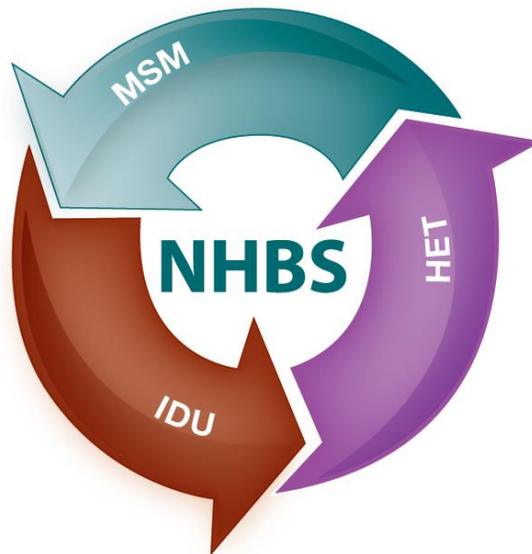


**National HIV Behavioral Surveillance:  
Heterosexually Active Persons at  
Increased Risk for HIV – Round 5  
(NHBS-HET5)**

# **OPERATIONS MANUAL**



NATIONAL HIV BEHAVIORAL SURVEILLANCE SYSTEM

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

Version Date: April 16, 2019

# Acknowledgements

This Operations Manual for the National HIV Behavioral Surveillance (NHBS) system was written by staff of the Behavioral Surveillance Team, Behavioral and Clinical Surveillance Branch (BCSB), Division of HIV/AIDS Prevention – Surveillance and Epidemiology (DHAP-SE), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

All material in this document is in the public domain and may be used and reprinted without permission; citation of the source is nevertheless appreciated.

## Suggested Citation:

Centers for Disease Control and Prevention. *National HIV Behavioral Surveillance, Heterosexually Active Persons at Increased Risk for HIV – Round 5: Operations Manual*. April 16, 2019. Available from: Cyprian Wejnert ([cwejnert@cdc.gov](mailto:cwejnert@cdc.gov)).

## Contacts

### Corresponding Author:

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

### Contributing Authors:

Dita Broz, PhD, MPH  
Teresa Finlayson, PhD  
Amanda Smith, MPH

### General NHBS Inquiries:

Cyprian Wejnert, PhD  
Team Lead, Behavioral Surveillance Team  
Centers for Disease Control and Prevention  
1600 Clifton Rd, Mailstop E-46  
Atlanta, Georgia 30333  
Telephone: (404) 639-6055; E-mail: [cwejnert@cdc.gov](mailto:cwejnert@cdc.gov)

# Table of Contents

---

## **1 Introduction**

1.1 Overview.....	1-1
1.2 Justification .....	1-1
1.3 Staff Responsibilities .....	1-1
1.4 Respondent-Driven Sampling .....	1-2
1.4a RDS methods .....	1-2
1.4b RDS assumptions .....	1-3
1.4c RDS and bias .....	1-3
1.5 Operations Checklist .....	1-4
1.6 References .....	1-4

## **2 Staffing, Training, and Evaluation**

2.1 Overview .....	2-1
2.2 Staffing .....	2-1
2.2a Management staff .....	2-1
2.2b Field staff .....	2-5
2.2c Data manager .....	2-6
2.3 Spanish-speaking Staff .....	2-6
2.4 The Importance of Skill Standardization and Quality Assurance .....	2-6
2.5 Project Staff Training .....	2-7
2.5a Required trainings .....	2-7
2.5b Recommended trainings .....	2-9
2.6 Project Staff Evaluations .....	2-10
2.6a Pre-implementation evaluation and performance recommendations ...	2-10
2.6b Ongoing evaluations and retraining procedures .....	2-10
2.6c Evaluators .....	2-10
2.6d Project staff .....	2-13
2.6e <i>Interviewer Report</i> .....	2-14

### **3 Project Preparation**

3.1 Overview .....	3-1
3.2 Project Logo and Marketing Materials .....	3-1
3.3 Project Supplies .....	3-1
3.3a Portable computers and survey software .....	3-2
3.3b Materials .....	3-2
3.3c Forms and logs for project management.....	3-2
3.3d Prevention and referral materials .....	3-4
3.3e Other supplies and materials .....	3-5
3.4 Access to the DCC Data Portal .....	3-5
3.5 Local Safety Procedures.....	3-5
3.5a General principles of field safety.....	3-5
3.5b Steps for field safety.....	3-6
3.5c Techniques for handling dangerous or difficult situations .....	3-7
3.5d Safeguarding portable computers .....	3-8
3.6 Field Incident Reporting Procedures .....	3-8

### **4 Field Sites**

4.1 Overview .....	4-1
4.2 Field Site Location .....	4-1
4.2a Restrictions on field sites .....	4-1
4.2b Additional considerations for vans .....	4-2
4.3 Multiple Field Sites .....	4-3
4.3a Cross-group recruitment .....	4-3
4.4 Field Site Set-up .....	4-4
4.4a Talk with neighbors and local police .....	4-4
4.4b Field site safety .....	4-4
4.5 Hours of Operation .....	4-5
4.5a Additional considerations for vans .....	4-5
4.6 Crowd Control .....	4-5
4.7 Appointment System .....	4-6
4.7a Scheduling appointments .....	4-7

4.7b Standby appointments .....	4-8
<b>5 Seeds</b>	
5.1 Overview .....	5-1
5.2 Identifying and Recruiting Seeds .....	5-1
5.2a Characteristics of seeds .....	5-2
5.2b Number of seeds .....	5-3
5.2c Selecting additional seeds .....	5-3
5.3 Assessing Seeds .....	5-4
5.4 Screening and Interviewing Seeds .....	5-5
5.4a Screening and interviewing by appointment .....	5-5
5.4b Screening and interviewing in the field .....	5-5
5.5 Referral Cards .....	5-6
5.5a Making referral cards .....	5-6
<b>6 Coupons</b>	
6.1 Overview .....	6-1
6.2 Coupon Number .....	6-1
6.3 Coupon Options .....	6-1
6.3a Number of coupons distributed .....	6-1
6.3b Coupon activation dates .....	6-3
6.3c Coupon expiration dates .....	6-4
6.3d Photo coupons .....	6-4
6.4 Making Coupons .....	6-5
6.5 Coupon Tracking System .....	6-7
6.5a Tracking coupons distributed .....	6-7
6.5b Tracking coupons returned .....	6-7
<b>7 Check-in, Interview, and Check-out</b>	
7.1 Overview .....	7-1
7.2 Participant Information and Tracking .....	7-1
7.2a Coupon Manager Program .....	7-1
7.2b Participant Tracking Form .....	7-3

7.3	Check-in .....	7-3
7.3a	Validate coupon or referral card .....	7-4
7.3b	Create record in the CMP .....	7-5
7.3c	Fill out Participant Tracking Form .....	7-6
7.3d	Escort participant to interviewer .....	7-6
7.4	NHBS Interview .....	7-6
7.4a	Eligibility screener .....	7-6
7.4b	Consent .....	7-8
7.4c	NHBS survey .....	7-9
7.5	Data Error Log .....	7-11
7.6	HIV Counseling, Testing, and Referral .....	7-12
7.6a	Counseling and testing .....	7-12
7.6b	Referrals to care and services .....	7-12
7.7	Recruiter Training .....	7-12
7.7a	Eligibility to recruit others .....	7-12
7.7b	Offering the chance to recruit others .....	7-13
7.7c	Conducting recruiter training .....	7-13
7.8	Check-out .....	7-14
7.8a	Participant information .....	7-14
7.8b	Coupon manager duties .....	7-15

## **8 Recruiter Reward Process**

8.1	Overview .....	8-1
8.2	Verify Participant's Identity .....	8-2
8.2a	Unable to locate recruiter ID in the CMP .....	8-2
8.3	Ask <i>Recruiter Questions</i> .....	8-3
8.4	Verify and Pay Reward .....	8-4

## **9 HIV and Other Testing**

9.1	Overview .....	9-1
9.2	Testing .....	9-1
9.2a	HIV testing .....	9-2

9.2b	Hepatitis testing .....	9-6
9.2c	STI testing .....	9-6
9.2d	Future testing .....	9-7
9.3	Staffing and Training .....	9-7
9.4	Specimen Collection .....	9-8
9.4a	Fingerstick specimens .....	9-8
9.4b	Venipuncture specimens .....	9-9
9.5	Specimen Storage and Processing .....	9-10
9.5a	Fingerstick specimens .....	9-10
9.5b	Venipuncture specimens .....	9-10
9.6	Specimen Transport and Shipping .....	9-10
9.6a	Local transport of venipuncture specimens .....	9-10
9.7	Returning HIV Test Results .....	9-10
9.8	Referrals to Care and Services .....	9-12
9.9	Data Management .....	9-13
9.9a	HIV testing .....	9-13
9.9b	Hepatitis testing .....	9-14
9.9c	STI testing .....	9-14

## **10 Process Monitoring and Ongoing Formative Assessment**

10.1	Overview .....	10-1
10.2	Process Goals .....	10-1
10.3	Process Monitoring Reports .....	10-1
10.3a	<i>Recruitment Monitoring Report</i> .....	10-2
10.3b	<i>Coupon Manager Program Report</i> .....	10-2
10.3c	<i>Sample Characteristics – Screened Report</i> .....	10-3
10.3d	<i>Sample Characteristics – Interviewed Report</i> .....	10-4
10.3e	<i>Test Results Report</i> .....	10-5
10.3f	<i>Seed Report</i> .....	10-7
10.3g	<i>Respondent-Driven Sampling Report</i> .....	10-7
10.3h	<i>Possible Previous Participant Report</i> .....	10-8
10.3i	<i>Interviewer Report</i> .....	10-9

10.4 Ongoing Formative Assessment .....	10-10
<b>11 Data Submission and Management</b>	
11.1 Overview .....	11-1
11.2 Data Submission .....	11-1
11.3 Data Management .....	11-1

## **Appendices**

- A NHBS-HET5 Operations Checklist
- B Field Supervisor – Project Management Evaluation Form
- C Field Supervisor – HIV Testing Operations Evaluation Form
- D Coupon Manager Evaluation Form
- E Interviewer Evaluation Form
- F HIV Counseling and Testing Evaluation Form
- G Data Manager Evaluation Form
- H Field Site Checklist
- I Participant Tracking Form
- J CMP Log
- K Rapid Testing Quality Control Log
- L Rapid Testing Temperature Log
- M Appointment and Phone Results Cards
- N Phone Results Procedures and Log
- O Field Incident Report
- P Information Cards
- Q Recruiter Training Script
- R Recruiter Training Talking Points
- S Instructions for Creating Referral Cards, Coupons, and Information Cards
- T Data Entry for Laboratory-based HIV Testing
- U Process Monitoring Reports

# Acronyms

---

<b>Acronym:</b>	<b>Definition:</b>
CAPI	Computer Assisted Personal Interview
CBO	Community-based Organization
CDC	Centers for Disease Control and Prevention
CITI	Collaborative Institutional Training Initiative
CLIA	Clinical Laboratory Improvement Amendments
CMP	Coupon Manager (software) Program
DBS	Dried Blood Spot
DCC	NHBS Data Coordinating Center
DHAP	Division of HIV/AIDS Prevention
EIA	Enzyme Immunoassay
FTE	Full-time Equivalent
FWA	Federalwide Assurance
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HRA	High-risk Area
HRSA	Health Resources and Services Administration
IFA	Immunofluorescent Antibody
IRB	Institutional Review Board
MOU	Memorandum of Understanding
MSA	Metropolitan Statistical Area
NAT	Nucleic Acid Testing
NGA	Notice of Grant Award
NHBS	National HIV Behavioral Surveillance
NHBS-HET	National HIV Behavioral Surveillance among Heterosexually Active Persons at Increased Risk for HIV
NIH	National Institutes of Health
OFR	Office of Financial Resources
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
PHRP	(National Institutes of Health) Protecting Human Research Participants
PI	Principal Investigator
PII	Personally Identifiable Information

PRA	Paperwork Reduction Act
PWID	Person Who Injects Drugs
QDS™	Questionnaire Development System
RDS	Respondent-driven Sampling
RDS-A	Respondent-driven Sampling Analyst (software)
RDSAT	Respondent-driven Sampling Analysis Tool (software)
SRP	Self-reported (HIV) Positive
STI	Sexually Transmitted Infection

## **1.1 Overview**

The *NHBS-HET5 Operations Manual* is designed to guide project staff during the implementation of NHBS. All project staff should read this manual, as well as the *NHBS Round 5 Model Surveillance Protocol* in order to prepare for data collection activities. Copies of the operations manual and the protocol should also be available for reference at each field site and at the project office.

The operations manual provides a detailed description of the procedures needed to conduct NHBS using respondent-driven sampling (RDS). This includes:

- Staffing the project (**Chapter 2**)
- Preparing materials (**Chapter 3**)
- Selecting field sites (**Chapter 4**)
- Identifying seeds (**Chapter 5**)
- Creating coupons (**Chapter 6**)
- Interviewing participants (**Chapter 7**)
- Paying recruiter rewards (**Chapter 8**)
- Conducting HIV testing (**Chapter 9**)
- Reviewing process monitoring reports (**Chapter 10**)
- Performing data management activities (**Chapter 11**)

## **1.2 Justification**

The primary purpose of the operations manual is to develop and document procedural guidelines to be used for conducting NHBS. The manual ensures operational standardization of NHBS activities across all 22 project sites.

## **1.3 Staff Responsibilities**

CDC staff are responsible for writing the *NHBS-HET5 Operations Manual* and providing technical assistance to project sites during implementation. Local NHBS staff are

responsible for conducting the project using the procedures described in the manual and for submitting all required data to CDC in a timely manner through the NHBS Data Coordinating Center (DCC) data portal.

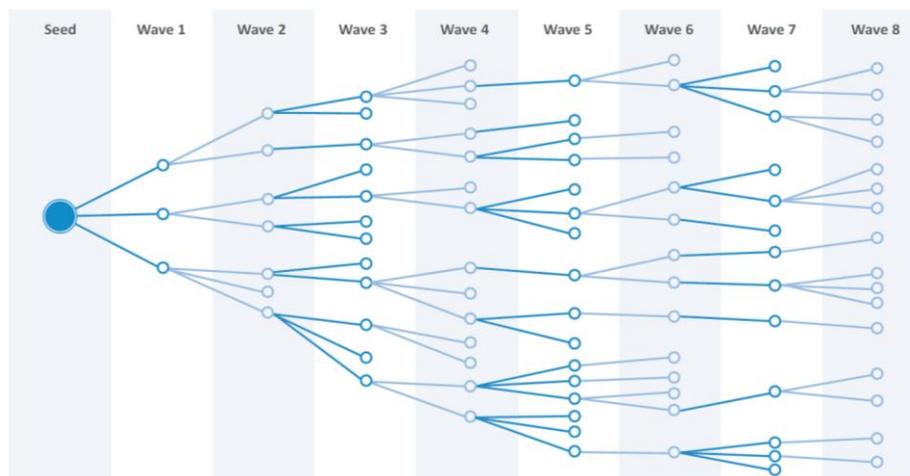
## 1.4 Respondent-Driven Sampling

The sampling method used during the HET cycles of NHBS is RDS, a type of peer-driven chain-referral sampling (Heckathorn 1997, 2002). Although there are biases associated with chain-referral sampling that can affect the composition of the sample achieved, RDS can control for these biases through its methods of data collection and analysis. Moreover, RDS is capable of producing population estimates when the data are analyzed with specialized software programs, like the RDS Analyst (RDS-A) or the RDS Analysis Tool (RDSAT). It is important for project staff to have a basic knowledge of RDS methods and theory so that they understand the importance of conducting NHBS in a way that will minimize bias.

### 1.4a RDS methods

RDS begins with the non-random selection of a small number of initial recruiters or “seeds.” These seeds recruit project participants who in turn recruit other participants. This chain of recruiters and recruits then continues for multiple “waves” of recruitment (see **Figure 1.1**). Ongoing recruitment is fostered with a dual incentive system: one incentive for participating in the project and another incentive for each person recruited who participates. Recruiters are linked to their recruits by a unique number on the recruitment coupons, and they are limited in how many people they can recruit based on the number of recruitment coupons they are given. In NHBS, the maximum number of coupons that can be distributed to each participant is five.

**Figure 1.1 – RDS recruitment waves**



Source: *Biobehavioral survey guidelines for Populations at Risk for HIV*. Geneva: World Health Organization; 2017.

### **1.4b RDS assumptions**

According to Salganik and Heckathorn (2004; see also Heckathorn 2007), there are six assumptions about RDS that should be met to appropriately analyze the data and calculate population estimates:

- 1) Participants know one another as members of the target population.
- 2) Participants are linked by a network composed of a single component.
  - *Social networks have to be sufficiently connected for the chain-referral process to work.*
- 3) Sampling occurs with replacement.
  - *The sampling fraction (ratio of the sample size to the population size) is small enough that it is unlikely that the same participant will be sampled more than once.*
- 4) Participants can accurately report their personal network size (i.e., the number of relatives, friends, and acquaintances who belong to the target population).
  - *An accurate personal network size is needed for data weighting.*
- 5) Recruits are randomly selected from the recruiter's network.
  - *Recruitment is not preferential with respect to key variables, such as race and gender.*
- 6) Participants recruit people with whom they have a reciprocal relationship (i.e., the participant knows the recruit and the recruit knows the participant).

### **1.4c RDS and bias**

One bias with chain-referral sampling is that people with large personal networks (i.e., who know many other people) are more likely to recruit participants, and are therefore more likely to be overrepresented in the sample. A second bias with chain-referral sampling is that people tend to know others who are like themselves. This tendency for “within-group” association is called “homophily” and it affects recruitment because participants often recruit people who have similar characteristics to themselves. Due to homophily, the final sample could be composed of individuals who have characteristics similar to those of the seeds.

The biases associated with chain-referral sampling can be minimized with RDS by limiting the number of coupons given to each recruiter and by generating long chains of recruitment. As recruitment chains become longer with each wave of recruitment, the sample approaches an “equilibrium” in composition. Equilibrium is the point at which the composition of the sample no longer changes, even with further waves of recruitment. At equilibrium, the characteristics of the sample become independent of those of the seeds. In addition, by conducting data analysis in RDS-A or RDSAT, data are weighted by the participant's personal network size (those with smaller networks are given more weight than those with larger networks) and by the probability of one subpopulation recruiting another (e.g., men recruiting women). This weighting further reduces some of

the biases inherent in chain-referral sampling and is the means by which RDS produces population estimates.

RDS has to be implemented correctly so that its underlying assumptions are not violated and bias is minimized. For instance, seeds should not be chosen from networks that are so sparse and disconnected that peer-recruitment would be unsuccessful. Hours of operation and locations of field sites should be considered carefully so that certain subpopulations, like Hispanic persons, are not limited in their ability to participate in the survey, and are thereby underrepresented in the sample. Recruiters should not give coupons to strangers. Project sites need to make this clear to participants when training them to recruit others. Sites should also monitor the recruitment of strangers as part of their ongoing formative assessment.

## **1.5 Operations Checklist**

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

## **1.6 References**

Heckathorn D. Respondent-driven sampling: a new approach to the study of hidden populations. *Social Problems* 1997; 44(2):174-199.

Heckathorn D. Respondent-driven sampling II: Deriving valid population estimates from chain-referral samples of hidden populations. *Social Problems* 2002; 49(1):11-34.

Heckathorn D. Extensions of respondent-driven sampling: analyzing continuous variables and controlling for differential recruitment. *Sociological Methodology* 2007; 37(1):151-207.

Salganik M and Heckathorn D. Sampling and estimation in hidden populations using respondent-driven sampling. *Sociological Methodology* 2004; 34(1):193-239.

## 2

## Staffing, Training, and Evaluation

### 2.1 Overview

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

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

### 2.2 Staffing

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

#### 2.2a Management staff

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

##### ***Principal investigator***

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

##### ***Project coordinator***

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

**Table 2.1 – Recommended positions and responsibilities for management staff**

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

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

<b>Responsibilities</b>	<b>Principal Investigator (PI)</b>	<b>Project Coordinator</b>	<b>Field Supervisor</b>
<b>Training and ongoing evaluations</b>	<ul style="list-style-type: none"> <li>• Ensure required trainings have been successfully completed by all project staff.</li> <li>• Conduct staff evaluations in collaboration with the project coordinator and field supervisor.</li> </ul>	<ul style="list-style-type: none"> <li>• Coordinate and conduct pre-implementation and ongoing trainings for project staff in collaboration with the field supervisor.</li> <li>• Conduct staff evaluations in collaboration with the PI and field supervisor.</li> </ul>	<ul style="list-style-type: none"> <li>• Coordinate and conduct pre-implementation and ongoing trainings for project staff in collaboration with the project coordinator.</li> <li>• Conduct staff evaluations in collaboration with the PI and project coordinator.</li> </ul>
<b>Data collection, management, analysis, and dissemination</b>	<ul style="list-style-type: none"> <li>• Ensure timely submission and entry of data to the DCC data portal.</li> <li>• Assume responsibility for quality control and data integrity.</li> <li>• Supervise the implementation of recommendations from CDC or the DCC to improve data quality.</li> <li>• Oversee development of policies pertaining to analyses and dissemination of data. (Health department only)</li> <li>• Oversee analyses of site data.</li> <li>• Ensure data is released in accordance with local policy and data use agreements. (Health department only)</li> <li>• Present reports and disseminate study findings.</li> <li>• Use study findings for the development, modification, and evaluation of local prevention programs.</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure daily transfer of data from portable computers to the QDS™ Warehouse.</li> <li>• Ensure that QDS™ Warehouse is maintained.</li> <li>• Ensure that coupon manager information, HIV testing data, and data errors are entered into the DCC data portal daily.</li> <li>• Review Process Monitoring Reports, ensure problems are addressed, and improvement seen.</li> <li>• Coordinate and implement policies pertaining to data analysis and dissemination.</li> <li>• Participate in data analysis and dissemination.</li> <li>• Evaluate need for ongoing formative assessment and make changes based upon findings.</li> </ul>	<ul style="list-style-type: none"> <li>• Schedule field site hours.</li> <li>• Review, tabulate, and reconcile forms and logs used in the field.</li> <li>• Review data errors with the coupon manager, interviewers, and HIV test counselors.</li> <li>• Oversee documentation of data errors.</li> <li>• Supervise entry of coupon manager information, HIV testing data, and data errors into the DCC data portal.</li> <li>• Review Process Monitoring Reports, identify issues of concern, and implement changes for improvement.</li> </ul>
<b>HIV testing operations</b>	<ul style="list-style-type: none"> <li>• Develop local HIV testing protocol and oversee HIV testing activities.</li> <li>• Ensure procedures are developed for making referrals to care and other services.</li> </ul>	<ul style="list-style-type: none"> <li>• Oversee maintenance of HIV testing supplies.</li> <li>• Ship HIV test specimens.</li> <li>• Receive and log HIV test results from lab.</li> <li>• Obtain CLIA waiver (if applicable).</li> <li>• Develop procedures for making referrals to care and other services.</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure proper documentation of HIV testing activities, including consent.</li> <li>• Ensure adherence to HIV testing procedures.</li> <li>• Ensure adherence to procedures for making referrals to care and other services.</li> </ul>
<b>Safety, security, and confidentiality</b>	<ul style="list-style-type: none"> <li>• Responsible for safety, security, and confidentiality of project staff, participants, materials, and data, including the development of local procedures and policies.</li> <li>• Report field incidents and adverse events to CDC within 2 business days of occurrence and to the IRB(s) per local policy.</li> </ul>	<ul style="list-style-type: none"> <li>• Coordinate development of local procedures for field incident reporting, safety, and handling participants known to project staff.</li> <li>• Report field incidents and adverse events to CDC within 2 business days of occurrence and to the IRB(s) per local policy.</li> </ul>	<ul style="list-style-type: none"> <li>• Assist in the development of local procedures for field incident reporting, safety, and handling participants known to project staff; and ensure adherence to all locally developed procedures.</li> <li>• Report field incidents and adverse events to CDC within 2 business days of occurrence and to the IRB(s) per local policy.</li> </ul>

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

Coupon Manager	Interviewer	HIV Test Counselor	Data Manager
<ul style="list-style-type: none"> <li>• Comply with guidelines for maintaining safety, data security, and participant confidentiality.</li> <li>• Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately.</li> <li>• Check in potential participants; provide recruiter training or, if interviewer provides recruiter training, reinforce recruiter training; check out participants; and pay incentives and recruiter rewards.</li> <li>• Manage all operational activities related to the coupon manager station and the Coupon Manager Program (CMP).</li> <li>• Upload CMP data to the DCC data portal daily.</li> </ul>	<ul style="list-style-type: none"> <li>• Comply with guidelines for maintaining safety, data security, and participant confidentiality.</li> <li>• Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately.</li> <li>• Accurately document participant information on the consent form and Participant Tracking Form (if applicable).</li> <li>• Conduct the eligibility screener, consent, and core questionnaire according to the instructions in the <i>Interviewer Guide</i>.</li> <li>• Maintain data integrity (i.e., all data collected accurately represent the information provided by participants during the interview).</li> <li>• Provide recruiter training (if applicable).</li> <li>• Assist with ongoing formative assessment as necessary.</li> </ul>	<ul style="list-style-type: none"> <li>• Comply with guidelines for maintaining safety, data security, and participant confidentiality.</li> <li>• Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately.</li> <li>• Conduct HIV counseling and testing per local and NHBS guidelines.</li> <li>• Have knowledge of information in package insert for rapid testing (if applicable).</li> <li>• Document HIV test results.</li> <li>• Accurately record information on lab slips, HIV Test Result Logs, and Specimen Transport or Shipping Logs.</li> <li>• For sites with separate interviewers and HIV test counselors: Ensure that the participant has consented to HIV testing.</li> <li>• Assist with ongoing formative assessment as necessary.</li> </ul>	<ul style="list-style-type: none"> <li>• Comply with guidelines for maintaining safety, data security, and participant confidentiality.</li> <li>• Implement local safety procedures and report adverse events to the field supervisor immediately.</li> <li>• Ensure upload of data from the portable computers to the QDS™ Warehouse.</li> <li>• Ensure daily receipt of forms and logs and review errors or concerns with the field supervisor or project coordinator.</li> <li>• Enter information from forms and logs into the DCC data portal.</li> <li>• Maintain QDS™ Warehouse and submit to the DCC data portal weekly.</li> <li>• Maintain data integrity (i.e., each record in the database represents the data an individual provided to the field team).</li> <li>• Review data reports from the DCC as soon as they are received, and provide requested data edits and explanations to resolve data issues via the DCC data portal.</li> <li>• Perform data analyses as needed.</li> </ul>

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

***Field supervisor***

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

A successful field supervisor has considerable knowledge of the communities in which

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

## **2.2b Field staff**

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

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

### ***Coupon manager***

The coupon manager is responsible for checking in and checking out participants, training recruiters (if interviewers do not train recruiters), distributing coupons, paying incentives and recruiter rewards, and using the CMP to monitor coupon activity.

