011	F002	Sat	3:00 PM	Y	F002	Primary	21	14	10	71%	9	90%	8	89%	7	88%	6	86%	7	100%	0	0	-	
13	7/10/2011	P004	Sun	1:00 PM	Y	P004	Primary	4	3	1	33%	0	0%									0	0	-	Event at Primary venue was rained-out. Alternate 1 was closed; went to Alternate 2.
14	7/10/2011	P004	Sun	1:00 PM	Y	C005	Alternate 2	12	10	8	80%	7	88%	5	71%	5	100%	4	80%	4	80%	1	0	0%	
15	7/13/2011	B008	Wed	8:00 PM	Y	B008	Primary	48	30	23	77%	19	83%	17	89%	15	88%	12	80%	14	93%	0	0	-	
16	7/15/2011	D008	Fri	10:00 PM	Y	D008	Primary	142	64	48	75%	35	73%	17	49%	17	100%	13	76%	15	88%	0	0	-	
17	7/16/2011	X001	Sat	11:00 PM	Y	X001	Primary	14	13	8	62%	7	88%	7	100%	7	100%	7	100%	7	100%	0	0	-	
18	7/20/2011	D012	Thu	9:30 PM	Y	D012	Primary	24	18	15	83%	12	80%	11	92%	7	64%	7	100%	7	100%	0	0	-	
						COLUMN TOTALS →		1275	512	346	68%	289	84%	238	82%	225	95%	197	88%	217	96%	3	1	33%	

* met MSM definition refers to men who had sex in the past 12 months

The total numbers of persons screened, completing the interview, and meeting the MSM definition in this report should be the same as those numbers in the Sample Characteristics Report. Notify the DCC if these numbers are not the same in the two reports, as the DCC will need to resolve the discrepancy.

Appendix V Sample Characteristics Report

The purpose of the Sample Characteristics Report is to monitor certain aspects of the local NHBS-MSM3 sample. These reports will produced by the Data Coordinating Center (DCC). The reports will consist of a series of standardized cross-tables organized into the following three sections:

1) NHBS-MSM3 eligibility criteria by whether or not the person screened eligible
2) Selected characteristics by whether or not the person met the MSM definition
3) Self-reported HIV status by the final HIV test result

Section 1 of the report provides data of persons screened for eligibility (i.e., where EL_MSM in (0,1,2). **Figure V.1** shows eligibility criteria by eligibility status to help project sites assess eligibility patterns so that operational adjustments can be made.

Figure V.1 An example of a Sample Characteristics Report, section 1

SAMPLE CHARACTERISTICS: ELIGIBILITY CRITERIA BY ELIGIBILITY STATUS

	Eligible				Total
	Yes		No		
Eligibility Criteria	N	(%)	N	(%)	N
1. Previous Participant					
Yes	0	0%	2	100%	2
No	238	83%	49	17%	287
Unknown	0		0		0
2. Age					
<18	0	0%	1	100%	1
?18	238	83%	50	17%	288
3. MSA Resident					
Yes	238	84%	45	16%	283
No	0	0%	6	100%	6
Unknown	0		0		0
4. Sex @ Birth/Gender					
Male/Male	238	83%	49	17%	287
Male/Female	0		1		1
Female/Male	0		0		0
Other	0	0%	1	100%	1
5. Sexual behavior (ever)					
Sex only with men	206	95%	11	5%	217
Sex with men and women	32	100%	0	0%	32
Sex only with women	0	0%	40	100%	40
No sex	0		0		0
6. Race/Ethnicity					
American Indian/Alaska Native	0		0		0
Asian	2	67%	1	33%	3
Black or African American	98	82%	21	18%	119
Hispanic	59	81%	14	19%	73
Native Hawaiian or Other Pacific Is	0		0		0
White	75	84%	14	16%	89
Multiple races	2	67%	1	33%	3
Unknown	2	100%	0	0%	2
TOTAL	238	82%	51	18%	289

Section 2 of the report provides data of eligible participants who consented and completed the survey (i.e., where EL_MSM =1 and CONSENTA=1 and COMPLETE=1). **Figure V.2**. shows select characteristics by whether the MSM analysis definition (i.e., had sex with a man in the past 12 months) was met to help project sites identify the characteristics of persons comprising the resulting sample as well as the proportion and demographics of men meeting the MSM definition.

Figure V.2 An example of a Sample Characteristics Report, section 2

SAMPLE CHARACTERISTICS: SELECTED CHARACTERISTICS of ELIGIBLE PARTICIPANTS by MSM DEFINITION

	Met MSM Definition				Total	
	Yes		No			
Characteristics	N	(%)	N	(%)	N	%
1. Age						
18-19	10	5%	1	4%	11	5%
20-24	16	8%	2	7%	18	8%
25-29	18	9%	4	14%	20	9%
30-34	37	19%	1	4%	38	17%
35-39	23	12%	3	11%	26	12%
40-44	25	13%	2	7%	27	12%
45-49	28	14%	3	11%	31	14%
50-54	25	13%	8	29%	33	15%
55-60	15	8%	4	14%	19	8%
2. Race/Ethnicity						
American Indian/Alaska Native	0	0%	0	0%	0	0%
Asian	1	1%	0	0%	1	0%
Black or African American	88	45%	7	25%	95	42%
Hispanic	48	24%	7	25%	55	24%
Native Hawaiian or Other Pacific Islanc	0	0%	0	0%	0	0%
White	58	29%	13	46%	71	32%
Multiple races	1	1%	0	0%	1	0%
Unknown	1	1%	1	4%	2	1%
3. Sexual identity						
Homosexual	157	80%	20	71%	177	79%
Bisexual	38	19%	1	4%	39	17%
Heterosexual	2	1%	4	14%	6	3%
4. Education						
Less than high school	12	6%	2	7%	14	6%
High school	49	25%	8	29%	57	25%
Vocational/tech school or some colleg	61	31%	7	25%	68	30%
College graduate or graduate school	74	38%	9	32%	83	37%
Unknown	1	1%	2	7%	3	1%
5. Income						
0 to $19,999	56	28%	7	25%	63	28%
$20,000 to $39,999	52	26%	7	25%	59	26%
$40,000 to $74,999	49	25%	8	29%	57	25%
$75,000 or more	40	20%	6	21%	46	20%
6. HIV result (self-reported)						
Positive	6	3%	18	64%	24	11%
Negative	186	94%	9	32%	195	87%
Indeterminate	1	1%	0	0%	1	0%
Unknown	4	2%	1	4%	5	2%
7. Recruitment venue						
Bar	37	19%	0	0%	37	16%
Café or restaurant	4	2%	1	4%	5	2%
Dance club	55	28%	6	21%	61	27%
House Ball events	25	13%	0	0%	25	11%
Fitness club or gymnasium	6	3%	1	4%	7	3%
Gay Pride or a similar event	37	19%	2	7%	39	17%
Social organization	14	7%	14	50%	28	12%
Park or beach	0	0%	0	0%	0	0%
Retail business	6	3%	2	7%	8	4%
Street location	6	3%	2	7%	8	4%
Rave or circuit party	0	0%	0	0%	0	0%
Sex establishment or environment	7	4%	0	0%	7	3%
Other venues	0	0%	0	0%	0	0%
8. Geographic Area						
2134	27	14%	0	0%	27	12%
2135	10	5%	5	18%	15	7%
2144	38	19%	2	7%	40	18%
2156	6	3%	3	11%	9	4%
2158	2	1%	2	7%	4	2%
2167	52	26%	3	11%	55	24%
3144	60	30%	10	36%	70	31%
Unknown	2	1%	3	11%	5	2%
TOTAL	197	100%	28	100%	225	100%

Section 3 of the report provides data of eligible participants who consented to and completed the survey as well as those who consented to and completed HIV testing (i.e., where CONSENTA=1 and COMPLETE=1 and (CONSENTB=1 or HIVCNSTA=1) and SOURCE_HIVTEST=1). **Figure V.3** shows two tables one that indicates the characteristics of persons completing HIV testing to help project sites identify 1) the percentage of persons who were confirmed to be HIV-positive through laboratory testing; 2) the proportion of those who were confirmed positive who did not self-report being HIV-positive during the survey; and 3) the proportion of persons who self-reported being HIV-positive, but whose test result was negative (e.g., possible false-negative) or indeterminate. The row variable for Rapid Test will be generated for project sites that conduct rapid testing to monitor false-negative and indeterminate results. The second table in this report will only show the percentage of HIV positive cases who were previously not diagnosed with HIV infection.