A successful coupon manager has excellent communication skills, a thorough understanding of RDS, considerable knowledge of the communities in which NHBS is conducted, and a strong grasp of the CMP.

### ***Interviewers***

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

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

### ***HIV test counselors***

HIV test counselors must be certified to conduct the specific type of HIV test being used by the project site and are responsible for following local HIV counseling and testing standards and NHBS HIV testing guidelines. HIV test counselors are responsible for

providing tailored prevention messages to each participant based upon risk behaviors identified during the interview or counseling session. In addition, HIV test counselors must also provide anonymous referrals to medical care and case management and ensure that HIV-positive participants are linked to these services.

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

### ***2.2c Data manager***

The data manager is responsible for uploading local data files; ensuring data quality, data entry, and submission to the NHBS Data Coordinating Center (DCC) data portal; and communicating issues to the DCC, CDC, and other project staff. Data managers must ensure that data are stored in a manner that meets the required security and confidentiality standards for HIV/AIDS surveillance data. Data managers will spend approximately 15% of their time on the project.

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

## ***2.3 Spanish-speaking Staff***

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

## ***2.4 The Importance of Skill Standardization and Quality Assurance***

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

(5) retraining recommendations. Interview standardization and quality assurance is especially important and is discussed in detail in the *NHBS Round 5 Interviewer Guide*.

## **2.5 Project Staff Training**

The project coordinator and field supervisor are responsible for ensuring that all staff members have:

- Completed all required trainings.
- Demonstrated a thorough understanding of NHBS guidance documents, locally developed procedures, and the ethical principles and standards for HIV surveillance.
- Mastered their job-specific duties and responsibilities and successfully met the recommended performance standards prior to the start of data collection.

### **2.5a Required trainings**

Required trainings for project staff are described below and can also be found in **Table 2.3**. Completed trainings should be documented in the Operations Checklist (**Appendix A**).

#### **Field Operations Training**

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

**Required participants:** *Project coordinator and field supervisor to attend in-person CDC training and live webinar sessions. All relevant field staff to attend local training.*

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

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

**Table 2.3 – Pre-implementation guidance and trainings**

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

\*If applicable.

can successfully handle difficult situations.

*Required participants: All project staff*

### ***HIV counseling and testing***

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

*Required participants: All HIV test counselors*

### ***DCC data management training***

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

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

## ***2.5b Recommended trainings***

Recommended trainings for project staff are described below and can also be found in **Table 2.3**. As with the required trainings, completed trainings should be documented in the Operations Checklist.

### ***Human subjects and scientific ethics training***

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

*Recommended participants: All field staff*

### ***Cultural and health diversity course***

A cultural and health diversity course is recommended for all project staff who interact with participants. The goals of this training are to increase sensitivity to social, cultural, and linguistic differences among participants and to raise disability awareness. Courses are often offered at local universities, state health departments, medical schools, or companies that specialize in diversity training. Free online courses can also be found, like those available through the Health Resources and Services Administration's (HRSA's) Culture, Language, and Health Literacy Resources webpage (<https://www.hrsa.gov/cultural-competence/index.html>). Other online sources of training

include the curricula developed by the National Center for Cultural Competence (<https://nccc.georgetown.edu/resources/distance.php>).

*Recommended participants:* All field staff

## **2.6 Project Staff Evaluations**

To help project sites evaluate pre-implementation and ongoing staff performance, **Table 2.4** outlines pre-implementation evaluation and performance recommendations, a recommended ongoing evaluation schedule, retraining recommendations, and a recommended retraining evaluation schedule. In addition, model evaluation forms for each staff position can be found in **Appendices B** thru **G**. Project sites should describe their plans for conducting staff evaluations and retraining in the Operations Checklist and discuss these plans with their CDC project officer.

### **2.6a Pre-implementation evaluation and performance recommendations**

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

### **2.6b Ongoing evaluations and retraining procedures**

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

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

### **2.6c Evaluators**

The project coordinator, principal investigator, or field supervisor should complete pre-implementation and ongoing evaluations for all project staff to ensure thorough job knowledge and successful job performance. Once data collection begins, however, the field supervisor will be busy managing operations. Therefore, ongoing evaluations should ideally be conducted by the project coordinator or principal investigator.

**Table 2.4 – Evaluation and retraining recommendations**

Staff Member	Evaluator	Pre-implementation Evaluation and Performance Recommendations	Recommended Ongoing Evaluations Schedule	Retraining Recommendations	Recommended Retraining Evaluation Schedule*
Field Supervisor	PI or PC	Successfully meets NHBS performance recommendations.	<b>Project Management:</b> For the first three weeks, one evaluation per week, and then one per month.	Retrained on any skills that are below standard.	Successfully meets NHBS performance recommendations.
			<b>HIV Testing Operations:</b> One evaluation per month.	Retrained on any skills that are below standard.	
Coupon Manager	PI, PC, or FS	Successfully completes two consecutive mock check-in/check-out activities using the CMP and, if applicable, two consecutive recruiter trainings.	Two consecutive check-in/check-out activities using the CMP and, if applicable, two consecutive recruiter trainings during the first two weeks, and then one evaluation every two weeks.	<b>Minor errors:</b> Retrained on any skills that are below standard prior to resuming coupon manager duties.	Successfully completes the <i>next</i> two check-in/check-out activities using the CMP and, if applicable, the <i>next</i> two recruiter trainings.  If evaluations are unsuccessful, follow the retraining and evaluation recommendations for major errors (see below).
				<b>Major errors:</b> Retrained completely prior to resuming coupon manager duties.	Successfully completes two consecutive <i>mock</i> check-in/check-out activities and, if applicable, two consecutive recruiter trainings.
Interviewers	PI, PC, or FS	Successfully completes two consecutive full mock interviews (screening, consent, and interview) and, if applicable, two consecutive recruiter trainings.	Two consecutive interviews and, if applicable, two consecutive recruiter trainings during the first two weeks, and then one evaluation every ten interviews. (If evaluating every 10 <sup>th</sup> interview is not practical because of the interviewers' work schedules, ongoing evaluations may be conducted less frequently; but at a minimum, each interviewer should be evaluated at least once every two weeks.)	<b>Minor errors:</b> Retrained on any skills that are below standard prior to resuming interviewing.	Successfully completes the <i>next</i> two full interviews (screening, consent, and interview) and, if applicable, the <i>next</i> two recruiter trainings.  If evaluations are unsuccessful, follow the retraining and evaluation recommendations for major errors (see below).
				<b>Major errors:</b> Retrained completely prior to resuming interviewing.	Successfully completes two consecutive full <i>mock</i> interviews (screening, consent, interview) and, if applicable, two consecutive recruiter trainings.

**Table 2.4 – Evaluation and retraining recommendations (continued)**

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

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

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

Pre-implementation and ongoing evaluation forms should be kept on file since each evaluation is intended to build upon the previous assessment. To protect staff confidentiality, completed evaluation forms should be stored in a secure and locked location.

When conducting an evaluation, it is important for the evaluator to have a complete understanding of the duties and responsibilities for the position, the performance recommendations, and the criteria for evaluation (evaluation form). To accurately assess an interviewer, the evaluator should follow along with the survey either using his own portable computer or observing the interviewer's portable computer.

Recommendations for evaluators:

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

### **2.6d Project staff**

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

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

## **2.6e Interviewer Report**

To help project sites assess the interviewers and provide feedback for improving their techniques, the DCC will produce an *Interviewer Report* containing the following four tables: Interview Length, Interviewer Confidence in Responses, Testing Consent, and Coding of “Other” Insurance. An explanation of each table is provided in **Section 10.3i** of this manual. Project sites should review the report weekly and discuss the findings with their interviewers to identify strengths and areas for improvement.

### 3.1 Overview

The purpose of this chapter is to describe the preparations that should be made prior to starting data collection. These preparatory tasks include: 1) developing a project logo and marketing materials, 2) obtaining project supplies, 3) requesting access to the NHBS Data Coordinating Center (DCC) data portal, and 4) establishing local safety and field incident reporting procedures. Other preparatory tasks, such as training staff and planning HIV counseling, testing, and referral services are described in **Chapters 2** and **9** of this manual, respectively.

### 3.2 Project Logo and Marketing Materials

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



Content posted on social media, like a Facebook Page, should be treated the same as all other NHBS marketing materials; it must be reviewed and approved by the local program review panel and the site's CDC project officer (see **Section 6.2b** of the *NHBS-IDU5/HET5 Formative Assessment Manual*).

Because respondent-driven sampling (RDS) relies on peer recruitment rather than recruitment by project staff, marketing materials should be used in a limited manner. Marketing materials may not be necessary to encourage participation and could actually hinder recruitment by advertising the project to the wrong target population, resulting in a large influx of self-referred and ineligible individuals. Marketing materials are best used to garner community support by relaying the project's goals and objectives to local stakeholders. Project sites may also find it helpful to add their project logo to their coupons to promote project identity and to benefit from any name recognition the project has generated in the community.

### 3.3 Project Supplies

This section describes the supplies that project sites should obtain before starting data

collection. The Field Site Checklist (**Appendix H**) has a model list of supplies that sites can modify to meet their local needs.

### **3.3a Portable computers and survey software**

NHBS surveys must be conducted using portable computers, such as tablets or laptops. Therefore, project sites should check that their portable computers are functioning properly and they should ensure that enough are available for use in the field (including at least one backup). Please refer to the *NHBS Round 5 Interviewer Guide* for detailed instructions on the preparation and use of portable computers for conducting NHBS surveys. Sites that have experienced problems with portable computers during past cycles should discuss this with their CDC project officer and develop strategies for preventing data loss during the current cycle.

Project sites must use Questionnaire Development System™ (QDS™) version 5.0 modules to collect and manage NHBS data. These modules include the Design Studio, the Computer Assisted Personal Interview (CAPI), and the Warehouse Manager. Sites will use the Design Studio to program their local questions; the CAPI, to collect interview data; and the Warehouse Manager, to store the interview data. Because of the risk of a malfunction, QDS™ version 5.0 modules should not be installed on any computers that also have other versions of the modules, such as version 2.6.1, the version previously used in NHBS.

When not in use, portable computers that contain data must be stored in a locked file cabinet or locked box in a secured room in the project office. That being said, it is not always feasible for staff members to return the portable computers to the project office after field operations have concluded for the day. In these circumstances, a senior staff member may take the portable computers home, but the computers must still be securely stored in either a locked file cabinet or a locked box.

### **3.3b Materials**

Project sites should ensure that they have an adequate number of consent forms, incentives, flashcards, and other materials needed to conduct NHBS activities. Further information on creating the flashcards is contained in the *NHBS Round 5 Interviewer Guide*.

### **3.3c Forms and logs for project management**

To ensure successful project management and quality data collection, sites should develop procedures for the day-to-day operations of NHBS. Several forms and logs described throughout this manual are used to collect, track, and report information for different operational aspects of NHBS. The field supervisor and other project staff are responsible for completing, reviewing, and correcting the information in these documents in accordance with their local procedures and the *NHBS Round 5 Model Surveillance Protocol*. Sites can customize the documents for local use and they can develop

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

**Table 3.1 – Summary of forms and logs for project management.**

<b>Form or Log</b>	<b>Purpose</b>	<b>Location in This Manual</b>
<i>Field Site Checklist</i>	Facilitate the setup and operation of field sites.	Appendix H
<i>Project Staff Evaluation Forms</i>	Observe and evaluate project staff.	Appendices B - G
<i>Appointment Book or Log</i>	Schedule and track appointments.	Chapter 4
<i>Participant Tracking Forms</i>	Record participant information, completed activities, and data errors.	Appendix I
<i>CMP Log</i>	Record the numbers on the coupons distributed to each recruiter.	Appendix J
<i>Rapid Testing Quality Control Log</i>	Record external rapid test control results.	Appendix K
<i>Rapid Testing Temperature Log</i>	Record temperatures at which rapid tests and quality controls are stored and run.	Appendix L
<i>Lab slips</i>	Identify test specimens.	Chapter 9
<i>Appointment and Phone Results Cards</i>	Make appointments or provide contact information for returning test results.	Appendix M
<i>Phone Results Log (if applicable)</i>	Record information for returning test results over the phone.	Appendix N
<i>HIV Testing Log</i>	Record HIV testing data.	(Appendix L*)

\*Located in the *NHBS Round 5 Model Surveillance Protocol*.



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

Project staff should use a binder to store forms and logs in a central and easily referenced location. Sites providing HIV test results over the phone should collaborate with their CDC project officer to develop a protocol for returning results (**Appendix N** of this manual contains model procedures sites can use to develop a protocol, along with a

Phone Results Log they can use to track the provision of results). Hard copies of forms that contain confidential information (e.g., HIV Testing Log and Phone Results Log) should be stored in a locked file cabinet and handled in a manner which complies with the *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action* (available at <http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>). In addition to the aforementioned forms and logs, project staff may want to keep other materials and information in the project binder for easy reference, such as memorandums of understanding (MOUs) with field site owners or managers.

### **3.3d Prevention and referral materials**

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

- **Informational and educational pamphlets.**
  - Data describing the current state of the HIV, STI, and hepatitis epidemics.
  - Modes of transmission for HIV, STI, and hepatitis.
  - Strategies for preventing HIV infection through sex and drug use.
  - HIV, hepatitis, and other testing services.
  - Syringe services programs (also known as syringe or needle exchange programs).
  - Alcohol and substance use disorder treatment services.
- **List of referral agencies** and contact persons to provide to participants who are HIV-positive so that they can receive medical care and case management services. Furthermore, so that project sites can readily make any other 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 STI clinics, substance use disorder treatment centers, mental health service providers, and agencies that offer free HIV, STI, and hepatitis testing. Further information on referrals to care and services are described in **Section 9.8** of this manual.
- **Supplies** used to reduce HIV risk, such as condoms and lubricant.



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

### **3.3e Other supplies and materials**

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

### **3.4 Access to the DCC Data Portal**

As described in **Chapter 11** of this manual, project sites must regularly submit the QDS™ Warehouse with their core surveys to the DCC data portal. They will also use the data portal to enter information into the Data Error Log, the HIV Test Results Log, and if applicable, the Hepatitis Test Results Log and the secure file transfer program. Project staff that need access to the DCC data portal should first receive approval from the principal investigator of the directly funded health department and then apply for access following the instructions in the *NHBS-HET5 Data Management Training Materials*.

### **3.5 Local Safety Procedures**

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

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

#### **3.5a General principles of field safety**

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

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

- Plan ahead, be alert, and use common sense.
- Have a first aid kit available.
- Always have at least 3 staff members at each field site during the hours of operation.

### ***3.5b Steps for field safety***

Project sites should consider the following steps for field safety:

#### ***Plan ahead***

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

#### ***Be alert***

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

#### ***Use common sense***

- Limit the amount of cash you carry.
- Do not leave your cell phone unattended.

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

### ***3.5c Techniques for handling dangerous or difficult situations***

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

#### ***Aggressive or threatening individuals***

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

#### ***Sexual harassment***

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

#### ***Inebriated, high, or drowsy participants***

A participant may not be able to complete the interview or give accurate responses for a variety of reasons. For example, he may be unable to give intelligible answers to the questions or he may nod off during an interview if he has had little sleep or has recently used alcohol or drugs. If the participant is unable to provide coherent answers during eligibility screening, then he should be made ineligible; and if he cannot provide coherent

answers during the core survey, his interview should be stopped (see the *NHBS Round 5 Interviewer Guide* for further information).

### **3.5d Safeguarding portable computers**

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

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

### **3.6 Field Incident Reporting Procedures**

Project sites should develop field incident reporting procedures and include them in the Operations Checklist. These procedures should adhere to all local IRB requirements. In the event that an incident does occur, project staff should notify their field supervisor within 24 hours. The field supervisor, project coordinator, or principal investigator should then use a Field Incident Report to notify their CDC project officer of the incident within 2 business days. A model Field Incident Report is provided in **Appendix O** that sites can customize for local use. Incidents that are adverse events should also be reported to the local IRB(s) within 2 business days or earlier if mandated by local IRB requirements (see Chapter 9 of the *NHBS Round 5 Model Surveillance Protocol*).

### 4.1 Overview

During RDS cycles, data collection activities are conducted at fixed locations called field sites. Field sites are usually existing or rented office space or vans parked at specific places. Because all respondents must access a field site to participate in the project, selecting the appropriate number and location(s) of field sites is critical for successfully conducting RDS. Findings from formative assessment will help project sites decide the optimal number and location(s) of their field sites. This chapter provides specific guidance on selecting and managing these field sites.

### 4.2 Field Site Location

Project sites should consider several factors when selecting a field site location. Ideally, the field site should be centrally located and easily accessible by foot, car, or public transportation. Multiple field sites may be needed in project sites that have limited public transportation, cover large geographic areas, or are racially segregated. If a single field site is used, it should be located in an area where all subpopulations of low-income persons have equal access and would be equally willing to go, such as a location that serves as a “bridge” between the major subpopulations. Similarly, if multiple field sites are used, at least one of the field sites should be readily accessible to the major subpopulations of low-income persons to ensure cross-group recruitment (see **Section 4.3a** below). Results of formative assessment should be used to determine whether a single field site location is sufficient to reach all the major subpopulations of low-income persons or whether more than one field site is needed. Furthermore, if formative assessment indicates that confidentiality is a concern among potential participants, project sites should choose a nondescript location for their field site.

#### 4.2a Restrictions on field sites

To maintain the integrity of the RDS method, project sites must adhere to some restrictions when choosing field sites:

- Field sites should not be located in facilities that serve the homeless population or near areas where *large numbers* of homeless people congregate. The incentives provided in RDS studies are extremely attractive to economically disadvantaged populations, like the homeless; and as a result, they may be more likely to participate in the project, biasing the sample.
- Field sites should not be placed in substance use disorder treatment centers, syringe exchange programs, methadone clinics, or near areas where *large*

*numbers* of people who use drugs congregate. Like the homeless, people who use drugs may be more attracted to the RDS incentives than are members of the broader low-income population, which could bias the sample. The sample could be even further biased if members of the broader low-income population are reluctant to enter facilities providing services to people who use drugs due to the stigma associated with drug use.

- To minimize participation by persons who inject drugs (PWID), field sites should not be the same as those used for NHBS-IDU5. Because NHBS-IDU5 immediately preceded NHBS-HET5, PWID who live in the project area will already be familiar with NHBS, and as a result, may be more willing to participate in the project. Using the same field sites for both NHBS-IDU5 and NHBS-HET5 could compound this problem and further increase participation by PWID. Since persons who have injected drugs in the past 12 months (current PWID) do not meet the HET definition, a large proportion of participants who are current PWID would impede enrollment (they would not be able to recruit other participants and they would not count toward the enrollment goal of 500 persons who meet the HET definition).

### ***Single-service facilities***

Field sites should not be located in facilities that primarily or exclusively provide a specific service, like HIV care, STI treatment, or substance use disorder counseling. Locating a field site in such a facility could bias the sample toward people who receive that service. This problem becomes compounded when there is stigma associated with the particular service offered, as is often the case with HIV care. People with HIV infection may be more likely to go to a field site in an HIV clinic, while those without HIV infection may be less likely to go there because of a negative perception or fear of HIV.

### ***Multi-service facilities***

Field sites can be located in facilities that provide multiple services, such as HIV testing, general medical care, mental health counseling, and social services. When facilities provide a vast array of services, it is not likely that the sample will become biased toward people who receive any one particular service. Nevertheless, project sites should ensure that the services are not directed toward any specific subpopulation(s) of low-income persons because this could also result in a biased sample.

### ***4.2b Additional considerations for vans***

Project sites that plan to use a van must identify fixed locations where the van will be parked on each day of project operations. They should also create a set schedule of hours of operation at each location. Fixed locations and schedules are essential for ensuring that people always know where to go to participate in the survey and at what times. Depending on parking regulations and availability, it may be necessary to obtain a

parking permit for each location or to reserve the location in advance. As was discussed for field sites above, vans should not be parked near facilities or in areas where large numbers of homeless people or people who use drugs congregate; near substance use disorder treatment centers, syringe exchange programs, or methadone clinics; near the location(s) where the van was parked in NHBS-IDU5; near facilities that primarily or exclusively provide a specific service; or near any other area that would not comply with the restrictions on field sites.

### **4.3 Multiple Field Sites**

Since more than one field site may be necessary to reach all the major subpopulations of low-income persons in a large city, project sites may use multiple field sites for conducting operations. Nonetheless, project sites should not operate an additional field site merely to reach a small, insular subpopulation of low-income persons or a subpopulation that is not important to the local HIV epidemic. When deciding whether to use multiple field sites, project sites should consider the resources and logistical issues involved in operating multiple sites.

In addition, project sites should consider how operating multiple field site locations may bias the final composition of the sample. If a field site which focuses on a specific subpopulation of low-income persons operates for too many hours each week, that subpopulation may become overrepresented in the sample; whereas if the field site operates for too few hours, the subpopulation may become underrepresented. For this reason, field sites that focus on a specific subpopulation of low-income persons should have operating hours that are roughly proportional to the size of the subpopulation. For example, if a field site focuses on a subpopulation that comprises 20% of low-income persons, then approximately 20% of the total hours of operation each week should be spent at that field site to avoid biasing the sample. This recommendation only applies to field sites that focus on a specific subpopulation of low-income persons; it does not apply to field sites that all subpopulations are equally willing and able to attend.

Multiple field sites *cannot* operate simultaneously. Therefore, each field site must operate on a different day of the week or, if operating on the same day, at different hours. To avoid participant confusion, the days and hours of operation at each field site, as well as directions to the sites, should be clearly listed on all referral cards (see **Section 5.5a** of this manual), coupons (see **Section 6.4** of this manual), and information cards (see **Section 7.8b** and **Appendix P** of this manual).

#### **4.3a Cross-group recruitment**

Cross-group recruitment means recruitment between two different groups of participants. In regard to field sites, cross-group recruitment occurs when a participant from one field site recruits a person who participates at a different field site, and vice-versa. Cross-group recruitment is necessary to satisfy two of the RDS assumptions (see **Section 1.4b**

of this manual):

- Participants are linked by a network composed of a single component.
- Recruits are randomly selected from the recruiter's network.

During formative assessment, project sites considering multiple field sites must assess whether cross-group recruitment is likely to occur among the planned field sites. If cross-group recruitment is not likely to occur with a particular field site, that field site should only be used if formative assessment indicates that a subpopulation which is important to the local HIV epidemic would be significantly underrepresented in the sample without it.

## **4.4 Field Site Set-up**

The field site should be welcoming and comfortable for participants while maintaining their safety and privacy. It should have adequate space for the coupon manager station, 2 or more interview areas, and a waiting area for potential participants. Interviews should be conducted in private offices or rooms to provide privacy and protect participant confidentiality. Alternatively, partitions could be used to divide an open space and white noise machines could be used to mask voices. If there is not sufficient space inside the field site for a waiting area, project sites may be able to set up a makeshift waiting area outside the field site using folding chairs. Project sites that have separate interviewers and HIV testing staff will also need space for HIV counseling and testing. Furthermore, the spaces used for specimen collection and rapid test processing must comply with all quality assurance requirements.

### **4.4a Talk with neighbors and local police**

Before setting up the field site, project sites should meet with local police officials to explain the study's objectives and methods and to discuss any safety concerns in the area. It is often useful to identify a liaison in the police department who can serve as a point of contact throughout the project cycle and can help resolve any problems that may arise. Project sites should also meet with the owners of neighboring businesses to inform them of the study. During data collection, it is possible that potential participants will loiter outside the field site or form a line waiting to gain entrance, which could disturb nearby businesses. Business owners may be less likely to complain about this if they are aware of the study and project staff have made a commitment to cooperate with them to minimize any disruptions to their businesses.

### **4.4b Field site safety**

Project sites are responsible for the safety of both their staff and the participants while at the field site. They should develop local safety procedures for their staff and provide them with training on how to respond to threatening situations and other field incidents

(see **Section 3.5** of this manual). To prevent theft, project sites should store incentives, computers, supplies, and other potentially valuable items in safe locations that are not visible to participants. Most importantly, file cabinets that contain data collection forms should be in limited-access areas and must remain locked when not in use. Protecting participant confidentiality should always be a primary objective. Project sites that use a van should have one staff member monitor the area immediately surrounding the van, as well as control who is allowed to enter the van.

## **4.5 Hours of Operation**

Field sites must have a fixed schedule of hours when they operate. These hours should be clearly listed on all referral cards, coupons, and information cards, and they should be posted on the field site door in case potential participants show up when the field site is closed. Field sites should operate during a broad range of hours, including evening and weekend hours to accommodate participants who work during standard business hours. If hours of operation are too restrictive, certain subpopulations of low-income persons may be less likely to participate, which could bias the sample. Project sites should also ensure that project staff are allotted time each day for lunch or to take a break, which may require the closing of the field site. Once data collection has begun, project sites should not change their hours of operation unless absolutely necessary. That being said, if project sites must adjust their hours of operation, they should update all their materials immediately and post the new hours so that potential participants do not become confused by the change.

### **4.5a Additional considerations for vans**

Project sites using vans should also develop contingency plans in case the van is unavailable due to mechanical or staffing problems. For example, they could send project staff to the van's usual location to greet potential participants and tell them when the van will be available again. If an appointment system is used, the project staff should also re-schedule the appointments that had to be cancelled. For safety reasons, project sites must send at least two staff members to notify potential participants; project staff should never work alone in the field.

## **4.6 Crowd Control**

As the project becomes established in the community and recruitment increases, more and more members of the community will be interested in participating. These potential participants may crowd the field site or line up outside it. To help control these crowds, project sites should develop plans for managing large numbers of potential participants. For example, they could employ an appointment system, whereby a participant could only be interviewed at a scheduled time (see **Section 4.7**). If project sites do not wish to schedule appointments, they could use a "take-a-number" system to see participants on a

first-come, first-served basis. With this system, project staff would determine how many interviews they could conduct each day and then hand out the corresponding number of tickets. Rather than using tickets, project staff could also track participants by listing their survey IDs (coupon numbers) in the order that they arrived at the field site. Potential participants should be told how long they would have to wait to be interviewed, and if the wait will be long, they could be told to return at a later time that day.



Project sites cannot implement any additional sampling strategies to manage enrollment, such as randomly selecting potential participants for each day's available interview spots. Such a system would undermine the RDS sampling method.

In previous RDS cycles, people who were not participants often crowded the field sites. For example, potential participants were sometimes accompanied by their family or friends. If this becomes problematic, project sites could ask these individuals to wait outside or ask potential participants not to bring others with them. However, allowances would have to be made for participants who have children. Children cannot remain unattended and they cannot sit in on their parent's interview. To protect the confidentiality of participants and ensure the reliability of their responses, no one is allowed to sit in on a participant's interview. Infants do not pose a concern for confidentiality, but they could still distract the participant during the interview. Accordingly, project sites should institute a clear policy regarding children at the field site. Since banning children could create a participation barrier for parents, project sites should ask potential participants to bring someone to watch their children during the interview. The policy on children should be posted at the field site and reinforced during recruiter training and the scheduling of appointments.

## **4.7 Appointment System**

Scheduling appointments for interviews allows project sites to better manage enrollment and may reduce crowding and loitering at the field site. Project sites should develop their appointment system based on the number of interviewers and test counselors they have available and the time required for interviewing and testing. Interviewing and HIV testing should take approximately 1 hour, but additional time may be needed to process rapid tests or conduct other tests. More time may also be necessary at the beginning of data collection when project staff are less accustomed to operations.



Potential participants should be able to schedule appointments by phone (preferably toll-free), but voice mail should **not** be activated on the phone to prevent any participants from leaving confidential information, like their name or phone number. If voice mail cannot be turned off, participants should be instructed to not leave a message, and if they do, the message should be deleted immediately.

To maximize participant enrollment, project sites with appointment systems should also consider allowing a limited number of participants to “walk-in” for interviews. “Walk-ins” could be seen on a first-come, first-served basis if someone does not show up for an appointment or cancels one at the last minute.

#### **4.7a Scheduling appointments**

Guidance to help project sites schedule appointments is outlined in the steps below:

- 1) Greet the potential participant and ask him for his coupon. Check the “Activation Date” (if applicable) and the “Expiration Date” on the coupon to verify that the coupon is valid before scheduling the appointment. If the potential participant does not have his coupon with him, instruct him to return with his coupon or call the field site to schedule an appointment over the phone. When scheduling over the phone, ask the potential participant for his coupon information (the coupon number to schedule the appointment and the activation and expiration dates to verify the validity of the coupon).
- 2) Record all appointments in a single appointment book or log kept at the field site. To schedule an appointment, write the potential participant’s coupon number next to his appointment time. *Never* collect or write the potential participant’s name or personal identifying information in the appointment book or log.
- 3) Tell potential participants the approximate time required to complete the survey and HIV test.
- 4) Make sure potential participants are aware that they must first answer some background questions to determine if they have been selected to participate in the survey. They should also understand that if they are not selected for the survey or do not complete the interview, they will not be paid an incentive.
- 5) Emphasize that potential participants should be on time for their appointment. If they need to reschedule their appointment, they should call before the scheduled appointment time.
- 6) Tell potential participants that children are not permitted to sit in on their interview, and they should therefore arrange for someone to watch their children at home or at the field site.
- 7) Remind potential participants that they must bring their coupon to the appointment or they cannot be interviewed.



Project sites should not reserve appointment spots for members of any specific subpopulation of low-income persons. Denying available appointment spots to individuals who are not members of the specific subpopulation would undermine the RDS sampling method and bias the sample. Nevertheless, sites that are

having difficulty enrolling an important subpopulation should discuss scheduling options with their CDC Project Officer.

#### **4.7b Standby appointments**

Standby appointments allow potential participants to fill in for those who do not show up for their appointments or who cancel them at the last minute. Project sites should consider using standby appointments to address the problem of excessive “no-shows” rather than overbooking appointments. Standby appointments are less likely to harm relations with participants because those waiting for standby appointments know that they may not be able to be interviewed at their scheduled time.

Guidance to help project sites schedule standby appointments is outlined in the steps below:

- 1) Identify possible standby appointment times by choosing those that generate higher rates of “no-shows” or choosing a few at set intervals throughout the day.
- 2) Highlight the standby appointment times in the appointment book or log, and create a standby column adjacent to these times.
- 3) To schedule a standby appointment, write the potential participant’s coupon number in the standby column next to his standby appointment time. Explain to the potential participant that he is being scheduled for a standby appointment in the event that someone does not show up for a regularly scheduled appointment.
- 4) Ask the potential participant to call or return to the field site to see whether his standby appointment time has become available and he can be interviewed.
- 5) If the standby appointment time did not become available, ask the potential participant if he would like to schedule a different standby appointment time or schedule a guaranteed appointment time.

### **5.1 Overview**

Seeds are non-randomly selected members of the target population who initiate the RDS chain-referral process. Because they start the recruitment process, seeds play an important role in RDS studies and should be selected carefully. Seeds are usually referred by key informants or recruited by project staff during outreach. After a seed completes an interview, he is asked to recruit up to five people he knows who live in the project area. While a successful recruitment chain may grow from each seed, project sites should not expect or depend on all seeds to be productive. Analyses from prior NHBS cycles found that less than half of seeds produced substantive recruitment chains.

### **5.2 Identifying and Recruiting Seeds**

Key informants consulted during formative assessment can be the starting point for identifying and recruiting seeds. Key informants serve as “cultural experts,” providing insight into the characteristics, behaviors, and peer networks of low-income persons in the project area. Examples of key informants include community leaders, service providers and outreach workers in low-income communities, and residents of high-risk areas (HRAs) and other low-income areas. Enlisting the assistance of a diverse group of key informants will help project sites identify a diverse group of seeds.

Key informants should be told what characteristics are desired in a seed (see **Sections 5.2a** and **5.3** below) and what the basic eligibility criteria are for a seed. A seed must:

- be male or female (transgender persons are *not* eligible to participate in NHBS-HET cycles),
- be between the ages of 18 and 60 years old (CDC recommends that seeds be 40 years of age or younger),
- have had vaginal or anal sex with someone of the opposite gender in the past 12 months,
- have a low household income,
- have *never* injected drugs, **AND**
- if male, have *never* had sex with another man.

Since seeds who do not meet the eligibility criteria could provide false answers during screening, key informants should be asked to not reveal the eligibility criteria to potential seeds.

Project sites are not required to recruit seeds just through key informants. Seeds may also be recruited directly by project staff during outreach activities, or alternatively, key informants who are residents of HRAs or other low-income areas could serve as seeds. Seeds should be identified through a variety of sources since multiple seeds from the same source would likely be members of the same peer network (the group of people that a person knows in the project area). Ideally, seeds should *not* know one another.

When potential seeds are referred or recruited, the project staff should briefly describe the survey to them using the information in their local consent form or in the model Recruiter Training Script (**Appendix Q**). Without revealing the eligibility criteria, staff should also make it clear to potential seeds that their participation is not guaranteed. In prior RDS cycles, staff told potential seeds that a computer would be used to ask them some background questions and then the computer would determine whether they had been selected to participate in the survey.

If a potential seed is identified during formative assessment, project sites may collect the phone number of that seed so he can be contacted at the start of data collection to schedule an interview. This option only applies to seeds identified *prior* to the start of data collection; sites should never collect any contact information on seeds recruited *at* the start of data collection or *during* data collection. Phone numbers must be collected directly from the potential seed; phone numbers cannot be obtained from a key informant or any other third party. Furthermore, once sites have scheduled an interview appointment for a potential seed, they must destroy all records containing the seed's phone number. Most importantly, these records must be destroyed before the potential seed is interviewed. Sites that wish to collect the phone numbers of potential seeds should refer to **Section 5.3** of the *NHBS-IDU5/HET5 Formative Assessment Manual* for detailed guidance and a model Seed Contact Form. Before sites can collect any phone numbers, they must first discuss their plans with their CDC project officer and obtain approval.

### **5.2a Characteristics of seeds**

The ideal seed is someone who is motivated to recruit, has a large peer network, and is well respected in the community. These characteristics increase the likelihood that the seed will be able to recruit other individuals to participate in the survey. Moreover, seeds should be diverse with respect to factors such as age, race/ethnicity, geography, and any other factors that may create more insular peer networks. For example, if people from the north side of a city do not interact with people from the south side, cross-group recruitment between people from these two sides of the city would be very limited or non-existent. Accordingly, the project site should select some seeds from the north side and some from the south side to ensure that people from both sides are represented. Similarly, if people who are black do not interact with people who are Hispanic, the site should select some seeds who are black and some who are Hispanic. Nonetheless, selecting seeds by demographic characteristics alone will not guarantee access to diverse peer networks. For example, if a black seed is a member of a Hispanic peer network, he

may produce a recruitment chain that is racially and ethnically similar to a chain produced by a Hispanic seed.

Seeds should also reflect those subpopulations which are of greatest importance to the local HIV epidemic among heterosexually active persons. During formative assessment, project sites should identify those subpopulations from which seeds should be chosen to yield a representative sample of at-risk persons. In addition, CDC strongly recommends that sites select seeds who are 40 years of age or younger to decrease the likelihood that recruitment chains become locked in networks of older persons. During previous RDS cycles, older persons demonstrated a much greater willingness and ability to participate in the survey, and as a result, would overwhelm the sample. If someone over the age of 40 would be an exceptional seed, however, sites may use that person as a seed if they demonstrate that the person is broadly networked to all age groups and they obtain approval from their CDC project officer.

### ***5.2b Number of seeds***

There is no specific number of initial seeds that will guarantee project sites reach the sample goal of 500 eligible persons who meet the HET definition (has a household income at or below 150% of the HHS poverty guidelines adjusted for geographic differences in the cost of living, has not injected drugs in the past 12 months, and if a man, has not had sex with another man in the past 12 months). However, based on prior RDS cycles, sites should select 3-10 seeds to initiate the recruitment process. To determine the most appropriate number of seeds, sites should consider how closely subpopulations of low-income persons are networked in their local community. If two or more subpopulations are *not* closely networked, sites will need to select a small number of seeds (2-3) from each of the subpopulations (see **Chapter 4** of this manual for a description of ways to focus on specific subpopulations using field sites). On the other hand, if two or more subpopulations are closely networked, a small number of seeds from any of the closely-networked subpopulations will be sufficient to start recruitment.

Project sites should not select seeds from every possible network of low-income persons in the community. Instead, they should focus on those networks that include the subpopulations at greatest risk for HIV infection. In most cases, fewer than 10 seeds will be needed. It is important that sites do not choose too many seeds because the sample size could be reached before equilibrium is achieved and the RDS method would be undermined. Sites must consult with their CDC project officer before deciding on the total number of seeds to select and they must obtain their project officer's approval.

### ***5.2c Selecting additional seeds***

If the initial seeds do not recruit participants or if enrollment is halted because all the recruitment chains have “dried up” (i.e., stopped recruiting), then additional seeds will need to be selected. With RDS, seeds do not all have to be chosen at the same time or at the beginning of data collection. Before selecting additional seeds, project sites should first conduct ongoing formative assessment to determine if there are any barriers to

survey participation that have caused recruitment to stall. Please see **Section 10.4** of this manual for additional information on how to assess barriers to participation. Sites should note that decisions about recruiting more seeds must be made in consultation with their CDC project officer.

### **5.3 Assessing Seeds**

All potential seeds should be assessed by either the key informant who referred them or the staff member who recruited them to determine if they are likely to be “productive” seeds and recruit others. The ideal characteristics of a seed are:

- **Connected to many other people in the community:** A good seed will know many other people in the project area. If one imagines a peer network with lines drawn between people to show relationships, a seed is someone who has numerous lines radiating out; that is to say, someone who is a focal point of the network.
- **Respected and well-liked:** People who are charismatic, influential, or considered leaders within their circle of friends or associates will make effective seeds since they can persuade people to participate in the survey and to recruit others. A good seed is someone who others in the community come to for information or advice.
- **Communicates well orally:** Seeds should be able to express themselves clearly when engaged in a conversation; this will give an indication of their ability to explain the project to others.

People who are extroverted or talkative but not socially connected to others will not make good seeds. The best seeds are people who understand the project and can accurately describe it, who support the project’s goals and objectives, and who can enthusiastically encourage others to participate.

Once referred or recruited, potential seeds should be asked questions to assess their suitability to be “productive” seeds. Examples of the types of questions project sites can ask are:

- *Do you know many people who live in [the project area]?*
- *Are you willing to recruit other people you know who live in [the project area] for the survey?*
- *Of the people you know who live in [the project area], can you think of 5 you have seen in the past 30 days that you could recruit for the survey? Do you think these people would be willing to participate in the survey?*
- *Have you been involved in any other health studies before?*

## **5.4 Screening and Interviewing Seeds**

If a potential seed satisfies the assessment criteria, he should be referred for eligibility screening using a referral card (see **Section 5.5** below). Project sites should use the referral card to make an appointment to screen the potential seed at one of their field sites or, if they are screening the potential seed in the field where he was recruited, they should use the pre-printed number on the referral card as the survey ID. If a potential seed is screened and found to be eligible, he will be offered the opportunity to participate in the survey and receive an HIV test. Seeds who complete the survey will be able to recruit other participants.

### **5.4a Screening and interviewing by appointment**

If a project site does not screen potential seeds in the field (see **Section 5.4b** below) or if a potential seed is not available to be screened when he is approached, the project site should make an appointment to screen and interview the potential seed at a field site at a mutually convenient time. Project staff who are recruiting seeds in the field should maintain a list of possible appointment dates and times or they should call the staff at the field site to schedule appointments. The day of the week, the date, and the time of the appointment should be recorded on a referral card. To avoid any confusion, the appointment information should be written out completely (e.g., Monday, June 3, 2019 at 1:00 pm). The day, date, and time of the appointment should also be recorded in an appointment book or log, along with the survey ID (pre-printed number on the referral card).

When giving the referral card to the potential seed, project staff should review the appointment information on the card and the directions to the field site. Staff should also tell the potential seed that he should call the project phone number on the referral card if he needs to reschedule his appointment. Because NHBS is an anonymous survey, project sites should never contact potential seeds to remind them of their appointments or to follow-up with them if they miss their appointments (this includes potential seeds identified during formative assessment who were contacted by phone at the start of data collection to schedule their interviews). Sites may want to include an expiration date on their referral cards to motivate potential seeds to keep their appointments or to promptly reschedule them. To achieve this goal, expiration dates should be no later than 1 to 2 weeks after a scheduled appointment. Of further benefit, expiration dates ensure that potential seeds enroll at the very beginning of data collection when they are needed to initiate recruitment chains.

### **5.4b Screening and interviewing in the field**

If a potential seed is available to be screened when he is approached, project sites may interview him in the field. To do this, sites must have all the materials and equipment needed to conduct an interview, test for HIV, and provide recruiter training. They will need referral cards, consent forms, portable computers with the survey, HIV test kits,

incentives, recruitment coupons, and a computer with the Coupon Manager Program (CMP). To operate in the field, project staff must protect the confidentiality of the potential seed at all times; no one outside of the project should be able to hear or observe any proceedings. If confidentiality cannot be guaranteed in the field, staff cannot interview potential seeds there. Instead, they will have to schedule an appointment to screen and interview the potential seed at a field site.

## **5.5 Referral Cards**

Referral cards serve as both appointment cards and coupons for seeds. They are given to seeds when they are scheduled for an appointment to be screened at a field site or when they are screened in the field at the time of recruitment. Each referral card should have a pre-printed number on it. Referral card numbers must be *unique* and *sequential*. They should be 4-digits long and range from 0001 to 0499. Project sites should not use numbers between 0500 and 0888 because these numbers are assigned to the NHBS-Trans project. Sites should also not use numbers greater than 1000 for referral cards because these numbers are reserved for recruitment coupons (see **Section 6.2** of this manual). Since the referral card numbers will serve as the survey IDs for the seeds, sites must strictly adhere to the aforementioned referral card numbering conventions.



Survey IDs (referral card numbers) used when practicing seed interviews should range from 900 to 999. If project sites only use numbers that begin with a “9” for practice interviews, the NHBS Data Coordinating Center (DCC) will be able to easily identify any practice interviews that are inadvertently included in the QDS™ Warehouse.

### **5.5a Making referral cards**

Project sites may have their referral cards professionally printed or they may make the cards themselves by following the instructions in **Appendix S**. Referral cards may be designed however a site wishes, but they must contain specific information on their front and back as illustrated in **Figures 5.1** and **5.2**. To help project staff distinguish between referral cards and recruitment coupons, cards should be printed on different colored paper and have a different size.

**Figure 5.1 – Example of the front of a referral card**

The diagram shows a rectangular referral card with the following text and fields:

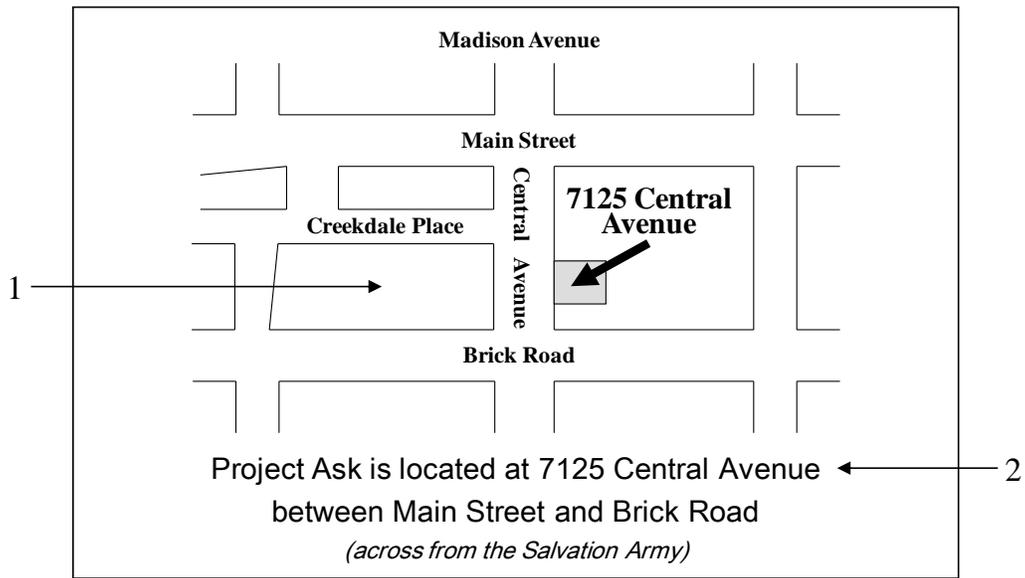
- 1 → **0001** **Project ASK** **0001** ← 2
- 3 → You have an appointment on  
Day: \_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_ Time: \_\_\_ : \_\_\_\_\_
- at 7125 Central Avenue, 2nd Floor. ← 4  
(Directions are on back.)
- 5 → Please call 1-888-865-4327 if you have any questions or if you need to reschedule.
- Coupon expires on: \_\_\_ / \_\_\_ / \_\_\_ ← 6

1. Referral card number ranging from 0001 to 0499.
2. Name of the local NHBS project.
3. Space to record the day, date, and time of the potential seed’s screening appointment.
4. Address of the field site.
5. Phone number to call for project information or to reschedule an appointment.
6. **Optional:** Space to record an expiration date.