Figure V.3 An example of a Sample Characteristics Report, section 3.

SAMPLE CHARACTERISTICS: HIV TEST RESULTS

	HIV Result								Total	
	Positive		Negative		Indeterminate		Unknown			
	N	%	N	%	N	%	N	%	N	%
1. Self-Reported HIV Status										
Self-reported positive	19	79%	1	4%	0	0%	4	17%	24	11%
Not self-reported positive	15	7%	173	86%	1	0%	12	6%	201	89%
2. Rapid Test										
Preliminary Positive	17	77%	1	5%	0	0%	4	18%	22	10%
Negative	0	0%	171	99%	1	1%	0	0%	172	76%
Not done	17	55%	2	6%	0	0%	12	39%	31	14%
Unknown	0		0		0		0		0	0%
TOTAL	**34**	15%	**174**	77%	**1**	0%	**16**	7%	**225**	

	Positive	
	N	%
1. Self-Reported HIV Status		
Self-reported positive	19	56%
Not self-reported positive	15	44%
TOTAL Positive	**34**	

Appendix W Venue-Based Sampling Report

With the data files provided by project sites, the Data Coordinating Center (DCC) will create a report to evaluate the local implementation of Venue-based Sampling (VBS) (See **Figure W.1**). **Table W.1** provides the description and definition for each column in the report. Data in the report are presented by both the venue type, which is a created by taking the first character of the Venue ID (UPCASE(SUBSTR(VENUE,1,1))) and the venue (i.e., VENUE).

Table W.1 Column description and definition, venue-based sampling report.

Column Name	Description	Definition
Venues Visited	The number of unique venues visited for each type of venues.	This information is obtained by counting the unique values for VENUE for each venue type.
Times Visited	The number of times a venue was visited.	This information is obtained by counting the unique values for VBS_EVNT for each venue.
Screened	The number of individuals screened for eligibility.	Sum of records where EL_MSM=0 or EL_MSM=1 by either the created variable for venue type or venue.
Eligible	The number of individuals screened who were eligible for the survey.	Sum of records where EL_MSM=1 by the created variable for venue type or venue.
Completed Interview	The number of eligible men who completed an interview. Total interviewed cannot be more than the number of people eligible.	Sum of records where COMPLETE=1 by the created variable for venue type or venue.
Met MSM Definition	The number of men who met the MSM definition. Men meeting this definition have had sex with a man in the past 12 months.	Sum of records where M_MSX12≤1 by the created variable for venue type or venue.
Age categories: 18-20	The number of men who met the MSM definition and who were aged 18-20	Sum of records where 18 ≤ AGE ≤ 20 by the created variable for venue type or venue.
Age categories: 21-29	The number of men who met the MSM definition and who were aged 21-29	Sum of records where 21 ≤ AGE ≤ 29 by the created variable for venue type or venue.
Age categories: 30-39	The number of men who met the MSM definition and who were aged 30-39	Sum of records where 30 ≤ AGE ≤ 39 by the created variable for venue type or venue.
Age categories: ≥ 40	The number of men who met the MSM definition and who were 40 years or older.	Sum of records where AGE ≥ 40 by the created variable for venue type or venue.

Race categories: Black	The number of black men who met the MSM definition.	Sum of records where RACEOMB=3 by the created variable for venue type or venue.
Race categories: Hispanic	The number of Hispanic men who met the MSM definition.	Sum of the records where RACEOMB=0 by the created variable for venue type or venue.
Race categories: White	The number of white men who met the MSM definition.	Sum of the records where RACEOMB=5 by the created variable for venue type or venue.
Race categories: Other	The number of men of other races who met the MSM definition.	Sum of the records where RACEOMB=1 or RACEOMB=2 or RACEOMB=4 by the created variable for venue type or venue.

Figure W.1 An example of a venue-based report

	Venues Visited	Times Visited	Screened	Eligible		Completed Interview		Met MSM Definition		Age Categories								Race Categories							
										18-20		21-29		30-39		≥40		Black		Hispanic		White		Other	
	No.	No.	No.	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Venue type																									
B	2		46	40	87%	37	93%	36	97%	0	0%	5	3%	12	6%	20	10%	14	7%	17	9%	6	3%	0	0%
C	1		7	5	71%	5	100%	4	80%	2	1%	0	0%	2	1%	0	0%	1	1%	1	1%	2	1%	0	%
D	3		32	66	72%	61	92%	55	90%	2	1%	11	6%	18	9%	24	12%	27	14%	19	10%	9	5%	0	0%
E	1		32	26	81%	25	96%	25	100%	0	0%	8	4%	8	4%	9	5%	23	12%	2	1%	0	0%	0	0%
F	1		9	8	89%	7	88%	6	86%	0	0%	2	1%	3	2%	1	1%	3	2%	1	1%	2	1%	0	0%
G	2		44	39	89%	39	100%	37	95%	8	4%	5	3%	5	3%	19	10%	12	6%	7	4%	17	9%	1	1%
O	1		32	30	94%	28	93%	14	50%	0	0%	0	0%	5	3%	9	5%	3	2%	0	0%	11	6%	0	0%
P	1		0																						
R	1		12	9	75%	8	89%	6	75%	0	0%	1	1%	2	1%	3	2%	2	1%	1	1%	2	1%	1	1%
S	1		8	8	100%	8	100%	6	75%	0	0%	0	0%	3	2%	3	2%	2	1%	0	0%	3	2%	1	1%
X	1		7	7	100%	7	100%	7	100%	0	0%	0	0%	2	1%	5	3%	1	1%	0	0%	6	3%	0	0%
Venue Code																									
B007	NA		15	14	93%	13	93%	12	92%	0	0%	2	1%	8	4%	6	3%	0	0%	0	0%	0	0%	0	0%
B008	NA		31	26	84%	24	92%	21	88%	0	0%	3	2%	4	2%	14	7%	0	0%	0	0%	0	0%	0	0%
C005	NA		7	5	71%	5	100%	4	80%	2	1%	0	0%	2	1%	0	0%	2	1%	2	1%	2	1%	2	1%
D007	NA		8	7	88%	7	100%	7	100%	2	1%	2	1%	2	1%	2	1%	2	1%	2	1%	2	1%	2	1%
D008	NA		49	28	57%	28	100%	24	86%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
D012	NA		35	31	89%	26	84%	24	92%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
E001	NA		32	26	81%	25	96%	25	100%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
F002	NA		9	8	89%	7	88%	6	86%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
G001	NA		18	17	94%	17	100%	16	94%	3	2%	3	2%	3	2%	3	2%	3	2%	3	2%	3	2%	3	2%
G002	NA		26	22	85%	22	100%	21	95%	5	3%	5	3%	5	3%	5	3%	5	3%	5	3%	5	3%	5	3%
O008	NA		32	30	94%	28	93%	14	50%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
P004	NA		0							0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
R005	NA		12	9	75%	8	89%	6	75%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
S001	NA		8	8	100%	8	100%	6	75%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
X001	NA		7	7	100%	7	100%	7	100%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
TOTAL			**289**	**8**		**88**		**193**		**12**	6%	**32**	17%	**60**	31%	**93**	40%	**88**	46%	**48**	25%	**58**	30%	**3**	2%

Appendix X Previous Participant Report

With the data files provided by project sites, the Data Coordinating Center (DCC) will create a report of possible previous participants. This table is designed to help project staff understand how well they are doing at identifying previous participants (see **Figure X.1**).

This report will provide aggregate data from all persons completing the eligibility screener who share the same date of birth, gender and race. The report will show all records for persons meeting these criteria even if the eligibility screening process identified them as a previous participant (i.e., E_PART=1) or ineligible (i.e., EL_MSM=0 or EL_MSM=2). It will also include records where the interviewer assessed a participant as not providing honest responses to the interview questions (i.e., VALIDITY=3). By including all the records, regardless of eligibility and validity of responses, project sites should have a better understanding of how well their staff is doing at identifying previous participants.