If days, times, and addresses of multiple field site locations cannot fit on the front of the referral card, project sites may include this information on the back of the card. The maps and directions normally printed on the back of the referral card can then be placed on a separate flyer that is distributed with each card.

**Figure 5.2 – Example of the back of a referral card**



1. Map showing the location of the field site.
2. Directions to the field site.



“HIV” or “AIDS” should not be included on the referral card because of the stigma associated with these terms.

## 6.1 Overview

Coupons have an extremely important role in RDS; they are used to identify and keep track of people recruited for the project. When a participant recruits another person for the project, he will give the recruited person a coupon. The coupon identifies that person as a valid recruit and is required for project participation. The coupon also contains a unique code number that allows the Coupon Manager Program (CMP) to link the recruited person to his recruiter. This recruiter-recruit linkage is an essential component of RDS analysis.

## 6.2 Coupon Number

Each coupon should have a pre-printed number on it. Coupon numbers must be *unique* and *sequential*. They should be 4-digits long and range from 1000 to 4999. Project sites should not use numbers less than 1000 for coupons because these numbers are reserved for seed referral cards (see **Section 5.5** of this manual). Sites should also not use numbers between 5000 and 8888 because these numbers are assigned to the NHBS-Trans project. Since the coupon numbers will serve as the survey IDs for the participants, sites must strictly adhere to the aforementioned coupon numbering conventions.



Survey IDs (coupon numbers) used when practicing non-seed interviews should range from 9000 to 9999. If project sites only use numbers that begin with a “9” for practice interviews, the NHBS Data Coordinating Center (DCC) will be able to easily identify any practice interviews that are inadvertently included in the QDS™ Warehouse.

## 6.3 Coupon Options

Based on their experience from prior RDS cycles and their findings from formative assessment, project sites should decide how many coupons to distribute to seeds and other participants. They should also determine whether to include an activation date and an expiration date on their coupons. Activation and expiration dates define a period when coupons are valid for project participation. Lastly, sites are not limited to just using paper coupons. If they wish, sites may also allow participants to photograph their coupons and send them to their recruits electronically.

### 6.3a Number of coupons distributed

Project sites may give up to 5 coupons to each participant who completes the survey and

agrees to recruit others (see Chapter 4 of the *NHBS Round 5 Model Surveillance Protocol*). The number of coupons given to each recruiter will vary from project site to project site depending on the likelihood that one of the distributed coupons will yield a participant who completes the survey. The lower the likelihood that a coupon will yield a participant, the greater the number of coupons a site must give out to ensure that enrollment does not decrease with successive recruitment waves and eventually die out. During previous RDS cycles, sites found that giving 2 or 3 coupons to each recruiter was usually sufficient for enrollment to progress successfully. Giving more coupons than this is likely to negatively impact data quality, as well as any RDS analyses performed on the data. Nevertheless, sites may want to give the maximum of 5 coupons to seeds, and then reduce the number of coupons given to subsequent participants. Since recruiting seeds requires a considerable investment of time and effort, giving the maximum number of coupons to seeds will optimize the chance that they produce recruitment chains.

Project sites should avoid giving more than 2 or 3 coupons to each recruiter to prevent the number of recruits from greatly exceeding the field staff's capacity to interview them. If the field staff were to become overwhelmed with recruits, many recruits would be denied the opportunity to participate in the project. Not only would this undermine the project's credibility in the community, but it would also increase the non-response bias in the sample. A large pool of recruits waiting to enroll could also diminish the effectiveness of differential coupon distribution, whereby different numbers of coupons are given to recruiters from under- and overrepresented subpopulations in order to adjust their enrollment (see below). Lastly, distributing too many coupons to each recruiter may increase the design effect, or variance, in the sample and it could prevent recruitment chains from growing long enough for the sample to reach equilibrium, an essential condition of the RDS method (see **Section 1.4c** of this manual).

In previous RDS cycles, some project sites gave fewer or no coupons as the data collection period approached its end date because they were concerned community relations would be harmed if the cycle ended with a large number of recruited individuals who could not be interviewed. This approach may have been helpful at extremely busy sites, but most others found it unnecessary. As the end of data collection approached, sites that continued to give the same number of coupons maintained community relations by emphasizing the project end date both during recruiter training and when describing the project to potential participants.

If participation by a specific subpopulation is less than what is expected based on formative assessment, project sites can increase the number of coupons given to recruiters from the underrepresented subpopulation to improve their enrollment. Likewise, to help prevent the sample from becoming biased if a specific subpopulation starts to dominate enrollment, sites can decrease the number of coupons given to recruiters from that subpopulation or stop giving coupons to them altogether. As mentioned above, this is referred to as differential coupon distribution. Differential coupon distribution is a drastic action, however, and should only be used when the sample would not represent those subpopulations of greatest importance to the local HIV

epidemic without intervention. Before increasing the number of coupons given to a select subpopulation, sites must first conduct ongoing formative assessment to determine why participation by that subpopulation is low and they must address any recruitment or participation barriers identified (see **Section 10.4** of this manual). If these actions do not improve enrollment by the underrepresented subpopulation, sites may then distribute more coupons to them. The under- or overrepresentation of a subpopulation often requires immediate intervention. Accordingly, sites should discuss any potential recruitment problems with their CDC project officer as soon as possible to prevent them from escalating into irreversible recruitment problems.

When deciding how many coupons to distribute, project sites need to balance the ability to enroll participants, which may require giving more coupons, with adherence to the best methodological practice, which necessitates giving fewer coupons. Sites should decide the exact number of coupons to distribute in consultation with their CDC project officer. If they want to change the number of coupons, they must also obtain approval from their CDC project officer; they may not change the number of coupons on their own. This is especially true for field staff. Field staff should *never* change the number of coupons given out. They must always distribute the number of coupons agreed to by their senior managers and their CDC project officer. In addition, whenever sites change the number of coupons distributed, they *must* record the change in the CMP.

### **6.3b Coupon activation dates**

A coupon activation date is a date when coupons become valid for participation in the project. On or after the coupon activation date, a potential participant may bring his coupon to one of the field sites to begin the check-in process. Project sites should decide whether to include an activation date on their coupons. If they do include an activation date, they will also have to decide how long to wait after a recruiter is given coupons for the coupons to become active. In previous RDS cycles, most sites set an activation date that was one day after the coupon was distributed.

Some project sites have found that activation dates allow them to better control participant flow and prevent their field sites from becoming inundated with large numbers of unplanned participants. It is also possible that activation dates decrease the likelihood that recruiters will recruit “strangers” (i.e., people they do not know personally). For example, if coupons do not become valid for a day, recruiters may be less likely to leave the field site and give their coupons to the first people they see hanging out on the street. Giving coupons to people hanging out on the street that the recruiter does not know is problematic because it violates the RDS assumption that participants only recruit from within their personal networks and do not recruit “strangers.”

On the other hand, some project sites have found that activation dates hinder recruitment. This was especially true for project sites that had several field sites far apart from one another and only operated in each field site once a week. Even with a short one-day

activation period, recruits at these project sites had to wait a week before they could participate in the survey at a convenient location. As a result of the long delay between the time they were recruited and the time they were able to participate, many recruits lost interest in the project and never tried to participate.

### ***Changing activation dates***

During the course of data collection, project sites may change the interval for their coupons to become valid if they think it will improve recruitment or operations. Similarly, sites that do not initially include an activation date on their coupons may later add one and sites that do initially include an activation date may later eliminate it. Before making any changes to coupon activation dates, however, sites should discuss the changes with their CDC project officer and obtain the project officer's consent.

### ***6.3c Coupon expiration dates***

A coupon expiration date is a date when coupons are no longer valid for participation in the project. After the coupon expiration date, participants may not enroll in the project. All project sites must include an expiration date on their coupons. At the very least, this date must be the last day planned for project operations. Sites may also choose an earlier expiration date if they wish. For example, in previous RDS cycles, some sites had coupon expiration dates that were 4 to 6 weeks after the coupons were distributed. These sites felt that an earlier expiration date resulted in faster recruitment. Yet, many sites found that earlier expiration dates were unnecessary because most recruits returned their coupons within one or two weeks of their recruiter's participation in the project. Moreover, less busy sites felt that early expiration dates were harmful to enrollment because they excluded potential participants. Another possible problem is that expiration dates may increase non-response bias by creating a selective participation barrier to those with less availability to take part in the project, such as working persons, women with children, and those who live far from field sites. For these reasons, early expiration dates should be used with caution. Sites that choose to have their coupons expire within a few weeks of distribution should carefully monitor recruitment and continuously assess participant characteristics for any biases.

### ***Changing expiration dates***

As with activation dates, project sites may change the interval before their coupons become invalid if they think it will improve recruitment or operations. Expiration dates may be made earlier or later, but they may not be eliminated. As mentioned above, at the very least, coupons must expire on the last day planned for project operations. Sites should discuss any proposed changes to their coupon expiration dates with their CDC project officer and obtain the project officer's approval for the change.

### ***6.3d Photo coupons***

Photo coupons are photographs of the fronts of paper coupons that participants can send to their recruits electronically (see **Figure 6.1**). Project sites have the option of allowing

participants to use photo coupons in addition to paper coupons. Sites choosing to permit photo coupons should explain this option to participants after they have been given their paper coupons. Participants would then be able to distribute their coupons either by handing out paper copies or by sending photocopies. Instructions for using the photo coupons can be incorporated into the recruiter training script (**Appendix Q**) or talking points (**Appendix R**).

**Figure 6.1 – Example of a photo coupon**



Participants should send one photo coupon to each person they would like to recruit, along with a general message that protects the privacy of the recruit. Participants should **not** refer to HIV/AIDS or other sensitive topics in their message. For example, participants could say:

*“You can use this coupon to take a health survey and earn up to \$<total incentive amount>.”*

Directions to the field site or other information normally found on the back of a paper coupon could be included in the message as well (alternatively, the participant could include a photograph of the back of the paper coupon). Only one coupon should be shown in each photograph and the coupon number must be clearly displayed. No participants should appear in the photographs. To ensure that participants take the photographs correctly, project sites could have the participants take a practice photograph at the field site or have them take all their photographs there. Because participants could send the same photo coupon to multiple recruits, project sites must accept all coupons on a first come, first served basis. Thus, for each coupon number, the first person who checks in with that number is the only one who can participate in the survey.

## **6.4 Making Coupons**

Coupons can be professionally printed or project sites can make the coupons themselves

by following the instructions in **Appendix S**. Coupons may be designed however a site wishes, but they must contain specific information on the front and back as illustrated in **Figures 6.2** and **6.3**. To reduce the likelihood that recruiters sell their coupons to potential participants, sites may choose to include the phrase “Not for Sale” on their coupons. In addition, project sites located in cities that are in close proximity to one another should share their coupon designs and ensure that they are sufficiently different. This will help alleviate participant confusion if coupons from a neighboring project site become introduced locally.

**Figure 6.2 – Example of the front of a coupon**



1. Coupon number ranging from 1000 to 4999.
2. Name of the local NHBS project.
3. Incentive type and amount for participants completing the survey.
4. Phone number to call for project information and if applicable, to schedule appointments. It is best to have a toll-free number because of the likely disadvantaged economic status of many participants.
5. Days and hours of field site operations.
6. Address of the field site.
7. Project logo or some other security feature, like a hologram or barcode.
8. **Optional:** Space to record an activation date.
9. Space to record an expiration date.



If the days, times, and addresses of multiple field site locations cannot fit on the front of the coupon, they can be included on the back of the coupon. The maps and directions normally printed on the back of the coupon can then be placed on a separate flyer that is distributed with each coupon.

**Figure 6.3 – Example of the back of a coupon**



1. Map showing location of the field site.
2. Directions to the field site.



“HIV” or “AIDS” should not be included on coupons because of the stigma associated with these terms.

To readily distinguish coupons from referral and information cards, they should be printed on different colored paper and have a different size. Furthermore, coupons should be small enough when folded to fit in a pocket, but not so small that they could be easily lost. In other RDS studies, it has been customary to cut coupons to the size of a dollar bill (approximately 6.5 inches by 2.5 inches) to underscore their intrinsic value.

## **6.5 Coupon Tracking System**

As part of records management, project sites should develop a system for tracking the coupons distributed and returned each week.

### **6.5a Tracking coupons distributed**

Project sites should use a log to keep track of the numbers on the coupons given out to participants. The CMP Log (**Appendix J**), which is used to back up the CMP, can be used to collect this tracking information. To facilitate tracking and records management, coupons should always be given out in order of their coupon numbers, starting with the smallest number.

### **6.5b Tracking coupons returned**

Project sites should keep track of the coupons returned by participants, including coupons

from ineligible participants and expired coupons. An easy way to manage returned coupons is to have a set of file folders or envelopes labeled with the dates for each week that data are collected (e.g., Week 1: 6/3 – 6/9, Week 2: 6/10 – 6/16, and so on). When a participant returns a coupon, the coupon should be marked “*USED*,” “*VOID*,” “*EXPIRED*,” or with similar terms to indicate that the coupon is no longer valid and the reason why. The coupon should then be placed in the folder or envelope labeled with the week the coupon was returned.

# 7

## Check-in, Interview, and Check-out

### 7.1 Overview

The purpose of this chapter is to provide step-by-step guidance for conducting NHBS operations at field sites. Operational activities include checking in potential participants when they arrive at the field site, conducting interviews, administering HIV tests, providing recruiter training, and checking out participants (see **Figure 7.1**). Information on identifying and managing field sites is presented in **Chapter 4** of this manual.

### 7.2 Participant Information and Tracking

Project sites should use the Coupon Manager Program (CMP) and the Participant Tracking Form (**Appendix I**) to record participant information and to track participants throughout the check-in, interview, and check-out process.

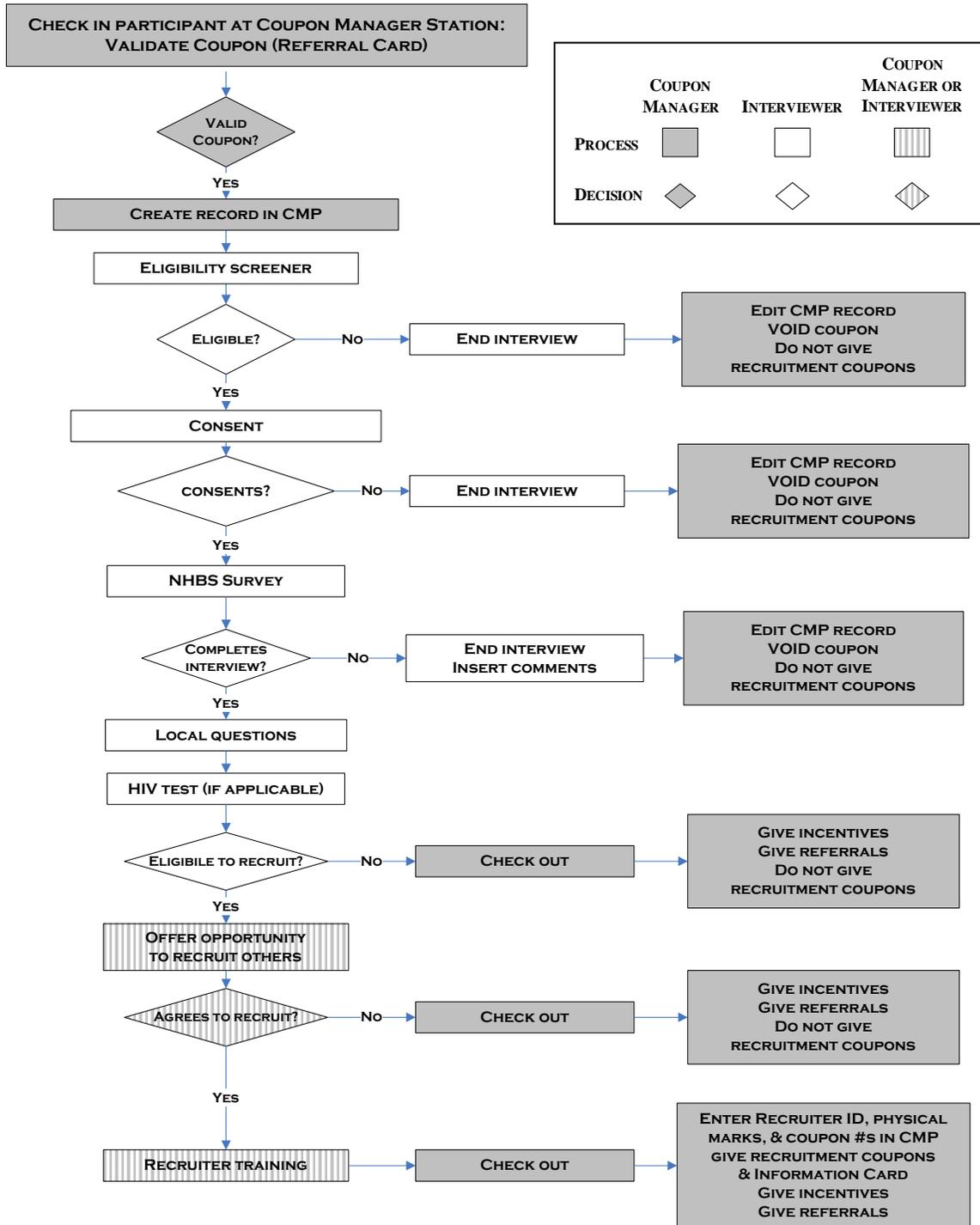
#### 7.2a Coupon Manager Program

The CMP is a software program that will be used during the check-in and check-out processes. This program has three main functions:

- 1) **Link recruiters with their recruits:** Each participant's data is linked to that of his recruits by their coupon numbers. This link is necessary to monitor the growth of recruitment chains and to analyze data using specialized RDS software programs, like the RDS Analyst (RDS-A) or the RDS Analysis Tool (RDSAT).
- 2) **Manage recruiter rewards:** The CMP tracks the rewards owed to participants for successfully recruiting others and ensures that participants are not paid for recruiting those who are not eligible or do not complete the interview.
- 3) **Collect responses to the *Recruiter Questions*:** The *Recruiter Questions* are used to measure non-response bias by asking about the demographic characteristics of individuals who refused to take coupons from the participant and the reasons why they refused. The CMP displays these questions when a participant returns to claim his rewards for recruiting others. The *Recruiter Questions* will be discussed further in **Section 8.3** of this manual.

Detailed instructions on using the CMP can be found in the *NHBS Coupon Manager Training Materials* on the NHBS Data Coordinating Center (DCC) data portal. The CMP should be installed on a laptop or desktop computer and kept at the "coupon manager

**Figure 7.1 – Check-in, interview, and check-out procedures**



station,” an area of the field site designated for checking in and checking out participants. A staff member should be assigned to operate the CMP and manage all operational activities at the coupon manager station; this person is referred to as the “coupon manager.” The coupon manager station should be stocked with all supplies needed for check-in and check-out activities, including an appointment book (if used), a CMP Log (see below), coupons, and incentives (if given by the coupon manager).

Project sites should adhere to the following safety and security measures when operating the CMP:

- The coupon manager should never be alone or in an isolated area.
- The CMP should never be left open and unattended, and the computer screen should never be visible to participants.
- Only a limited number of project staff should have access to the CMP.

Since all data collection software can experience errors and data loss, project sites should keep a CMP log, which is a hard copy of pertinent information entered into the CMP, such as the date of the interview, the participant’s coupon (or referral card) number, the interviewer ID, and the numbers on the recruitment coupons given to the participant. Please see **Appendix J** for a model CMP Log. Furthermore, at the end of each day of field site operations, project sites should back-up their CMP database to a secure location, like an external drive or network. Important participant information, like recruiter IDs and physical marks, are stored only in the CMP and would be lost if there was a software malfunction and the CMP was not backed up.

### **7.2b Participant Tracking Form**

Project staff should use the Participant Tracking Form to document and track the operational activities completed by each participant. The form should also be used to record HIV testing information and data edits for subsequent entry into the HIV Test Results Log and the Data Error Log on the DCC data portal. The form is helpful because it provides a hard copy of completed activities in the event of data loss, facilitates communication among project staff, and assists with data management. To tailor the form for local operations, project sites may add any additional fields they consider necessary.

## **7.3 Check-in**

With RDS, the enrollment process begins with the potential participant checking in at the coupon manager station. This section describes the steps the coupon manager should follow to check in someone.

### **7.3a Validate coupon or referral card**

The coupon manager should first greet the potential participant and ask him for his coupon (or referral card). If appointments are used, the coupon manager should verify the potential participant's appointment date and time. The coupon manager should then check the "Activation Date" (if applicable) and the "Expiration Date" on the coupon.

- ***If the coupon has not yet become active***, the coupon manager should return the coupon to the person and ask him to return after the activation date or on a scheduled appointment date.
- ***If the coupon has expired***, the coupon manager should not return the coupon to the person. Instead, the coupon manager should search the CMP for the coupon number and once located, change the status of the coupon to "Expired" if the CMP has not already changed the status automatically. The coupon manager should then mark the coupon "***EXPIRED***" and file it in the weekly folder or envelope. He should explain to the person that his coupon has expired:

*"I'm sorry, but your coupon has expired. We can't interview anyone with an expired coupon."*

- ***If the coupon has expired but local policy allows people with expired coupons to be interviewed***, the coupon manager should create a CMP record for the person as described in **Section 7.3b** below. Even if the CMP has automatically changed the status of the coupon to "Expired," the CMP will still allow the coupon manager to change the status to "Submitted" and create a CMP record.

Eligibility screening should take place during the interview and not during check-in. However, the coupon manager can deny enrollment to potential participants in the following situations:

- ***If the person does not have his coupon with him***, he cannot be interviewed under any circumstances. The coupon manager should make this clear to the person:

*"I'm sorry, but we can't interview you if you don't have your coupon with you. We'll have to reschedule your interview for another day. Please remember to bring your coupon with you next time."*

- ***If the person appears too intoxicated to consent to the interview or to complete it***, the person's coupon should be returned to him and his appointment should be re-scheduled for another day. The coupon manager

should use his own judgment as to how to best handle the situation and avoid confrontation. He could politely reply:

*“I’m sorry, we won’t be able to see you today. Can we reschedule your appointment for another day?”*

- **If the person is recognized as a previous participant**, the coupon manager should confiscate the coupon and tell the person that he cannot participate more than once. The coupon manager should search the CMP for the coupon number, and once located, change the status of the coupon to “Void” and record a note that the coupon was returned by a “Previous Participant.” He should then mark the coupon “VOID” and file it in the weekly folder or envelope.

The coupon manager should never presumptively screen out potential participants because they are visually- or hearing-impaired. Potential participants with these, or other disabilities should undergo eligibility screening by an interviewer to determine whether they are linguistically and cognitively able to complete the survey.

### **7.3b Create record in the CMP**

After validating the potential participant’s coupon (or referral card), the coupon manager should enter the coupon (or referral card) number in the CMP to create a record for that person. The CMP will verify the coupon number and indicate whether the coupon is newly submitted, expired, or void. The coupon manager should then enter the following information in the CMP:

- **Interviewer ID:** The interviewer ID is the ID of the interviewer assigned to the potential participant. It is also helpful for the coupon manager to write the interviewer ID on the potential participant’s coupon (or referral card).
- **Photo coupon:** The coupon manager should indicate if the potential participant is using a photo coupon by checking the “Photo coupon submitted” box.
- **Physical marks:** To help identify previous participants, project sites may choose to collect a potential participant’s distinguishing physical marks during check-in rather than during check-out (see **Section 7.8b** for further information on collecting physical marks). Sites could then search the CMP to determine whether the potential participant has the same distinguishing physical marks as do any previous participants.



It is important to *always* create a record in the CMP before the potential participant is screened by an interviewer. This ensures that there is a corresponding CMP record for each survey record.

### **7.3c Fill out Participant Tracking Form**

As part of the check-in process, the coupon manager should also begin to fill out a Participant Tracking Form for the person by recording the following information:

- Date
- Interviewer ID
- Survey ID (same as the coupon or referral card number)
- Whether or not the participant is a seed
- Field Site ID

### **7.3d Escort participant to interviewer**

Once the coupon manager has checked in the participant, he should introduce the participant to the assigned interviewer. He should also give the Participant Tracking Form and coupon (or referral card) to the interviewer. If the interviewer knows the person, the coupon manager should assign a different interviewer.