With venue-based sampling no additional data exist to confirm previous participants. Still, multiple records that are both eligible (EL_MSM=1) and have valid responses to questions (VALIDITY= 1 or 2) should be reported to the principal investigator, who will decide whether the records are separate interviews from the same person.

Figure X.1 An example of a Possible Previous Participant Report

INTERVIEWER IMPROVEMENT REPORT: POSSIBLE PREVIOUS PARTICIPANTS

SURID	IDATE	START	ICODE	EL_MSM	Validity	DOB	GENDER	RACEOMB	SCHOOL	zip
5449	17-Feb	13:13:16	80	1	1	5/6/1960	Male	Black	Grades 9 through 11	11575
7971	19-Feb	13:11:48	65	0	1	5/6/1960	Male	Black	Some College, Associate's Degree, or Technical Degree	11722
7793	6-Mar	12:13:16	70	1	1	12/11/1980	Male	Hispanic	Grades 12 or GED	11798
5705	16-Mar	13:15:08	47	1	3	12/11/1980	Male	Hispanic	Grades 12 or GED	11803
5843	28-Mar	16:45:06	47	0	1	12/11/1980	Male	Hispanic	Grades 12 or GED	11554
5313	10-Apr	15:06:56	80	1	1	6/16/1956	Female	Black	Grades 9 through 11	11714
5758	25-Apr	10:15:32	80	1	1	6/16/1956	Female	Black	Grades 9 through 11	11550
5601	16-Apr	13:15:56	80	1	1	11/16/1949	Female	White	Grades 12 or GED	11550
6205	5-May	9:05:46	47	0	1	11/16/1949	Female	White	Grades 12 or GED	11550

If two records are determined to be *separate* interviews (i.e. different Survey ID) from the same person, **DO NOT DELETE** the second record. Instead, follow the guidance on the DCC Data Portal's knowledge base to change the second record's eligibility.

Appendix Y List of Abbreviations and Acronyms

CBO	Community based organization
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments
DCC	Data Coordinating Center
EIA	Enzyme Immunoassay
FWA	Federalwide Assurance
HAPI ™	Handheld Assisted Personal Interview
HIV	Human Immunodeficiency Syndrome
IFA	Immunofluorescent Antibody
IRB	Institutional Review Board
NHBS	National HIV Behavioral Surveillance System
NHBS-MSM3	NHBS among men who have sex with men, Round 3
MSA	Metropolitan Statistical Area
MSM	Men who have sex with men
NGA	Notice of Grant Award
PI	Principal investigator
PEA	Post-event appointment
PGO	Procurement and Grants Office
QDS ™	Questionnaire Development System
VBS	Venue-based sampling
VDT	Venue and associated day-time period
WB	Western Blot

Appendix Z References

1. Centers for Disease Control and Prevention and Council of State and Territorial Epidemiologists. *Technical Guidance for HIV/AIDS Surveillance Programs, Volume III: Security and Confidentiality Guidelines*. Atlanta, Georgia: Centers for Disease Control and Prevention; 2006.

2. Clearview Complete HIV 1/2 package insert
http://www.invernessmedicalpd.com/pdf/Clearview%20COMPLETE%20HIV1-2%20PI_05901.03.pdf

3. Keys to Getting a Good Fingerstick and Capillary Blood Sample:
http://www.hemosense.com/docs/0200189_BloodSampleTipsEnglish_RevG.pdf

4. Performance of a Fingerstick and Fingerstick Procedure Illustrated:
http://library.med.utah.edu/WebPath/TUTORIAL/PHLEB/PHLEB.html

5. Oraquick Advance HIV-1/2 package insert
http://www.orasure.com/docs/pdfs/products/oraquick_advance/OraQuick-Advance-Procedure-English.pdf

6. Uni-Gold Recombigen package insert
http://www.lifesignmed.com/iCat/common/files/nccls/Unigold_HIV_NCCLS_6506.pdf