## **7.4 NHBS Interview**

This section provides a brief overview of the interview process and the activities that should be completed by the interviewer. Full details on the interview process are provided in the *NHBS Round 5 Interviewer Guide*. Before conducting any interviews in the field, all interviewers **must** read the guide to become familiar with the interview process and learn their responsibilities as interviewers.

The NHBS interview is composed of three main sections: the eligibility screener, the consent, and the survey. The interview is conducted using a portable computer and the entire process takes approximately 1 hour to complete. All interviews must be conducted in an area that affords privacy and protects the participant's confidentiality. Other individuals should not be able to hear the interviewer's questions nor the participant's responses.

### **7.4a Eligibility screener**

The eligibility screener is designed to ensure that participants meet the general NHBS and HET cycle-specific eligibility criteria. The portable computer will automatically determine whether someone is eligible to participate based on the following criteria:

#### ***General NHBS eligibility:***

- Is 18 years of age or older

- Has not previously participated in the current project cycle
- Lives in the participating MSA or Division
- Is able to complete the interview in English or Spanish
- Is able to provide informed consent

***HET cycle-specific eligibility:***

- Is between the ages of 18 and 60 years old
- Is male or female (transgender persons are ***not*** eligible to participate in NHBS-HET cycles)
- Has had vaginal or anal sex with someone of the opposite gender in the past 12 months

Individuals who do not meet one or more of the eligibility criteria will be told, “the computer has not selected you to participate in the health survey.” When this occurs, the interviewer should end the interview and thank the ineligible person for his time. The interviewer should then follow the prompts in the portable computer to ensure that the interview is ended correctly and the data are saved. After closing the Computer Assisted Personal Interview (CAPI), the interviewer should escort the ineligible person to the coupon manager station, give the coupon manager the person’s coupon, and tell the coupon manager that the person was not selected for the survey. The coupon manager should indicate in the person’s CMP record that his recruiter is not owed a reward, mark the coupon “*USED*,” and file the coupon in the weekly folder or envelope.



Interviewers and other project staff should not share the eligibility criteria with participants nor tell them that they are being screened for eligibility. Participants should always be told that the computer will determine if they have been selected to participate in the survey.

***Previous participants***

The coupon manager can prohibit previous participants from enrolling again if he recognizes them during check-in. Yet, sometimes previous participants are not recognized until after they have been checked in. If this happens, project staff should report their suspicions to the field supervisor. If the field supervisor concurs, the field supervisor should tell the person’s interviewer to indicate during eligibility screening that the person cannot complete the survey because he is a “known previous participant.” The portable computer will then automatically make the person ineligible.



Only the field supervisor, in consultation with project staff, can make the final determination that a person is a previous participant; project staff should not

decide this on their own.

### ***Intoxicated participants***

During screening, if an interviewer determines that a participant is too intoxicated with alcohol or drugs to competently consent to participate in NHBS or to understand the survey, the interviewer should indicate that the person is not alert and capable of completing the survey because he is “not able to understand or consent.” As with previous participants, the portable computer will automatically make the person ineligible.

### ***Participants outside the eligible age range***

If project staff suspect that a potential participant is outside the eligible age range (i.e., the participant is less than 18 years old or greater than 60 years old), they should report their suspicions to the field supervisor. The field supervisor and the project staff should then discuss whether the person appears to be too young or too old to participate in NHBS. If the field supervisor and the project staff agree that the person appears to be less than 18 years old, the field supervisor should tell the person’s interviewer to indicate during eligibility screening that the person cannot complete the survey because his “reported age is not plausible (< 18 years old).” On the other hand, if they agree that the person appears to be greater than 60 years old, the field supervisor should tell the person’s interviewer to indicate that the person cannot complete the survey because his “reported age is not plausible (> 60 years old).” The portable computer will then automatically make the person ineligible.



Only the field supervisor, in consultation with project staff, can make the final determination that a person is outside the eligible age range; project staff should not decide this on their own.

Project sites that identify a pattern of individuals outside the eligible age range attempting to participate in the survey should discuss the matter with their CDC project officer. If the situation is deemed problematic enough, it may be necessary to lower the threshold of suspicion for screening out individuals suspected of being too young or too old.

## ***7.4b Consent***

The interviewer should read the consent form to each eligible participant and answer any questions the participant may have. Depending on local Institutional Review Board (IRB) requirements, project sites may choose to have the interviewer paraphrase the information in the consent form instead of reading it verbatim. If the local IRB requires informed consent to be obtained before a potential participant is screened for eligibility, sites must do so. Consent to participate in NHBS should be obtained verbally and recorded in the portable computer (some local IRBs may also require sites to maintain written documentation of consent). Since all participants in NHBS *must* remain anonymous, project sites cannot require participants to provide their names or other

personal identifiers as part of the consent process. Participants can consent to either: 1) the NHBS survey *or* 2) the NHBS survey and an HIV test. If applicable, participants can also consent to hepatitis testing, STI testing, or having their blood specimen stored for future testing. Further details on the consent process are provided in the *NHBS Round 5 Interviewer Guide*.



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

Those who choose not to participate in the survey should be thanked for their time and asked to share the reasons they do not wish to participate. The interviewer should then follow the prompts in the portable computer to end the interview and save the data. After closing the CAPI, the interviewer should escort the person to the coupon manager station, give the person's coupon to the coupon manager, and tell the coupon manager that the person has not provided consent. The coupon manager should indicate in the person's CMP record that his recruiter is not owed a reward, mark the coupon "USED," and file the coupon in the weekly folder or envelope.

### ***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. This will give the participant a second chance to consent to HIV testing if he initially declined testing but then changed his mind during the survey.

### ***7.4c NHBS survey***

The interviewer should use a portable computer to administer the NHBS survey to eligible people who consent to participate. The survey takes approximately 40 minutes to complete and consists of the *Network Questions*, the core questionnaire, and if applicable, any local questions developed by the project site. To minimize the burden on participants, the local questions section should not take more than 10 minutes to administer.

Interviewers, as well as project staff responsible for interviewer training and evaluation, should read the *NHBS Round 5 Interviewer Guide* for important information on using the survey software, guidance on standardized interviewing, and explanations of the survey questions.

### ***Network questions***

RDS studies must meet certain assumptions to generate unbiased population estimates (see **Section 1.4b** of this manual). The *Network Questions* are based on three of these assumptions:

- 1) **Participants know one another as members of the target population:** The first *Network Question* asks the participant to classify his relationship to the person who gave him his recruitment coupon to determine whether the participant and his recruiter know one another or are “strangers.” Recruitment by a stranger violates the RDS assumption that “participants know one another.”
- 2) **Participants randomly recruit other participants from their personal networks:** The second *Network Question* asks the participant to estimate both the number of males and the number of females he knows and has seen in the past 30 days. The gender composition of the participants’ personal networks can be compared to the gender composition of the sample to help determine whether participants recruit randomly or preferentially from their personal networks.
- 3) **Participants can accurately report their personal network size:** The third *Network Question* automatically sums the number of males and females that the participant knows and asks him to confirm that number. This is his personal network size. During RDS analysis, participants with smaller networks are given more weight than participants with larger networks to compensate for their having a lower probability of being recruited (participants with smaller networks know fewer people who could potentially recruit them).

### ***Core questionnaire***

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

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

Additional interviewer instructions, explanations of the core survey questions, and procedures for coding the validity of the participant’s responses are contained in the *NHBS Round 5 Interviewer Guide*.

### ***Ending an interview early***

If a participant does not want to continue the survey, is too intoxicated to continue, or is behaving inappropriately, the interviewer should end the interview and record the reason for stopping the interview in the notes section of the Participant Tracking Form. The interviewer should then escort the participant to the coupon manager station and return the participant’s coupon to the coupon manager. The coupon manager should indicate in

the participant's CMP record that his recruiter is not owed a reward, mark the coupon "USED," and file the coupon in the weekly folder or envelope. A project site's IRB may require that the recruiter receive a reward if the participant was eligible and started the interview, but did not complete it. In this case, the coupon manager should indicate in the participant's CMP record that his recruiter is owed a reward.

The participant should not be given an HIV test, he should not be paid any incentives, and he should not be given coupons to recruit others. Sites that are required to provide an interview incentive by their local IRB may do so, but they *cannot* distribute recruiter coupons to the participant.

***Participants who have not had sex with someone of the opposite gender within the past 12 months***

In the core questionnaire, participants will again be asked about opposite-gender sex partners to confirm their eligibility. If a participant has not had sex with someone of the opposite gender within the past 12 months, the portable computer will automatically jump to the end of the core questionnaire so that the interview can be stopped. Unlike a participant who has his interview stopped for a reason other than eligibility (see "Ending an interview early" above), a participant found to be ineligible during the core questionnaire can still receive an HIV test if he consented to one and he should be paid interview and test incentives. The participant's recruiter should also be paid a recruiter reward. Nevertheless, since the participant has not recently had sex with someone of the opposite gender, he should *not* be given coupons to recruit others.

## ***7.5 Data Error Log***

The Data Error Log on the DCC data portal provides documentation of any corrections that need to be made to the data, such as the survey ID (please see the *NHBS-HET5 Data Management Training Materials*). If mistakes are made or problems occur during an interview, the interviewer should use the data edits section of the Participant Tracking Form to record the name of the problematic variable, the incorrect value (old value) for the variable, and the correct value (new value) for the variable. At the end of each day, the field supervisor should collect all the Participant Tracking Forms, review the data edits with the interviewers, and make sure the information on the forms is complete. If the same errors are made repeatedly, additional training should be provided to the interviewers to help them avoid future occurrences.

The data edits on the Participant Tracking Forms should be entered into the Data Error Log on the DCC data portal on a *daily* basis. Prompt entry of this information will help the data manager clarify data errors and corrections with the interviewers or the field supervisor if the project staff need to recall a specific problem.

## **7.6 HIV Counseling, Testing, and Referral**

This section summarizes the process of conducting HIV counseling, testing, and referral to care as part of NHBS. More detailed guidance on this process is provided in **Chapter 9** of this manual.

### **7.6a Counseling and testing**

After the interview is completed, participants who have consented to HIV testing should receive counseling and an HIV test. Project sites must conduct all HIV counseling and testing in accordance with the *NHBS Round 5 Model Surveillance Protocol* and their local testing policies. Most importantly, a participant **cannot** receive HIV counseling or his test result before he finishes the core questionnaire. Some sites are not required to provide pre-test counseling before they collect a specimen for HIV testing. These sites may collect a specimen for rapid HIV testing prior to starting the survey if they run the test in an area that is separate from the interview space and they adhere to the prohibition on counseling and providing test results before the end of the core questionnaire. This will allow these sites to run a participant's rapid HIV test while he is being interviewed. When the participant completes his interview, he would then receive HIV counseling and his rapid test result.



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

### **7.6b Referrals to care and services**

All participants with positive HIV test results, including preliminary positive rapid test results, should be referred to appropriate medical care and HIV case management services when they receive their test results (see **Section 9.8** of this manual). Participants who do not consent to HIV testing, but who report a previous positive test result should also be offered any needed care and service referrals.

## **7.7 Recruiter Training**

Recruiter training can be provided by the interviewers or the coupon manager. In previous RDS cycles, some project sites had the interviewers provide the recruiter training and then the coupon manager reviewed the instructions with the participant to reinforce them. If sites prefer, they can provide recruiter training after conducting the interview but before administering the HIV test.

### **7.7a Eligibility to recruit others**

At the end of the core questionnaire, the portable computer will display a message to the interviewer indicating whether the participant can receive coupons to recruit others.

Participants can recruit others if: 1) they were eligible and completed the core questionnaire, 2) they provided valid responses during the interview (i.e., the interviewer did not record his confidence in the participant's responses as "not confident at all"), and 3) they met the HET definition (had a household income at or below 150% of the HHS poverty guidelines adjusted for geographic differences in the cost of living, had not injected drugs in the past 12 months, and if a man, had not had sex with another man in the past 12 months).

At the end of the core survey, the portable computer will automatically display a message indicating whether the computer selected the participant to receive coupons. The interviewer should record this information on the Participant Tracking Form.

### **7.7b Offering the chance to recruit others**

When offering participants the chance to recruit others for the project, project staff should emphasize the following points:

- Recruiting is completely *voluntary*. Participants do not have to recruit others if they do not want to, and they will still be paid for completing the interview and testing for HIV.
- Recruiting is *important* to the project. The success of the project depends on people recruiting others to accrue a large sample of people from throughout the city.
- They have a chance to *earn* \$*<recruiter reward amount>* per person recruited, up to a maximum number of people recruited.

Project staff should *not* discuss the sale of coupons during recruiter training because this may give participants an idea they did not previously have. Nonetheless, if coupon selling becomes a problem for a project site, the site may choose to intervene by warning participants not to sell their coupons and by underscoring the negative repercussions of doing so. For example, during recruiter training, participants could be told:

*"Coupons cannot be sold. If the coupons are sold, they will be voided and no one will be able to use them to participate in the survey. You will not be paid for anyone with a coupon that has been sold and voided."*

If the interviewer provides the recruiter training and the participant decides not to recruit others, the interviewer should use the Participant Tracking Form to communicate to the coupon manager that the participant does not want to be a recruiter.

### **7.7c Conducting recruiter training**

During recruiter training, project sites should explain to participants how to properly recruit other people for the project and how to obtain their recruiter rewards. To motivate

recruiters and promote community buy-in, sites should also underscore the benefits of the project to participants and the community. Recruiter training is key to the success of RDS. If training is incomplete or unclear, recruiters will be less effective and recruitment chains may not grow. A model recruiter training script is included in **Appendix Q**, but sites may prefer to use talking points instead (see **Appendix R**). Sites should tailor the script or talking points to match their local operations and, if they plan on conducting interviews in Spanish, they should also translate the recruiter training documents into Spanish.

To reinforce recruiter training, sites are encouraged to employ a variety of different means. For example, they could show participants an instructional video while the participants are waiting to be interviewed. A video that emphasizes how participants can earn additional money as recruiters is very likely to capture participant interest. As another example, when the interviewers provide the recruiter training, it is helpful to have the coupon manager ask the participants questions about the recruitment process to ensure that they understand what is required.



During recruiter training, project staff should emphasize that participants should only recruit people they know and *not* strangers. One of the assumptions of RDS is that participants know one another as members of the target population.

The number of coupons given to each recruiter may vary throughout the course of the project cycle (see **Section 6.3a** of this manual). Accordingly, the recruiter training script may have to be updated to let recruiters know the current number of coupons being distributed. Toward the end of data collection, project sites should also tell recruiters when they will stop giving coupons out and when they plan to end enrollment.

## **7.8 Check-out**

With RDS, the interview ends with check-out at the coupon manager station. This section describes the steps that should be taken to complete the check-out process.

### **7.8a Participant information**

When a participant is ready to check out, the interviewer or test counselor should escort him to the coupon manager station, and the staff member should relay the following information to the coupon manager through the Participant Tracking Form:

- Whether the participant was eligible for the survey
- Whether the participant consented to the survey
- Whether the participant consented to the HIV test

- *If applicable*, whether the participant consented to other tests, such as hepatitis or STI tests
- *If applicable*, whether the participant consented to blood storage
- Whether the participant completed the interview
- Whether an HIV test specimen was obtained
- *If applicable*, whether a specimen was obtained for other tests, such as hepatitis or STI tests
- *If applicable*, whether a specimen was collected for blood storage
- Whether the participant is eligible to recruit others and agreed to do so
- *If applicable*, the number of coupons the participant should receive

### **7.8b Coupon manager duties**

The coupon manager's responsibilities during the check-out include editing the CMP record, distributing coupons, reinforcing (or providing) recruiter training, giving out incentives, and in some cases, providing prevention materials and offering referrals.

#### ***Editing the CMP record***

Once the coupon manager has received the participant information listed above, he should use the participant's survey ID (coupon number) to search for the participant's record in the CMP. The coupon manager should then edit the participant's CMP record:

- ***If the participant was not eligible, did not consent to the survey, or did not complete the survey***, the coupon manager should indicate in the participant's CMP record that his recruiter is not owed a reward, mark the participant's coupon "*USED*," and file the coupon in the weekly folder or envelope. A project site's IRB may require that the recruiter receive a reward if the participant was eligible and started the interview, but did not complete it. In this case, the coupon manager should indicate in the participant's CMP record that his recruiter is owed a reward. Participants who are not eligible, do not consent to the survey, or do not complete the survey ***cannot*** recruit others and should not be given coupons.
- ***If the participant completed the survey but did not agree to recruit others***, the coupon manager should indicate in the participant's CMP record that his recruiter is owed a reward, mark the participant's coupon "*USED*," and file the coupon in the weekly folder or envelope.

- ***If the participant completed the survey and agreed to recruit others***, the coupon manager should indicate in the participant’s CMP record that his recruiter is owed a reward, mark the participant’s coupon “*USED*,” and file the coupon in the weekly folder or envelope. Since the participant agreed to recruit others, the coupon manager should enter the participant’s recruiter information into his CMP record:

- Step 1) The coupon manager should explain to the participant that he needs to collect some additional information that will be used to identify the participant when he returns for his recruiter rewards. This information will help ensure that no one else can claim the participant’s rewards.
- Step 2) The coupon manager should create a recruiter ID for the participant based on the questions in **Table 7.1** and enter the ID in the participant’s CMP record. Since the smallest data entry error can make participant identification difficult or impossible, the coupon manager should be extremely careful entering recruiter IDs in the CMP and he should double-check the entries. Similarly, the coupon manager should ask participants to be consistent in their responses to the recruiter ID questions, especially if they have multiple aliases. It may be helpful to show the participants a flashcard with the list of questions used to create the recruiter ID to improve the accuracy of their responses.
- Step 3) The coupon manager should ask the participant to show him any distinguishing “physical marks,” like tattoos or birthmarks, that could be used for future identification (see **Table 7.2** for instructions on collecting and recording physical marks). He should also examine the participant’s face, neck, and arms for any other obvious “physical marks.” Relevant “physical marks” should be entered in the participant’s CMP record.
- Step 4) The coupon manager should determine how many coupons the participant should be given to recruit others and enter the numbers on the assigned coupons in the participant’s CMP record.
- Step 5) If necessary, the coupon manager can add comments to the participant’s CMP record that could help with participant identification or project management.



Some project sites prefer to collect the recruiter ID (Step 2) or “physical marks” (Step 3) during check-in when they are creating a CMP record for a potential participant (see **Section 7.3b** above). These sites use this information to help verify that the potential participant is not a previous participant.

**Table 7.1 – Recruiter ID questions**

- 1) What are the **FIRST 2** letters of **YOUR LAST** name?
- 2) What is the **FIRST** letter of **YOUR FIRST** name?
- 3) What is the **FIRST** letter of **YOUR MOTHER’S FIRST** name?
- 4) In which **MONTH** were you born? (2 digits)
- 5) What are the **LAST 2** digits of your **YEAR** of birth?
- 6) What is your gender?
- 7) What racial/ethnic group do you consider yourself to be in?

### ***Distributing coupons***

If the participant agrees to recruit others, the coupon manager should give him coupons and reiterate that he will only receive rewards for the people he recruits who are selected and complete the survey. The coupon manager should also give the participant an information card with the hours, location(s), and phone number of the field site(s). Participants can call the field site to see if they are owed any recruiter rewards (the coupon manager can use the participant’s survey ID or recruiter ID to locate his CMP record). Please see **Appendix P** for a model information card and **Appendix S** for instructions on how to create the cards. Project sites should also keep track of the coupons given out using the CMP Log (**Appendix J**).



Some participants may know fewer people than the number of coupons being distributed. For example, a participant may report that in the past 30 days he has only seen 2 people he knows, but the project site is giving 3 coupons to each recruiter. Regardless of how many people they know, **all** participants should be given the maximum number of coupons to which they are entitled because their pool of potential recruits may actually be larger than the number of people they know and have seen in the past 30 days.

### ***Reinforce recruiter training***

The coupon manager should verify that the participant understands how to use his coupons to recruit other people for the project. It is best to ask the participant open-ended question such as:

*“Can you explain to me what you need to do with these coupons?”*

*“Can you tell me who you need to give these coupons to?”*

The coupon manager should ask additional questions, if necessary, to ensure that the participant fully understands the recruitment process and knows that coupons should only be given to people he knows and *not* to strangers. The coupon manager should also remind the participant of any coupon activation or expiration dates.

**Table 7.2 – Collecting and recording physical marks**

The coupon manager should explain to the participant why it is important to collect his physical marks:

*“So that I can identify you when you come back to get paid for giving out your coupons, I need to ask if you have any tattoos or other physical marks, such as scars or birthmarks. Like the ID we just created, this information will prevent someone else from claiming your money.”*

Project sites should develop a protocol for collecting physical marks in a systematic manner. For example, the coupon manager could start with the face, then check the neck, the right arm, and the left arm. The coupon manager should also ask if the participant has any physical marks in other areas of his body that are not readily visible. However, the coupon manager should only examine and note physical marks that are in areas of the body that are not considered “private.” For example, it would be appropriate to view a tattoo on a female participant’s ankle, but not on her breast. A simple rule of thumb is that if an area is not visible when the participant is wearing a bathing suit, it should *not* be viewed.

Useful physical marks for identifying participants are mostly permanent and include:

- Tattoos
- Scars (other than from injecting)
- Visible birthmarks
- Height
- Eye color

In contrast, physical marks that can be temporary, such as hair color, facial hair, and piercings, are not reliable and should not be recorded. Physical marks that the coupon manager has not actually viewed should also not be recorded. When entering physical marks in the CPM, the coupon manager should describe the physical mark in as much detail as possible, noting its color(s), shape, and location on the body. For example, “Red ‘I ♥ Terri Lou’ tattoo on inner left forearm.”

### ***Giving out incentives***

The coupon manager (or field supervisor) should then give the participant the incentive for completing the survey and if applicable, the incentives for receiving the HIV and other tests. Participants do not have to agree to recruit others to obtain their incentives. To reduce the likelihood that participants provide a kickback to the person who recruited them, project sites could tell participants that the incentives are all theirs and that participants are not responsible for paying their recruiters. Sites should emphasize that the project is responsible for paying a participant's recruiter. For example, sites could tell participants:

*“All the money you received belongs to you; you do not have to share it with the person who gave you your coupon. We will pay that person for recruiting you; you do not owe them any money.”*

After the participant is paid, the coupon manager should document payment of each incentive in the participant's CMP record.



As mentioned previously, some local IRBs may require that project sites provide incentives to participants who are eligible and start the survey, but do not complete it.

The *NHBS Round 5 Model Surveillance Protocol* recommends an incentive 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, project sites are free to adjust these amounts based on standards in their local communities. Because the published literature, as well as experience from previous NHBS cycles, has demonstrated that cash is the most effective type of incentive for RDS projects, sites are required to provide cash incentives for NHBS.

That being said, project sites may provide an alternative form of remuneration, like a gift card or a gift check, if local policy prohibits the use of cash incentives *or* formative assessment shows that low-income persons in the project area prefer an alternative form of remuneration. 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 low-income persons in the project area (e.g., gift cards should only be from stores that are locally accessible and well regarded). To use an alternative form of remuneration instead of cash, sites must provide a written justification to their CDC project officer and they must receive CDC approval. **Table 7.3** shows the information sites should include in their justifications.

When a prospective participant is found to be ineligible, project sites may wish to provide a small thank you gift, such as bus or subway fare. In addition, sites that are conducting laboratory-based HIV testing and have local funds available (i.e., funds that do not come from the NHBS cooperative agreement) may compensate participants who return for their final HIV test results. Sites should specify the amount of compensation in their consent

form and they must obtain approval from their CDC project officer.

**Table 7.3 – Justifications for using an alternative form of remuneration**

<b>Justifications from project sites that are prohibited from using cash incentives</b>	<b>Justifications from project sites where low-income persons prefer an alternative form of remuneration</b>
<ol style="list-style-type: none"> <li>1) Describe the local policy that prohibits cash incentives for NHBS</li> <li>2) Show that the alternative form of remuneration is considered desirable by low-income persons in the project area</li> <li>3) Show that the alternative form of remuneration will not bias the sample because it is more desirable to some subpopulations of low-income persons</li> <li>4) Show that the alternative form of remuneration will not impede the ability of the project site to reach the sample goal of 500 persons who meet the HET definition</li> </ol>	<ol style="list-style-type: none"> <li>1) Show that the alternative form of remuneration is considered more desirable than cash by low-income persons in the project area</li> <li>2) Show that the alternative form of remuneration will not bias the sample because it is more desirable to some subpopulations of low-income persons</li> <li>3) Show that the alternative form of remuneration will not impede the ability of the project site to reach the sample goal of 500 persons who meet the HET definition</li> </ol>

***Providing prevention materials and offering referrals***

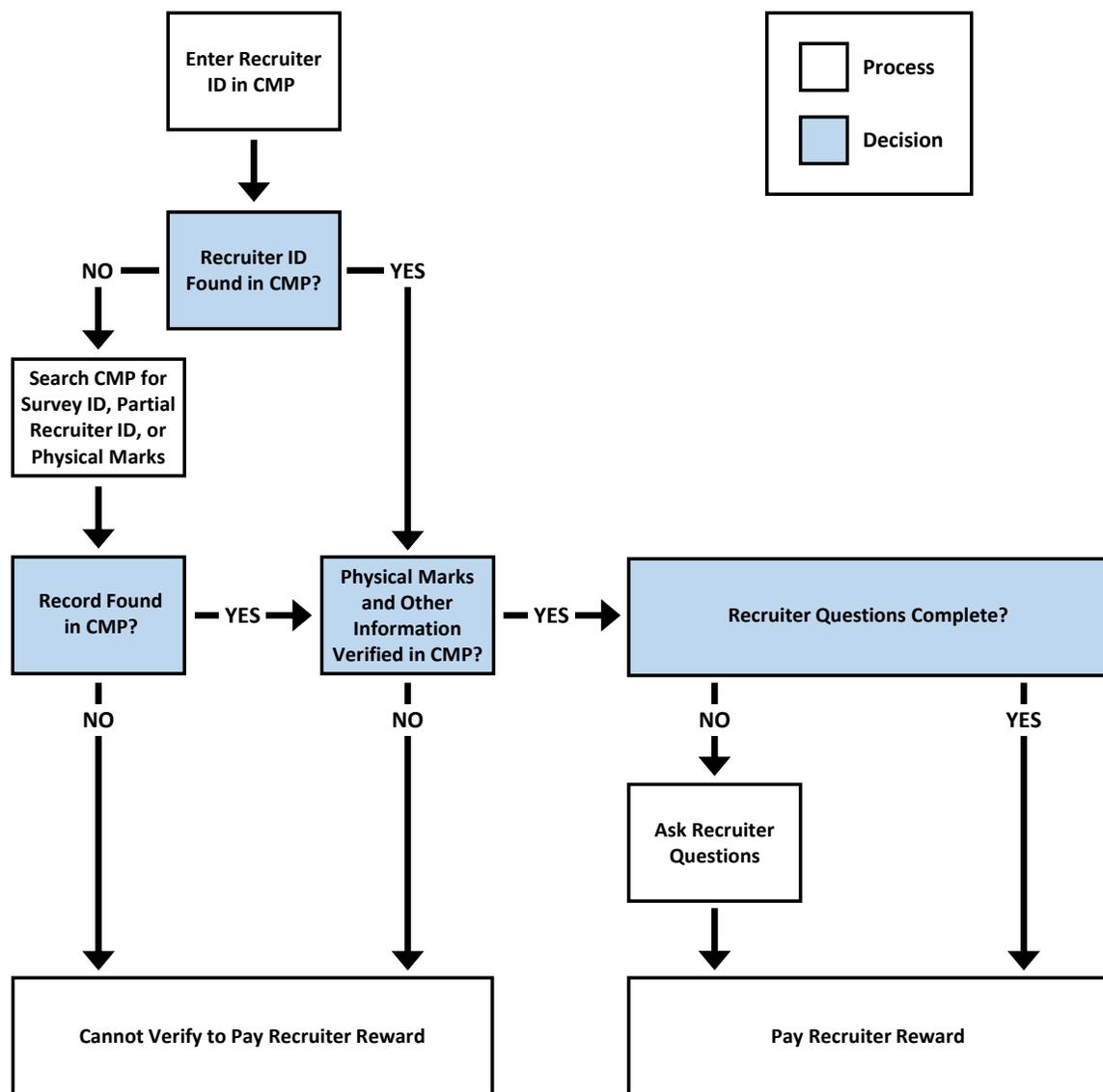
Providing participants with prevention materials and offering them referrals are important components of NHBS; they facilitate rapport with participants and engender trust with the local community. Project sites should provide participants with prevention materials such as condoms, lubricants, and informational pamphlets on HIV, STI, and hepatitis prevention.

Participants in need of health care or social services should be offered referrals to the appropriate local providers. Based on their formative assessment, project sites should identify those health care and social service providers most commonly used by low-income persons in their communities. Sites should maintain a list of the names of these providers and their contact information so that they can readily make any necessary referrals. This list should include HIV and STI clinics, agencies that offer free HIV tests, health clinics, mental health service providers, substance use disorder treatment centers, domestic violence shelters and programs, housing agencies and shelters, and other social service organizations that provide financial assistance or assistance with food, clothing, utilities, or employment.

### 8.1 Overview

The process for asking the *Recruiter Questions* and paying recruiter rewards is shown in **Figure 8.1**. These activities are performed by the coupon manager using the Coupon Manager Program (CMP). The CMP identifies unique participants, records their responses to the *Recruiter Questions*, and determines if they are owed recruiter rewards.

**Figure 8.1 – Recruiter Questions and recruiter reward process**



## **8.2 Verify Participant's Identity**

The first step in the process of asking the *Recruiter Questions* and paying recruiter rewards is to verify the participant's identity. The coupon manager should enter the recruiter ID into the CMP by asking the series of questions used to initially create the ID (see **Table 7.1** of this manual). The CMP will then automatically locate the participant's record. To verify the participant's identity, the coupon manager should confirm that the participant's physical marks match those listed in his record. The coupon manager should also check whether the participant's appearance is consistent with the year of birth, gender, and race/ethnicity in his recruiter ID.

### **8.2a Unable to locate recruiter ID in the CMP**

Sometimes the CMP may not be able to locate a record associated with a recruiter ID because:

- the participant is now providing responses that are different from those he provided when his recruiter ID was originally created (e.g., using an alias),
- the recruiter ID was initially entered in the CMP incorrectly, *or*
- the person trying to claim the recruiter reward is not the participant.

When a recruiter ID cannot be found in the CMP, the coupon manager should first try to re-create the recruiter ID by asking the questions again. Showing the participant a list of the questions can improve accuracy and is often helpful. If the record still cannot be located, the coupon manager should search the CMP for the participant's survey ID (coupon number) or a partial recruiter ID that contains information the participant is most likely to remember, such as his month of birth, year of birth, gender, and race/ethnicity. For example, instead of using the full recruiter ID "JOMJ1075MW" to search for the participant's record, the coupon manager could just use "1075MW." Alternatively, the coupon manager could search the CMP for the participant's physical marks.

Whenever a record is located by searching for a survey ID, partial recruiter ID, or physical marks, the coupon manager should confirm the participant's identity by checking the rest of the information in the participant's record, including his date of interview, month and year of birth, gender, race/ethnicity, and physical marks. In addition, if the recruiter ID was initially entered in the CMP incorrectly, the coupon manager should correct it.

If a recruiter or survey ID cannot be located in the CMP or the person's physical marks or demographic information do not match those listed in the record, the coupon manager should tell the person claiming the recruiter reward that there is not enough information to verify his identity, and as a result, he cannot be paid.

### 8.3 Ask Recruiter Questions

The *Recruiter Questions* are used to measure non-response bias by asking the participant about any individuals who refused the coupons they were offered (see **Table 8.1**). Once the coupon manager has verified the participant’s identity, the coupon manager should check the status of the *Recruiter Questions* in the participant’s record. If the status is listed as “Incomplete,” the coupon manager should ask the *Recruiter Questions* and enter the participant’s responses in the CMP. Since many participants only return to collect their rewards once, it is very important for the coupon manager to ask the *Recruiter Questions* the first chance he has.

**Table 8.1 – Recruiter Questions**

How many of the coupons did you give out?
Has anyone refused the coupons?
Of those who refused coupons, how many were male?
Of those who refused coupons, how many were female?
What is the race or ethnic background of those who refused coupons? That is, how many were American Indian or Alaska Native, Asian, Black or African-American, Hispanic or Latino, Native Hawaiian or Pacific Islander, or White?
Which of the following are reasons that people who refused gave you about why they did not take a coupon? ( <i>Read each one, check all that apply</i> ) <ul style="list-style-type: none"><li>● They didn’t have time</li><li>● They didn’t live in the area</li><li>● They didn’t trust you (recruiter)</li><li>● They don’t like research/surveys</li><li>● They already participated in this survey</li><li>● Some other reason (please specify): _____</li></ul>

As long as the status of the *Recruiter Questions* remains “Incomplete,” the questions should be asked and the responses confirmed *every* time a participant returns to the field

site to collect his recruiter rewards or calls the field site to see if he is owed any rewards. When asking the *Recruiter Questions* a subsequent time, the coupon manager should explain that he may be repeating questions he asked before. The coupon manager can help the participant remember his previous responses by telling him what has already been recorded in the CMP. For example, the first time a participant answers the *Recruiter Questions*, he states that he gave out 2 coupons and 1 person refused a coupon. When he returns for a second time, the coupon manager could say:

*“The last time you were here, you said you gave out 2 coupons. Have you given out any more coupons since that time?”*

*“You also said 1 person refused a coupon. Has anyone else refused a coupon?”*

If additional people have refused coupons, the coupon manager should then ask the remainder of the *Recruiter Questions*. Any inconsistencies in the participant’s responses should also be clarified.

Once the participant has given out all his coupons and answered the *Recruiter Questions*, the status of the *Recruiter Questions* will change to “Complete” and the questions do not need to be asked again.

## **8.4 Verify and Pay Reward**

Participants will receive a reward for each eligible recruit who completes the NHBS survey. The CMP will indicate the amount of the reward owed to the participant. The reward can be paid by either the coupon manager or the field supervisor. After the reward has been paid, the participant’s CMP record should be updated to show that a payment was made. If a participant is not owed a reward, the CMP will display “\$0” as the amount owed. To determine why a reward is not owed, the coupon manager can check the status of a participant’s coupons in his CMP record.

Project sites should consider the following when paying recruiter rewards:

- Reward payments can only be made directly to the participant.
- For safety reasons, rewards should be stored in a locked file cabinet or drawer.
- Participants may call the field site to find out whether they are owed a reward. They can identify themselves by their recruiter ID or their survey ID.
- Participants cannot receive replacement coupons for ineligible recruits. They may, however, receive replacement coupons for lost or stolen coupons if the numbers on those coupons can be identified and voided in the CMP.
- Some local IRBs may require that the participant still receive a reward when

his recruit is unable to complete the survey or chooses to end the interview early.

## 9.1 Overview

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

## 9.2 Testing

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

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

Information about NHBS methods, including the survey and testing, is provided to individuals during the consent process (see **Section 7.4b** of this manual). Consent for participation in each activity must be obtained separately and recorded in the portable computer. If consent is not recorded in the portable computer for a test that was conducted, that test result will not be included in the NHBS data set.



Project staff are not able to change the consent variable in the Data Error Log on the NHBS Data Coordinating Center (DCC) data portal. Consent for HIV and

other testing can only be recorded in the portable computer.

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

### **9.2a HIV testing**

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

Participants who initially decline HIV testing will have another opportunity to consent to testing at the end of the core questionnaire (see the *NHBS Round 5 Interviewer Guide* for further information). This will give the participant a second chance to consent to HIV testing if he changed his mind during the survey. It will also allow the interviewer to make a correction if the interviewer erroneously recorded that the participant declined testing. The HIV testing consent at the end of the core questionnaire is the last opportunity for the participant to provide consent for an HIV test. If the participant decides that he wants an HIV test after the core questionnaire has been completed, project sites may still perform the test, but it will not be considered an NHBS test. Therefore, the HIV test result will not be included in the NHBS data set and the participant should not receive an incentive for the test.

#### ***Rapid HIV testing***

Project sites should conduct rapid testing. Experience with previous NHBS cycles has shown that many participants do not return for their laboratory-based test results since these are usually not available for 1 to 2 weeks. Although a reactive rapid test result is considered preliminary, participants with preliminary positive test results should be immediately referred to care (see **Section 9.8** below). Receipt of a preliminary positive test result may also increase a person's likelihood of seeking additional testing or care.

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

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

Alternatively, project sites may operate under an existing waiver already held by their organization. There are 7 rapid tests that are currently CLIA-waived for use in field settings by non-laboratory staff: Abott Determine, Chembio DPP, Chembio SURE CHECK, Chembio STAT-PAK, bioLytical INSTI, Orasure OraQuick, and Trinity Biotech Uni-Gold. The package insert for each of the 7 rapid tests contains specific instructions for conducting that test, as well as instructions for running test controls. The insert lists the materials included in the test kit, required materials that are not included in the kit, specimen collection procedures, and testing requirements. Prior to the start of HIV testing, project staff who are administering tests or overseeing testing activities must carefully read and understand the package insert. They should also have a copy of the insert readily available at each field site for reference. Rapid testing must be conducted in an appropriate environment with respect to temperature and lighting. These requirements can be found in the package insert and should be adhered to at all times. Rapid testing should also be conducted in an area with adequate workspace.



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

Project sites conducting rapid testing on whole blood specimens collected by fingerstick can find some helpful hints for fingerstick blood collection in **Section 9.4a** (below). Before specimen collection begins, the participant's survey ID number should be recorded on the rapid test device. During rapid test development, the face of the test device should not be visible to any participant. Project sites should conduct rapid testing in an area that is separate from the interview spaces. This will be less disruptive to the interviews and will allow for a more accurate reading of the test results. Nevertheless, if sites must conduct testing in the same spaces as the interviews, they **cannot** collect the test specimen before the core questionnaire is completed (they can collect the specimen either between the core and local questionnaires or after both the core and local questionnaires). Furthermore, because counseling cannot be provided before the core questionnaire is completed, test results cannot be disclosed to participants until the end of that section of the survey.



Rapid and confirmatory counseling and testing should be conducted in a private area to maintain the participant's confidentiality and to avoid identifying those who are receiving confirmatory testing for a preliminary positive test result.

### ***Rapid-rapid algorithm***

Project sites have the option of conducting a 2-test rapid HIV testing algorithm (rapid-rapid algorithm) which does not require the collection of a confirmatory specimen for laboratory-based testing. With the rapid-rapid algorithm, sites would screen participants

with 1 rapid test and then confirm reactive test results with a second rapid test. A participant who self-reports being HIV-positive and whose first rapid test is *reactive* would not receive a second rapid test. However, if the first rapid test for a participant who self-reports being HIV-positive is *non-reactive*, a second rapid test would need to be conducted using a different type of test than the one used for the first test. For example, consider a project site that is using the Determine and INSTI tests for the rapid-rapid algorithm. If a participant enrolled at this project site self-reports being HIV-positive but has a non-reactive Determine test, the participant would receive a second rapid test using INSTI.

All participants with at least 1 reactive rapid test should be referred to care (see **Section 9.8** below). For participants who do not self-report being HIV-positive, counseling messages for those who have 2 reactive rapid tests would differ slightly from messages for those who have 2 discordant test results (i.e., the first test is reactive and the second test is non-reactive):

<p><b>Newly Diagnosed Participants with 2 Reactive Rapid Tests</b></p>	<p><b>Newly Diagnosed Participants with 2 Discordant Rapid Tests</b></p>
<p><i>“The result of your second test was also positive, which means you have HIV infection. I’d like to refer you to a health care provider who can do some additional testing and get you enrolled in medical care.”</i></p>	<p><i>“The result of your first test was positive, but the result of your second test was negative. Since these 2 tests gave us different results, we can’t be sure whether you have HIV infection. I’d like to refer you to a health care provider who can do some additional testing to determine if you have HIV infection and can get you enrolled in medical care if you do.”</i></p>

Project sites using the rapid-rapid algorithm may use any 2 rapid tests that employ different analytes or methods of detection. At present, the only two tests that are not sufficiently different to be used together in the algorithm are the Chembio SURE CHECK and the Chembio STAT-PAK. Ideally, the first rapid test used in the algorithm would be the most sensitive one, meaning the test that detects HIV infection earliest (please refer to the rapid test’s package insert for the time from HIV infection to test detection [the window period]). That being said, it may be most efficient to choose a rapid test with a shorter read time for the second test to minimize how long the participant has to wait for his test results (**Table 9.1** lists the read times for the current CLIA-waived rapid tests). When deciding which rapid tests to use, sites should also consider how the methods of the various tests would impact field operations. Sites should discuss these logistical considerations with their CDC project officer before choosing which rapid tests to use in the algorithm.

**Table 9.1 – Read times for CLIA-waived rapid tests**

<b>Trade Name</b>	<b>Time to Read Test</b>
bioLytical INSTI HIV-1/HIV-2 Antibody Test	< 5 minutes
Trinity Biotech Uni-Gold Recombigen HIV-1/2	10-20 minutes
Chembio DPP HIV-1/2	10-25 minutes
Chembio SURE CHECK HIV 1/2 Assay	15-20 minutes
Chembio HIV 1/2 STAT-PAK	15-20 minutes
Abott Determine HIV-1/2 Ag/Ab Combo Test	20-30 minutes
Orasure OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	20-40 minutes

***Quality assurance for rapid HIV testing***

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

- 1) Onsite testing records for individual test results, follow-up testing, and follow-up appointments. The NHBS HIV Testing Log (Appendix L of the *NHBS Round 5 Model Surveillance Protocol*) can be used for this purpose.
- 2) Scheduled supervisor observed counseling and testing sessions to ensure that the HIV test counselor conducts the entire testing process correctly according to protocol instructions. The HIV Counseling and Testing Evaluation Form (**Appendix F**) can be used to document staff performance.
- 3) External test control results recorded with each new test kit lot or other additional intervals determined by local protocols and the test package insert. It is important to note that external rapid test controls should be run in the environment in which testing will occur to ensure the tests are working and conditions are appropriate (e.g., sufficient overhead lighting). For example, if a site is doing all the testing in a van, the external controls should be run in the van. A model Rapid Testing Quality Control Log can be found in **Appendix K**.

- 4) Temperatures at which the tests and quality controls are stored and run. A model Rapid Testing Temperature Log can be found in **Appendix L**.

Rapid test results must be read within the timeframe indicated in the package insert for the specific test being used. In addition to monitoring the activities listed above, project sites should develop a system for recording the time the test was started and the time the test result was read. For example, these times could be recorded on the HIV Testing Log or the Participant Tracking Form (**Appendix I**). Guidance on rapid testing and rapid testing quality assurance can be found at <https://wwwn.cdc.gov/clia/resources/waivedtests/>. Additional guidance on HIV testing in non-clinical settings can be found at <https://www.cdc.gov/hiv/testing/nonclinical/index.html>.

### **9.2b Hepatitis testing**

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

If project sites wish to conduct hepatitis testing, they must use local funds for the collection, processing, and testing of specimens; they are not permitted to use NHBS funds for these activities. Furthermore, before specimen collection can begin, project sites must discuss their proposed plans for testing and referral to care with their CDC project officer and they must obtain approval.

### **9.2c STI testing**

Project sites may offer testing for STIs, such as gonorrhea and chlamydia, to determine the prevalence of these infections among NHBS participants and to describe behavioral risk factors associated with them. Specimens collected for gonorrhea or chlamydia testing can be obtained from 1 or more sites (e.g., pharyngeal, vaginal, or rectal). Supplemental and carryover NHBS funds can only be used for pharyngeal and vaginal gonorrhea and chlamydia testing in women 18 to 30 years old. Local funds must be used for all other STI testing, including testing for gonorrhea and chlamydia in women older than 30 years and in men of any age.

Project sites that would like to offer STI testing must discuss their proposed plans for testing and referral to care with their CDC project officer and they must receive approval before specimen collection can begin. Those project sites that received supplemental or carryover NHBS funds to conduct pharyngeal and vaginal gonorrhea and chlamydia testing in women 18 to 30 years old must follow the guidance outlined in the *NHBS-HET5 Operations Manual – STI Testing Supplement*.

### **9.2d Future testing**

During NHBS-HET5, CDC will not collect blood specimens for future testing. However, project sites may do so locally. Sites should notify their laboratory whenever a specimen is to be stored locally for future testing and they must obtain consent from the participant. The portable computer will automatically ask participants to consent to storage of their blood specimens if they consent to HIV or hepatitis testing, and it will automatically ask participants to consent to storage of their STI specimens if they consent to STI testing.



Consent for specimen storage must be documented to permit the local laboratory to conduct future testing. If consent is not documented, the specimen must be discarded.

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

- *An example of a test that may be performed is <planned test (e.g., a test for measuring HIV viral load)>.*
- *The tests that may be performed on your stored blood sample are for research purposes only and the results will not be returned to you.*
- *No information that identifies you will be linked to your blood sample; the laboratory staff performing the tests will not know that the sample is from you.*

### **9.3 Staffing and Training**

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

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

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

train project staff. As another option, the manufacturers of rapid tests often offer fingerstick training.

Project sites collecting blood specimens by venipuncture or fingerstick must adhere to the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard for universal precautions, personal protective equipment, and sharps disposal. The OSHA standards are available at: <https://www.osha.gov/SLTC/bloodbornepathogens/index.html>. Project sites are responsible for training their staff on these standards, and may be able to get training support from health departments, hospitals, and community-based organizations that perform HIV testing.

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

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

## **9.4 Specimen Collection**

Specimens for HIV tests can be collected with a fingerstick or venipuncture.



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

### **9.4a Fingerstick specimens**

Manufacturers of the rapid tests as well as health departments, hospitals, and community-based organizations that perform HIV testing often provide training on how to properly perform fingersticks and can train project staff. Some helpful hints for fingerstick blood collection are listed below:

- 1) The best location for the fingerstick is either the 3<sup>rd</sup> (middle) or 4<sup>th</sup> (ring) finger of the non-dominant hand. These fingers tend to be used less often and are thus less likely to have calluses or tough skin.

- 2) Warm the participant's hands and fingers to increase blood circulation if possible (an instant hand warmer can be used). To further increase blood circulation, it sometimes helps to massage the whole hand and finger to be stuck, not just the fingertip. While the tester is organizing the specimen collection materials, they can also have the participant open and close ("pump") his hand or squeeze and release a stress ball several times to increase blood circulation. Having the participant hold his hand below the level of his heart before performing the stick increases blood circulation as well.
- 3) Prior to the stick, clean the fingertip with a 70% isopropanol swab and allow it to air dry completely for a few seconds.
- 4) Using a sterile, disposable lancet, make the puncture just off the center of the finger pad at right angles to the ridges of the fingerprint so that the blood does not run down the ridges. Avoid the tip and center of the finger, as well as the edge of the nail bed and the side of the finger where there is less soft tissue. The participant's hand should be laid flat against a hard surface to ensure a deeper stick.
- 5) With a sterile gauze or cotton ball, wipe away the first drop of blood, which tends to contain excess tissue fluid. Allow a new drop of blood to form before collecting the blood specimen.



Project sites using dried blood spots (DBS) for laboratory-based confirmatory testing or for local storage and future testing can refer to **Sections 9.4a, 9.5a, and 9.6a** of the *NHBS-IDU5 Operations Manual* for detailed guidance on the collection, processing, storage, and shipping of DBS specimens. That information is not included in this manual.

### **9.4b Venipuncture specimens**

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



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

The date and survey ID number should be recorded on the collection tubes before blood

collection begins. If the tubes contain any type of additive, like EDTA, they should be inverted several times immediately after collection to mix the additive with the blood.

## ***9.5 Specimen Storage and Processing***

### ***9.5a Fingertick specimens***

If project sites are collecting a fingertick specimen for rapid testing, they should follow the instructions for specimen processing provided by the rapid test manufacturer. Sites should also refer to **Section 9.2a** of this chapter for additional guidance on rapid testing and the rapid-rapid algorithm.

### ***9.5b Venipuncture specimens***

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

## ***9.6 Specimen Transport and Shipping***

### ***9.6a Local transport of venipuncture specimens***

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

## ***9.7 Returning HIV Test Results***

Project sites must make final HIV test results available to participants, and they should keep track of the provision of results. After the NHBS survey is completed, sites offering rapid testing should provide counseling and return negative and preliminary positive test results to participants. Each box of rapid HIV tests comes with a set of “subject information” pamphlets that should be given to the participants when they receive their

rapid test results. The pamphlets provide an explanation of the rapid test and test results. For those participants with preliminary positive test results, sites should also collect specimens for confirmatory testing. Although participants have the right to refuse receipt of their rapid test results, it is still very important to collect a confirmatory specimen from participants with preliminary positive test results since only the final test result will be included in the NHBS dataset. Depending on whether project sites are using the rapid-rapid algorithm or laboratory-based confirmatory testing, they should follow the guidance outlined below:

***For project sites using the rapid-rapid algorithm:*** If a participant states that he does not want to receive his rapid test result before he provides a specimen for rapid testing, the project site should collect specimens for both rapid tests at the same time and, if applicable, DBS for local storage and future testing. In situations where the participant declines receipt of his rapid test result after a specimen for the first rapid test has been collected, project sites should request that the participant provide a specimen for the second rapid test so he can receive his testing incentive (project sites should consult their local IRBs to find out if they can withhold testing incentives from participants who refuse to provide a specimen for confirmatory testing).

***For project sites using laboratory-based confirmatory testing:*** If a participant states that he does not want to receive his rapid test result before he provides a specimen for rapid testing, the project site should not conduct a rapid test. Instead, they should collect a specimen for laboratory-based testing and, if applicable, for local storage and future testing. In situations where the participant declines receipt of his rapid test result after a specimen for rapid testing has been collected, project sites should request that the participant provide a specimen for laboratory-based testing so he can receive his testing incentive (project sites should consult their local IRBs to find out if they can withhold testing incentives from participants who refuse to provide a specimen for confirmatory testing).

Project sites conducting laboratory-based testing can give participants their results in person or, if permitted by local policies, over the phone. Sites planning to provide HIV test results over the phone should refer to **Appendix N** for guidance. To properly schedule appointments for returning laboratory-based test results, sites should check with their local laboratory to find out the test turnaround time. Appointments for returning test results should be made with the Appointment Cards in **Appendix M**.

Because only about 30% of participants obtained their laboratory-based test results during previous NHBS cycles, project sites are strongly encouraged to use the rapid-rapid algorithm so that participants living with HIV can receive their final test result and a referral to care at the time of interview. Alternatively, sites could try to increase the number of participants who return for their laboratory-based test results by scheduling appointments for participants to get their results, and if *local* funds are available, by providing incentives to participants who obtain their results.

As discussed in Chapter 5 of the *NHBS Round 5 Model Surveillance Protocol*, test counselors should target prevention messages to specific risks identified during the survey. Project sites that have separate interviewers and testing staff should develop procedures for communicating risk information between staff. For example, test counselors could administer a separate risk assessment or the interviewer could confidentially pass risk information to the test counselor. The collection of any risk information for test counseling must comply with the Assurance of Confidentiality for HIV/AIDS Surveillance Data (see Appendix M of the *NHBS Round 5 Model Surveillance Protocol*).

## **9.8 Referrals to Care and Services**

All referrals to care, support services, case management, or partner notification services must be made anonymously. Project sites must establish relationships with agencies that accept anonymous referrals before data collection can begin. The policy on anonymous referrals does not just apply to HIV care and services, but also to care and services for other health conditions (like hepatitis, STIs, and substance use disorder) and to social services (like housing, domestic violence, and employment).

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

Project sites can strengthen their referral process by collaborating with local entities such as community-based organizations (CBOs) or HIV clinics. An anonymous referral to care or services should involve more than simply telling a participant where to go to receive care or services. Sites should make an effort to actually link the participant to the needed care or services. For example, project staff could offer to help a participant schedule a medical appointment by calling a contact at a clinic and then handing the phone to the participant and leaving the room so that the participant can schedule his appointment privately. Referral to organizations that can make the appropriate linkage to care and follow-up are also acceptable.

Project staff can offer referrals during counseling or during other project activities, but any contact (either in-person or by phone) with a referral agency that requires the participant to give his name or other PII cannot occur until after the participant has checked out of NHBS. To maintain the anonymity of NHBS participants, all activities involving a referral agency that requires PII must be completely separate from NHBS activities, and project staff must make this clear to participants. For standardization, project sites should develop a script to explain the anonymous referral process to participants. A copy of the referral script should be included in the Operations Checklist

and should contain the following points:

- Acceptance of a referral is completely voluntary.
- Declining a referral will not adversely affect any incentives the participant is entitled to receive.
- The referral agency is totally separate from the local NHBS project.
- The referral agency will collect the participant's name, but it will not be shared with the local NHBS project. The individual's participation in NHBS will remain anonymous.
- The local NHBS project will not give any of the participant's information to the referral agency, and the referral agency will not give any of the participant's information to the local NHBS project.

At the end of the referral script, project sites should ask the participants whether they have any questions. When making referrals, sites should never be coercive. They should always respect the wishes of the participants; participants have the right to decline any referrals to care or services.



Project sites conducting rapid tests should make immediate referrals to care or services for participants with preliminary positive test results. Those sites using laboratory-based confirmatory testing should not wait until they receive final test results before making referrals because the participants could be lost to follow-up.

## **9.9 Data Management**

### **9.9a HIV testing**

While in the field, project sites should record HIV test results on a hard copy of the HIV Testing Log (see Appendix L of the *NHBS Round 5 Model Surveillance Protocol*). The hard copy of the HIV Testing Log, as well as any other HIV testing forms or logs, must be secure and in the possession of project staff at all times when in use in the field; otherwise, the forms and logs should be kept locked in a file cabinet or file box. Data from the hard copy of the HIV Testing Log should be entered into the online HIV Test Results Log on the DCC data portal on a **daily basis**. It is important for project sites to enter these data daily so that the process monitoring reports generated by the DCC are up-to-date and reflect each project site's latest data. Sites should refer to the *NHBS-HET5 Data Management Training Materials* for specific instructions on data entry and a listing of required variables. To aid in understanding data entry for laboratory-based testing, a categorical list of the trade names of HIV tests is included in **Appendix T**.

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

### **9.9b Hepatitis testing**

Data management requirements for hepatitis testing are similar to those for HIV testing. Hard copies of hepatitis testing forms and logs must be secure and in the possession of project staff at all times when in use in the field; otherwise, the forms and logs should be kept locked in a file cabinet or file box.

Project sites that conduct hepatitis testing with local funds may enter their test results in the DCC data portal if they wish. At data closeout, the DCC will then be able to include the site’s hepatitis test results in the site’s final NHBS dataset. While in the field, these sites should record their hepatitis test results on a hard copy of the Hepatitis Testing Log (see Appendix J of the *NHBS Round 5 Model Surveillance Protocol*). They should then enter the results into the online Hepatitis Test Results Log on the DCC data portal. It is useful for sites to enter the results in the portal on a daily basis so that the process monitoring reports generated by the DCC are up-to-date and reflect the site’s latest data.

### **9.9c STI testing**

Data management requirements for STI testing are similar to those for other testing in NHBS. Hard copies of STI testing forms and logs must be secure and in the possession of project staff at all times when in use in the field; otherwise, the forms and logs should be kept locked in a file cabinet or file box. As outlined in **Table 9.2**, data and specimen submission requirements for STI testing vary depending on the type of test performed, the source of test funding, and the testing laboratory. Project sites required to submit the Local STI Test Results Log (please see the *NHBS-HET5 Operations Manual – STI Testing Supplement*) should send this log through the secure file transfer program on the DCC data portal.

**Table 9.2 – Data and specimen submission requirements for STI testing**

Test Type	Funding Source and Laboratory	Submission Requirement
Pharyngeal and vaginal gonorrhea and chlamydia testing in women 18 to 30 years old	Supplemental NHBS funds and testing performed at the <i>CDC</i> laboratory	Project sites are required to submit pharyngeal and vaginal specimens to the CDC laboratory for testing. CDC will then return results to project sites through the STI Test Results Log on the DCC data portal. At the end of data collection, sites are required to complete the STI Results Returned Monitoring Log and submit the log to CDC through the secure file transfer program on the DCC data portal.
	Supplemental or carryover NHBS funds and testing performed at a <i>local</i> laboratory	Project sites are required to record test results on the Local STI Test Results Log and submit the log to CDC through the secure file transfer program on the DCC data portal. At the end of data collection, sites are required to complete the STI Results Returned Monitoring Log and submit the log to CDC through the secure file transfer program on the DCC data portal.
Any STI testing other than pharyngeal and vaginal gonorrhea and chlamydia testing in women 18 to 30 years old	Local funds and testing performed at a local laboratory	Project sites are <i>not</i> required to submit test results or specimens to CDC. However, if they wish, sites may share test results with CDC by recording the results on the Local STI Test Results Log and submitting the log to CDC through the secure file transfer program on the DCC data portal.

## 10

# Process Monitoring and Ongoing Formative Assessment

### ***10.1 Overview***

Process monitoring and ongoing formative assessment enable project sites to maintain the highest standards for data collection and will help them achieve the overall project objective of enrolling a sample of 500 people who meet the HET definition (has a household income at or below 150% of the HHS poverty guidelines adjusted for geographic differences in the cost of living, has not injected drugs in the past 12 months, and if a man, has not had sex with another man in the past 12 months). The information sites obtain through these assessment methods will complement the information they gathered during the formative assessment conducted at the start of the project cycle.

### ***10.2 Process Goals***

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

- 85% of those who are screened for eligibility meet the eligibility criteria.
- 90% of those who complete an interview consent to an HIV test.
- A minimum of 500 interviews are completed by people who meet the HET definition.

Achieving these process goals is critical to the success of NHBS. Failure to meet the goals would jeopardize the external validity of NHBS data and would thereby undermine the generalizability of project findings and recommendations. Project sites should continuously monitor their recruitment and enrollment data. If their data do not meet the target goals, sites should conduct ongoing formative assessment to identify any operational problems and to develop appropriate solutions (see **Section 10.4** for information on ongoing formative assessment).

### ***10.3 Process Monitoring Reports***

The NHBS Data Coordinating Center (DCC) will produce the process monitoring reports for project sites to assess recruitment and enrollment, coupon distribution, eligibility, sample characteristics, HIV and hepatitis testing, seeds, RDS methods, previous participants, and interviewer skills. The reports will be posted on the DCC data portal and should be reviewed by project sites weekly. Sites should then discuss the findings in

the reports with their CDC project officer at least every two weeks. If a problem is identified in the reports, the site's CDC project officer may recommend that the site address the problem by adjusting operations or by providing additional staff training. The CDC project officer may also recommend that the site further evaluate the problem by conducting ongoing formative assessment. In addition, if sites wish, they may create their own reports to monitor any issues of local interest.

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

### **10.3a Recruitment Monitoring Report**

The *Recruitment Monitoring Report* (**Section U.1** of this manual) contains data from non-seed participants and provides information on eligibility, enrollment, testing, and recruitment:

- The number of participants screened.
- The number and proportion of participants screened who were eligible.
- The number and proportion of eligible participants who completed the interview.
- The number and proportion of eligible participants who consented to HIV testing.
- *If applicable*, the number and proportion of eligible participants who consented to STI testing.
- *If applicable*, the number and proportion of eligible participants who consented to hepatitis testing.
- *If applicable*, the number and proportion of eligible participants who agreed to blood storage for future testing.
- The number and proportion of participants who completed the interview who were eligible to recruit others.

This report should be reviewed to identify problems such as a low proportion of eligible participants; low or declining enrollment; a low proportion of participants consenting to HIV testing, STI testing, hepatitis testing, or blood storage; and a low proportion of participants eligible to recruit others.

### **10.3b Coupon Manager Program Report**

The *Coupon Manager Program Report* (**Section U.2** of this manual) consists of six tables:

- Coupon Tracking

- Number of Coupons Distributed to Recruiters
- Number Who Reported Coupon Refusals
- Gender of Coupon Refusals
- Race/Ethnicity of Coupon Refusals
- Reasons for Coupon Refusals

Project sites should use this report to monitor recruitment, manage coupon distribution, and evaluate participation barriers. The Coupon Tracking table shows the specific number of coupons distributed to each participant, as well as the total number of coupons distributed and the total number returned. The number of coupons distributed less those returned indicates how many coupons are circulating in the community. This information can help sites manage coupon distribution, including differential coupon distribution and the phasing out of coupons at the end of the project cycle. The proportion of distributed coupons that are returned is a critical measure; a low value signals a barrier to recruitment or participation. If a site is using photo coupons, this table will allow the site to track the number of photo coupons returned and the proportion of all coupons returned that are photo coupons. The Number of Coupons Distributed to Recruiters table can also help project sites track and manage coupon distribution, especially differential coupon distribution. It lists the number of coupons given to each recruiter, by recruiter type and the date any changes were made to this number.

The Number Who Reported Coupons Refusals table shows how many participants reported that people refused to accept the coupons they offered. A large number of participants reporting coupon refusals signifies a substantial barrier to survey participation, necessitating immediate action to identify and address the barrier. On the other hand, if very few participants are even asked about coupon refusals, the coupon manager may not be asking the *Recruiter Questions* as required. Further coupon manager training and monitoring may then be needed.

The Gender of Coupon Refusals and the Race/Ethnicity of Coupon Refusals tables display the demographic characteristics of people who refused to accept the coupons offered by participants. Project sites can use this information to determine whether any particular demographic subpopulations are more likely to decline participation in the survey. The specific reasons why people decline participation are listed in the Reasons for Coupon Refusals table. The information in the three “coupon refusals” tables will enable sites to more effectively identify and address any participation barriers they experience. The data presented in these tables are collected with the *Recruiter Questions* (see **Section 8.3** of the manual).

### **10.3c Sample Characteristics – Screened Report**

The *Sample Characteristics – Screened Report* (**Section U.3** of this manual) shows the

characteristics of participants who were screened for eligibility, stratified by whether they were eligible to take the survey. The characteristics examined are:

- Age
- Gender
- Race/Ethnicity
- MSA Resident
- Known Previous Participant
- Able to Participate (i.e., able to complete the survey in English or Spanish)
- Too Young to Participate
- Too Old to Participate
- Heterosexual Sex (sex with someone of the opposite gender) in the Past 12 Months

Project sites should review this report to monitor the proportion of participants screened who were not eligible based on key demographic variables (age, gender, and race/ethnicity) and who were not eligible based on each eligibility criterion (MSA resident, known previous participant, able to participate, too young or too old to participate, and sex with someone of the opposite gender in the past 12 months). A high proportion of participants who are not eligible may signify a need to improve recruiter training or it may be a warning sign that people are fraudulently trying to enroll in the survey. For example, a large proportion of participants who are less than 18 years old or greater than 60 years old may mean that participants do not understand the eligible age range for NHBS-HET. Sites should therefore modify their recruiter training to emphasize that coupons should only be given to people who are between 18 and 60 years old. In contrast, a substantial proportion of participants who are thought to be too young or too old may be a sign that a network of underage or overage individuals is trying to enroll in the survey by misrepresenting their age. Sites should discuss this matter with their CDC project officer and if necessary, lower the threshold of suspicion for screening out individuals suspected of being too young or too old.



Because RDS relies on peer recruitment, schemes to fraudulently enroll in the survey can rapidly spread from one person to another and inundate a local project.

### ***10.3d Sample Characteristics – Interviewed Report***

The *Sample Characteristics – Interviewed Report* (**Section U.4** of this manual) shows the demographic characteristics of participants who completed the interview, stratified by whether they met the HET definition. The characteristics listed are:

- Age
- Gender
- Race/Ethnicity
- Education
- Homeless in Past 12 Months
- Income
- Low Income
- Injection History
- Zip Code

Project sites should review the tables in this report to monitor the demographic characteristics of participants who successfully completed the interview and met the HET definition. The characteristics of these participants should reflect those of the local population of heterosexually active persons at increased risk for HIV infection, as described in the site’s formative assessment reports.

The Low Income and Injection History tables indicate why participants did not meet the HET definition. If a large proportion of participants do not meet the HET definition, project sites can check these tables to determine why not; are participant incomes too high or did participants inject drugs in the past 12 months? Sites should also examine the tables of demographic characteristics to see if any subpopulations are less likely to meet the HET definition, and they should plot their recruitment chains to see if the members of any chains are less likely to meet the definition. Sites could then adjust recruitment to address any specific problems identified. For example, in previous NHBS-HET cycles, the social networks of homeless persons were closely tied to the social networks of persons who inject drugs (PWID). Accordingly, the enrollment of a large number of participants who were homeless resulted in the recruitment of a large number of PWID who did not meet the HET definition. If this occurs again, sites could reduce the number of coupons given to homeless persons to minimize the recruitment of PWID. As another example, if the members of a particular recruitment chain are more likely to have high incomes and not meet the HET definition, sites could reduce the number of coupons given to members of that chain to limit its further growth.

### ***10.3e Test Results Report***

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

- HIV Rapid Test Result
- HIV Self-reported Test Result

- Specimen Sent to CDC Lab
- Hepatitis B Test Result
- Hepatitis C Test Result

Using this report, project sites can monitor their HIV and hepatitis test results. The HIV Rapid Test Result table compares the result of the first rapid test in the rapid-rapid algorithm with the result of the second rapid test, and the HIV Self-reported Test Result table shows whether or not the participant self-reported being HIV-positive compared to his final test result. A lack of concordance between the first and second rapid tests in the HIV Rapid Test Result table may indicate improper specimen collection or the over-reading of rapid test results, necessitating additional staff training. The HIV Self-reported Test Result table can be used to track HIV prevalence among participants. Other important information provided by this table is the proportion of participants who are unaware that they are infected with HIV or who are unwilling to disclose that they are infected with HIV (i.e., did not report being HIV-positive, but had a final HIV test result that was positive), and the proportion of possible false-negative HIV test results (i.e., did report being HIV-positive, but had a final HIV test result that was negative or indeterminate).

The Specimen Sent to CDC Lab table tracks the shipment of dried blood spot (DBS) specimens to the CDC lab. This table will not be applicable for NHBS-HET5 since project sites are not collecting DBS for the CDC lab this cycle.

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

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

### **10.3f Seed Report**

The *Seed Report* (Section U.6 of this manual) contains two tables:

- Seed Monitoring
- Seed Characteristics

The Seed Monitoring table shows the number of seeds who were screened, the number found to be eligible, the number who completed an interview, and the number who were eligible to be recruiters. These data will help project sites assess the success of seed enrollment. The Seed Characteristics table indicates the gender, race/ethnicity, and age for each seed, as well as whether or not the seed was eligible to recruit. If the *Sample Characteristics – Interviewed Report* shows underrepresentation of any subpopulations, sites should review the Seed Characteristics table to determine whether this lack of sample diversity could be due to a lack of seed diversity.

### **10.3g Respondent-Driven Sampling Report**

The *Respondent-Driven Sampling (RDS) Report* (Section U.7 of this manual) includes six tables:

- Recruitment by Stranger
- Field Site Enrollment
- Cross Recruitment
- Race/Ethnicity by Field Site
- Age by Field Site
- Recruitment Chains

Project sites should review the Recruitment by Stranger table to determine whether recruitment is occurring outside of personal networks (i.e., participants are being recruited by strangers). If participants are being recruited by strangers, sites may need to improve their recruiter training so that participants only recruit individuals they know personally, or they may need to provide additional interviewer training so that interviewers accurately follow-up when a participant responds that he was recruited by a stranger. Interviewers should be able to help participants differentiate between recruitment by a stranger and recruitment by an acquaintance. A high level of recruitment by strangers may also indicate that a “recruitment scheme,” like selling coupons or receiving kickbacks from recruits, is occurring in the community.

The Field Site Enrollment table will show enrollment by field site for each day of the week. This table will not only allow project sites to track the pace of enrollment by field site and day of operation, but it will also help them identify incorrect field site IDs.

Consider the example in which field site 1 operates on Mondays and field site 2 operates on Tuesdays. If the Field Site Enrollment table indicates that participants were interviewed at field site 1 on a Tuesday, the project site would have to investigate the discrepancy to determine whether the interviewer recorded the wrong field site ID or whether he programmed the wrong date in the portable computer. Correct field site IDs are essential for ensuring the accuracy of the Cross Recruitment table (see below).

One of the assumptions of RDS is that participants are linked together in a single social network, although this assumption may be difficult or impossible to meet if the participants are geographically dispersed. The Cross Recruitment table helps project sites examine this assumption by cross tabulating a participant's field site with his recruiter's field site. Cross-group recruitment among field sites occurs when a participant is enrolled at a different field site than his recruiter was. A lack of cross-group recruitment may indicate that participants are not members of a single social network, which may affect the interpretation of NHBS results. In some cases, however, the absence of cross-group recruitment among field sites may be necessary to ensure adequate representation of all the major subpopulations of low-income persons.

Ideally, field site locations should be accessible to all major subpopulations of low-income persons (see **Chapter 4** of this manual). The Race/Ethnicity by Field Site and the Age by Field Site tables list the demographic characteristics of participants accessing each of the field site locations and will show whether any important subpopulations are not accessing a particular field site. This information can help project sites determine if ongoing formative assessment is needed to assess the field site for potential barriers to accessibility. Alternatively, if a field site was selected to reach a specific subpopulation, project sites can use these tables to monitor how successful the field site is at reaching that subpopulation.

RDS depends on multiple waves of recruitment (i.e., long recruitment chains) to achieve equilibrium and yield an unbiased sample (see **Chapter 1** of this manual). Therefore, to help project sites monitor the number and length of their recruitment chains, the Recruitment Chains table will illustrate these chains. The length of the chains (i.e., the number of recruitment waves) will show sites how well enrollment is progressing and the density of the chains (i.e., the number of recruits per recruitment wave) will indicate how effectively potential participants are being recruited.

### ***10.3h Possible Previous Participant Report***

To help project sites identify participants who may have taken the survey more than once, the *Possible Previous Participant Report* (**Section U.8** of this manual) contains a table listing participants who have the same date of birth, gender, and race/ethnicity. This table just includes those participants who were not identified as previous participants during eligibility screening.

To help determine whether participants with the same date of birth, gender, and

race/ethnicity are the same person, project sites should check the participants' physical marks and recruiter IDs in the Coupon Manager Program (CMP). To further assess whether two participants are the same person, sites should analyze their survey data and examine participant characteristics that should not change over time (e.g., country of birth, age of sexual debut) or characteristics that are not likely to change during the data collection period (e.g., educational level, zip code). When sites identify two participants with valid, completed interviews who have the same or similar information, they should discuss their findings with their CDC project officer and decide whether the second record should be treated as that of a previous participant and deleted from the analysis dataset.



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

### **10.3i Interviewer Report**

The *Interviewer Report* (Section U.9 of this manual) consists of the following tables:

- Interview Length
- Interviewer Confidence in Responses
- Testing Consent
- Coding of “Other” Insurance

Project sites should review the tables in this report to identify possible interviewer deficiencies or areas for improvement. These reports are intended to supplement the sites' ongoing evaluation of their interviewers (see **Section 2.6** and **Appendix E** of this manual). Whenever interviewers perform below acceptable standards, sites should provide them with any additional training needed and closely monitor their progress. If the interviewers fail to show improvement, sites should remove them from their positions until they can demonstrate a sufficient level of competence.

The Interview Length table shows the number of interviews completed by each interviewer and the amount of time each spent on eligibility screening, the consent process, and the core survey. Project sites should compare each interviewer's screening, consent, and survey times to the overall times to check for any extreme values which may indicate a need for further training or more frequent monitoring. Interviewers who spend more time completing a section of the survey may be having difficulty administering that section, whereas interviewers who spend less time may be administering the section too hastily or incompletely. For example, interviewers whose average time for consent is much shorter than that of their peers may not be spending sufficient time ensuring that people who are eligible fully understand NHBS procedures and the options for project participation.

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

The Testing Consent table shows the number and proportion of participants who completed an interview who consented to HIV testing, STI testing, hepatitis testing, and specimen storage. This information is stratified by interviewer so project sites can determine whether certain interviewers are less successful than others at obtaining consent for testing or specimen storage. If lower consent rates are found among some interviewers, additional training may be necessary to help these interviewers improve their testing messages and communication skills. The table will also show if some interviewers are mistakenly obtaining consent for STI testing, hepatitis testing, or specimen storage even though they are not offered by the site. Interviewers making this error would be in need of additional training too.

Whenever an interviewer selects "Some other health insurance" for the type of health insurance that a participant has, the specific name of that "other" plan will be listed in the Coding of "Other" Insurance table. Project sites should review this table to ensure that interviewers are not selecting "Some other health insurance" for a type of insurance that could be coded as one of the existing response options ("Private health plan," "Medicaid," "Medicare," "Some other government plan," "TRICARE/CHAMPUS," or "Veterans Administration coverage"). If sites find "other" health plans that should have been coded as one of the existing response options, they should provide their interviewers with refresher training on the principal health insurance plans in their locality. They should also review how to properly administer the health insurance questions and code the participants' responses according to the instructions in the *NHBS Round 5 Interviewer Guide*.

## **10.4 Ongoing Formative Assessment**

Ongoing formative assessment is the collection and assessment of additional quantitative and qualitative data to improve project operations. Project sites should use ongoing formative assessment to evaluate and address operational problems that have been identified through process monitoring or reported by field staff. Ongoing formative assessment may involve examining existing recruitment and enrollment data, observing people in low-income communities or around field sites, having informal conversations with participants, conducting street intercept surveys, or discussing operational issues with key informants or focus groups. Sites should refer to the *NHBS-IDU5/HET5 Formative Assessment Manual* for additional information on ongoing formative

assessment and for instructions on formative assessment methods.

When conducting ongoing formative assessment, project sites should begin with the least labor-intensive and time-consuming methods (e.g., the review of existing data, observations, and informal conversations) and then, if simpler methods do not yield results, they should proceed to more labor-intensive and time-consuming methods (e.g., street intercept surveys, key informant interviews, and focus groups). Sites should also assess whether an operational problem is associated with a particular demographic subpopulation, field site, or staff member. **Table 10.1** provides examples of some operational problems and the methods that could be used to evaluate them.

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

**Table 10.1 – Operational problems and potential evaluation methods**

Operational Problem	Potential Evaluation Methods
<p>Low or declining enrollment</p>	<p><b><i>Quantitative:</i></b></p> <p>Project sites should review the Coupon Tracking table in the <i>Coupon Manager Program Report</i> to determine how many coupons have been distributed and the number and proportion of coupons returned. The number of coupons distributed less the number returned equals the number of coupons currently in circulation in the community. A small number of coupons in circulation means there are few potential participants who can enroll in NHBS. A low proportion of coupons returned indicates a barrier to recruitment or participation, which should be further assessed using the “coupon refusals” tables in the <i>Coupon Manager Program Report</i>. The Recruitment Chains table in the <i>Respondent-Driven Sampling Report</i> will also help sites monitor the progress of recruitment and enrollment.</p> <p><b><i>Qualitative:</i></b></p> <p>Project sites should use observations, informal conversations with participants, or street intercept surveys to determine whether enrollment is being hindered by such factors as the field site location or hours of operation, the incentive amount or type, a poor reputation for the project, safety or confidentiality concerns, or the time commitment required.</p>
<p>A large proportion of participants are not eligible</p>	<p><b><i>Quantitative</i></b></p> <p>Project sites should review the <i>Sample Characteristics – Screened Report</i> to determine if there are any particular eligibility criteria that potential participants are failing or if certain demographic subpopulations are less likely to be eligible.</p> <p><b><i>Qualitative</i></b></p> <p>If a large proportion of participants are not eligible because their age is outside the eligible range or they are not MSA residents, project sites should observe recruiter training to ensure that project staff are providing the necessary training. Sites should also conduct exit interviews with participants to see if they know that they should only recruit people who are</p>

**Table 10.1 – Operational problems and potential evaluation methods (continued)**

Operational Problem	Potential Evaluation Methods
<p>A large proportion of participants are not eligible <i>(continued)</i></p>	<p>18 to 60 years old and live in the project area.</p> <p>If a high proportion of participants are thought to be too young or too old, project sites should conduct observations, informal conversations with participants, street intercept surveys, or key informant interviews to find out if people in the community are misrepresenting their age so that they can participate in the survey.</p>
<p>The demographic characteristics of participants do not match those of the local population of heterosexually active persons at increased risk for HIV infection</p>	<p><b><i>Quantitative</i></b></p> <p>Project sites should review the <i>Sample Characteristics – Screened Report</i> to determine whether members of the underrepresented subpopulation are less likely to be eligible, and they should examine the <i>Sample Characteristics – Interviewed Report</i> to determine whether members of the subpopulation are less likely to meet the HET definition. Sites should also check the “coupon refusals” tables in the <i>Coupon Manager Program Report</i> to find out if members of the underrepresented subpopulation are more likely to refuse coupons, and they should review the Seed Characteristics table in the <i>Seed Report</i> to assess whether a lack of sample diversity could be due to a lack of seed diversity. Sites should use the RDS Analysis Tool (RDSAT) to examine any variables relevant to the underrepresented subpopulation (e.g., examine “race/ethnicity” if Hispanic persons are underrepresented). They should check the affiliation matrix in the RDSAT output to see if members of the underrepresented subpopulation are substantially less likely to be recruited by members of other subpopulations and they should check the recruitment count in the output to see if members of the underrepresented subpopulation are less effective recruiters (i.e., are less likely to recruit other participants).</p> <p><b><i>Qualitative</i></b></p> <p>If members of the underrepresented subpopulation are less likely to be eligible, project sites should observe the recruiter training provided by project staff and conduct exit interviews with participants from the underrepresented subpopulation to</p>

**Table 10.1 – Operational problems and potential evaluation methods (continued)**

Operational Problem	Potential Evaluation Methods
<p>The demographic characteristics of participants do not match those of the local population of heterosexually active persons at increased risk for HIV infection <i>(continued)</i></p>	<p>see if they understand who should be recruited. Sites should also use street intercept or key informant surveys to determine whether there are misperceptions in the community regarding the eligibility criteria.</p> <p>If members of the underrepresented subpopulation are more likely to refuse coupons or less likely to recruit others, project sites should have informal conversations with participants or community members from the underrepresented subpopulation to determine whether recruitment and participation are being hindered by such factors as the field site location or hours of operation, the incentive amount or type, safety or confidentiality concerns, or a poor reputation for the project.</p> <p>If members of the underrepresented subpopulation are substantially less likely to be recruited by members of other subpopulations, project sites should conduct informal conversations with participants, street intercept surveys, key informant interviews, or focus groups to see if members of the underrepresented subpopulation are less likely to mix socially with members of other subpopulations.</p>
<p>Stranger recruitment</p>	<p><b><i>Quantitative</i></b></p> <p>Project sites should review the <i>Respondent-Driven Sampling Report</i> to check whether a high proportion of participants were recruited by a stranger. They could also analyze their survey data to determine if certain demographic subpopulations are more likely to recruit people who are strangers.</p> <p><b><i>Qualitative</i></b></p> <p>Project sites should observe the recruiter training provided by project staff to see if participants are properly instructed to only recruit people they know personally and they should monitor their interviewers to see if they correctly follow-up when a participant responds that he was recruited by a stranger. Project sites should conduct observations in the area around the field site to determine whether people are</p>

**Table 10.1 – Operational problems and potential evaluation methods (continued)**

<b>Operational Problem</b>	<b>Potential Evaluation Methods</b>
Stranger recruitment <i>(continued)</i>	congregating outside the field site trying to obtain coupons or if participants are just handing out coupons to people they see on the street. They should also have informal conversations with participants or interview key informants to see if there are any “recruitment schemes” occurring in the community, such as selling coupons or receiving kickbacks from recruits.

# 11

# Data Submission and Management

## 11.1 Overview

The purpose of this chapter is to briefly describe NHBS data submission and management procedures. Project sites will submit their data to the NHBS Data Coordinating Center (DCC), which is managed by ICF International. Specific instructions on how to submit data to the DCC are described in the *NHBS-HET5 Data Management Training Materials*. The DCC will also provide training videos that the data management staff from each site are required to view. If needed, the DCC can provide additional one-on-one staff training.

## 11.2 Data Submission

The DCC is responsible for managing NHBS data nationally and they will produce the process monitoring reports described in **Chapter 10** of this manual. Project sites are responsible for entering or submitting the following data via the DCC data portal:

- Coupon Manager Program (CMP) data
- QDS™ Warehouse containing the NHBS core interview files
- HIV test results
- Hepatitis test results (optional)
- Returned STI test results data (required from sites that received supplemental or carryover NHBS funds for STI testing)
- STI test results (required from sites that received supplemental or carryover NHBS funds for STI testing *and* performed testing at a local laboratory)
- Data corrections

Sites should observe the schedule in **Table 11.1** for entering or submitting their data through the DCC data portal, and they should refer to the *NHBS-HET5 Data Management Training Materials* for specific guidance on using the portal.

## 11.3 Data Management

Project sites must develop a local data management plan that outlines the activities necessary for ensuring the systematic, complete, and timely submission of NHBS data. The local plan should also identify the specific staff member(s), along with backup staff,

who will sync the CMP data; submit the QDS™ Warehouse; enter HIV test results and, if applicable, enter hepatitis test results and submit STI test results; enter data corrections; and serve as the DCC’s point-of-contact. Another essential element of the local plan is a system for tracking surveys and data corrections. Sites should use the Participant Tracking Form (**Appendix I**) to track key survey information (e.g., survey ID, interview date, eligibility status), as well as to record any needed data edits. Sites should always review and process their data in accordance with their local plan and the *NHBS Round 5 Model Surveillance Protocol*. Moreover, sites should **promptly** respond to all DCC communications with either the requested information or a timeline when the requested information will be sent.

**Table 11.1 – Data entry and submission schedule**

<b>Data</b>	<b>Action</b>	<b>Frequency</b>
CMP data	Sync to the data portal	<b>Daily</b> , at the end of field site operations
QDS™ Warehouse	Submit to the DCC through the data portal	<b>Weekly</b>
HIV test results	Enter in the HIV Test Results Log	<b>Daily</b> , after rapid or laboratory test results are obtained
Hepatitis test results (optional)	Enter in the Hepatitis Test Results Log	<b>Daily</b> , after rapid or laboratory test results are obtained
Returned STI test results data (if applicable*)	Complete the STI Results Returned Monitoring Log and submit to CDC through the secure file transfer program	<b>Once</b> , at the end of data collection
STI test results (if applicable†)	Complete the Local STI Test Results Log and submit to CDC through the secure file transfer program	<b>Monthly</b>
Data corrections	Enter in the Data Error Log	<b>Daily</b> , as soon as errors are identified

\*Required from project sites that received supplemental or carryover NHBS funds for STI testing.

†Required from project sites that received supplemental or carryover NHBS funds for STI testing *and* performed testing at a local laboratory.



At the end of each day of field operations, project sites should upload the interview data from the portable computers to prevent data loss or theft.



<b>FWA Expiration Date</b>			
<b>Date IRB Package Submitted</b>			
<b>Date IRB Approval Received</b>			
<b>Date Amendment Approval Received (if applicable)</b>			

**Instructions for completing the table:**

**Name of IRB:** List the name of each IRB that reviewed your NHBS-HET5 package (do not list an IRB that is deferring to another one).

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

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

**Date IRB Package Submitted:** For each applicable IRB, list the date you sent the NHBS-HET5 package to the IRB or sent an amended package from a previous NHBS cycle.

**Date IRB Approval Received:** For each applicable IRB, list the date you received approval to conduct NHBS-HET5.

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

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

Yes     No

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

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

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

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

f. How will interviewers read the consent form to participants? (*check all that apply*)

Read consent form verbatim

Read summary of consent form (*attach summary*)

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

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

g. Will participants provide verbal consent or written consent?

Verbal consent     Written consent

g1. ***If written consent:*** Describe how you will protect the confidentiality of participants:  
*(e.g., by having the participant sign the consent form with his survey ID instead of his name, by having the interviewer sign the consent form, by not recording a survey ID or any other linkages to NHBS data on a signed consent form)*

## II – Project Identification

- a. Record your NHBS-HET5 project name:
- b. Insert or attach your NHBS-HET5 project logo:

## III – Field Sites

a. List your field site location(s) in the following table (add rows as necessary):

Field Site ID	Name & Address	Dates of Lease or MOU	Project Staff	Days & Hours	Population(s) Targeted

***Instructions for completing the table:***

**Field Site ID:** List the 1- or 2-digit ID code for each field site.

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

**Dates of Lease or MOU:** List the dates of your lease or memorandum of understanding (MOU) for the field site.

**Project Staff:** List the project staff that will be working at each field site (e.g., field supervisor, coupon manager, number of interviewers, number of test counselors, security, etc.).

**Days & Hours:** List the days and hours of field site operation.

**Population(s) Targeted:** List any subpopulations of low-income persons that are expected to have greater access to the field site.

- b. Attach a map with your field site(s) indicated. If you are unable to create a map electronically, please print a map and manually indicate the locations of the field site(s).
- c. Describe the setup of your field site(s) (waiting area, coupon manager station, rooms for interviewing and HIV testing, etc.) and the planned flow of participants:
- d. Will you conduct interviews or HIV tests in a van?

Yes     No

d1. *If Yes:* Describe your contingency plans if the van is not available due to mechanical problems (include method of informing participants if operations have stopped):

#### **IV – Seeds**

- a. What is the total number of seeds you plan on recruiting: \_\_\_\_\_
- b. Use the following table to list the characteristics of each seed you plan on recruiting (add rows as necessary and only complete a field if it is relevant to seed selection):

#	Gender	Race/Ethnicity	Age Range	Geographic Area*
1				
2				
3				
4				

\*Geographic area of residence, such as neighborhood, zip code, etc.

- c. Insert or attach a copy of your referral card. (If you are also creating a referral card in Spanish, include a copy of that card as well.)

#### **V – Coupons**

- a. How many coupons will you distribute to each recruiter at the start of data collection?

Number of coupons distributed to seeds: \_\_\_\_\_

Number of coupons distributed to non-seeds: \_\_\_\_\_

b. Will you use coupon activation dates?

Yes  No

b1. *If Yes:* What is the coupon activation period (e.g., 1 day): \_\_\_\_\_

c. Will you use coupon expiration dates?

Yes  No

c1. *If Yes:* What is the coupon expiration period (e.g., 4 weeks): \_\_\_\_\_

d. Will you allow participants to use photo coupons?

Yes  No

e. Insert or attach a copy of your coupon. (*If you are also creating a coupon in Spanish, include a copy of that coupon as well.*)

## **VI – Recruiter Training**

a. Attach a copy of your recruiter training script or talking points.

b. Insert or attach a copy of your information card.

## **VII – Phone**

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

Phone #: \_\_\_\_\_

Phone #: \_\_\_\_\_

b. Is voicemail activated on your project phone?

Yes  No

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

## **VIII – Interview Appointment System**

a. Will you use an appointment system to schedule interviews?

Yes  No

a1. **If Yes:** Describe how interview appointments will be scheduled:  
*(Include whether “walk-ins” will be accepted and whether standby appointments will be used.)*

a2. **If No:** Describe how you will manage interviews:

## IX – Incentives

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

a1. Interview– Amount: \_\_\_\_\_ Type: \_\_\_\_\_

a2. HIV testing– Amount: \_\_\_\_\_ Type: \_\_\_\_\_

a3. Recruitment– Amount: \_\_\_\_\_ (per recruit) Type: \_\_\_\_\_

**NOTE:** If you use an alternative form of remuneration instead of cash, you must provide a written justification to your CDC project officer and obtain their approval (please see **Table 7.3** of the *NHBS-HET5 Operations Manual*).

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

Local compensation provided for:	Amount	Type
Ineligibles		
<b>Participant</b> who passed the eligibility screener but completed only part of the interview		
<b>Recruiter</b> whose recruit passed the eligibility screener but completed only part of the interview		
Returning for HIV test result <i>(NOTE: only non-NHBS funds can be used)</i>		
STI testing <i>(if applicable)</i>		
If a participant only provides a pharyngeal specimen for STI testing <i>(if applicable)</i>		
If a participant only provides a vaginal specimen for STI testing <i>(if applicable)</i>		
Other activity or test <i>(specify):</i>		

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

## X – Project Staff Training and Evaluation

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

<b>Name of Staff Member</b>					
<b>Position</b>					
<b>ID Code (if applicable)</b>					
<b>Received Confidentiality Training</b>					
<b>Date Signed Confidentiality Agreement</b>					
<b>Read NHBS-HET5 Operations Manual</b>					
<b>Read NHBS-HET5 Operations Manual – STI Testing Supplement (if applicable)</b>					
<b>Read NHBS Round 5 Interviewer Guide (for field supervisor and interviewers)</b>					
<b>Read Package Insert for Rapid HIV Test (for HIV test counselors conducting rapid tests)</b>					
<b>Date HIV Counseling and Testing Certification Expires (for HIV test counselors)</b>					
<b>Viewed NHBS-HET5 Formative Assessment Webinar</b>					
<b>Viewed NHBS-HET5 Human Subjects Webinar</b>					
<b>Attended NHBS-HET5 Field Operations Training</b>					
<b>Viewed NHBS-HET5 Data Management Training Videos</b>					
<b>Viewed NHBS-HET5 Coupon Manager Training Videos</b>					

<b>Other Training</b> ( <i>specify type and dates</i> ):					
<b>Other Training</b> ( <i>specify type and dates</i> ):					
<b>Evaluated and Met Performance Criteria for Position(s)</b>					

**Instructions for completing the table:**

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

**Position:** List each staff member’s position(s).

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

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

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

**Read the NHBS-HET5 Operations Manual:** Prior to the start of data collection, all project staff must read the *NHBS-HET5 Operations Manual*. Record *Yes* to indicate that a staff member read the manual.

**Read the NHBS-HET5 Operations Manual – STI Testing Supplement:** Prior to the start of data collection, all project staff in sites that are conducting STI testing must read the *NHBS-HET5 Operations Manual – STI Testing Supplement*. Record *Yes* to indicate that a staff member read the manual.

**Read the NHBS Round 5 Interviewer Guide:** Prior to the start of data collection, the field supervisor and all interviewers must read the *NHBS Round 5 Interviewer Guide*. Record *Yes* to indicate that these staff members read the guide.

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

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

**Viewed NHBS-HET5 Formative Assessment Webinar:** Record *Yes* to indicate that a staff member viewed this webinar.

**Viewed NHBS-HET5 Human Subjects Webinar:** Record *Yes* to indicate that a staff member viewed this webinar.

**Attended NHBS-HET5 Field Operations Training:** Record *Yes* to indicate that a staff member attended this training.

**Viewed NHBS-HET5 Data Management Training Videos:** Record *Yes* to indicate that a staff member viewed these videos.

**Viewed NHBS-HET5 Coupon Manager Training Videos:** Record *Yes* to indicate that a staff member viewed these videos.

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

**Evaluated and Met Performance Criteria for Position(s):** Prior to the start of data collection, all project staff must be evaluated and meet the performance criteria for their position(s). See **Appendices B** thru **G** of the *NHBS-HET5 Operations Manual* for evaluation forms listing the performance criteria for each position. Record *Yes* to indicate that a staff member was evaluated and met these criteria.

- b. Based on the evaluation recommendations in **Table 2.4** of the *NHBS-HET5 Operations Manual*, describe your plans for evaluating project staff during data collection (specify who will conduct the evaluations and estimate their weekly time commitment for this task):
- c. Since the field supervisor will be busy managing operations during data collection, the principal investigator or project coordinator should ideally conduct staff evaluations. If the field supervisor will also evaluate staff, describe how you will ensure that this added responsibility does not interfere with the field supervisor's ability to manage operations:  
(*e.g., assign an experienced staff member to serve as acting field supervisor when the field supervisor is conducting evaluations*)

## **XI – HIV and Other Testing**

### ***a. Rapid HIV Testing***

a1. Do you have a CLIA certificate of waiver?

Yes     No

a2. Trade name of rapid HIV test: \_\_\_\_\_  
(*e.g., Alere Determine, Insti, Uni-Gold*)

a3. Type of specimen collected:

Blood from fingerstick

Blood from venipuncture

a4. How will you confirm a reactive rapid HIV test result?

- Rapid testing
- Laboratory-based testing

***If Laboratory-based testing:*** Skip to question XIa7.

a5. Trade name of **confirmatory** rapid HIV test: \_\_\_\_\_  
(e.g., Alere Determine, Insti, Uni-Gold)

a6. Type of **confirmatory** specimen collected:

- Blood from fingerstick
- Blood from venipuncture

a7. Describe the procedures you will use to ensure that rapid test results are read during the time frame indicated in the test package insert:

a8. Will you run the rapid test(s) in the same room as the one where the participant is being interviewed?

- Yes
- No

***If Yes:*** You cannot collect the test specimen until after the core questionnaire is completed. When will you collect the test specimen?

- Between the core and local questionnaires
- After both the core and local questionnaires

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

b1. Will you conduct laboratory-based HIV testing?

- Yes
- No

***If No:*** Skip to section XIc (HIV Specimen Storage, Transport, and Processing).

b2. Type of specimen collected:

- Blood from venipuncture
- Dried blood spot (DBS)

b3. **If collecting blood via venipuncture**, will an alternative specimen collection method be offered if venipuncture is not possible (i.e., the phlebotomist is not available or venipuncture is not possible on the participant)?

Yes    No    N/A

**If Yes:** Describe your alternative testing plan:

b4. Trade name of 1<sup>st</sup> laboratory-based test: \_\_\_\_\_  
(e.g., Abott Architect HIV Ag/Ab Combo Assay, Bio-Rad GS HIV-1/2 Plus O, Geenius HIV-1/2 Supplemental System, Aptima HIV-1 RNA Qualitative Assay, Bio-Rad Genetic Systems HIV-1 Western Blot, etc.)

b5. Trade name of 2<sup>nd</sup> laboratory-based test: \_\_\_\_\_  
(e.g., Abott Architect HIV Ag/Ab Combo Assay, Bio-Rad GS HIV-1/2 Plus O, Geenius HIV-1/2 Supplemental System, Aptima HIV-1 RNA Qualitative Assay, Bio-Rad Genetic Systems HIV-1 Western Blot, etc.)

b6. *If applicable*, trade name of 3<sup>rd</sup> laboratory-based test: \_\_\_\_\_  
(e.g., Abott Architect HIV Ag/Ab Combo Assay, Bio-Rad GS HIV-1/2 Plus O, Geenius HIV-1/2 Supplemental System, Aptima HIV-1 RNA Qualitative Assay, Bio-Rad Genetic Systems HIV-1 Western Blot, etc.)

b7. *If applicable*, trade name of 4<sup>th</sup> laboratory-based test: \_\_\_\_\_  
(e.g., Abott Architect HIV Ag/Ab Combo Assay, Bio-Rad GS HIV-1/2 Plus O, Geenius HIV-1/2 Supplemental System, Aptima HIV-1 RNA Qualitative Assay, Bio-Rad Genetic Systems HIV-1 Western Blot, etc.)

b8. Name and contact information for the laboratory performing testing:

b9. Attach your laboratory specimen slip or form.

### ***c. HIV Specimen Storage, Transport, and Processing***

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

c2. *If applicable*, describe how and where specimens will be stored before they are sent to the local laboratory:

c3. *If applicable*, describe the schedule for sending specimens to the local laboratory:

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

c5. *If applicable*, describe how project staff will communicate to the local laboratory which specimens are from participants who are self-reported HIV-positive:

***NOTE: Regardless of the results of any screening tests performed, specimens from self-reported HIV-positive participants must receive confirmatory testing.***

c6. Will you obtain consent to store specimens *locally* for additional testing?

Yes    No

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

#### ***d. HIV Counseling and Testing Procedures***

d1. Stepwise, describe your HIV counseling and testing procedures:

d2. Attach any other HIV testing forms or logs that you plan on using (e.g., specimen transport or shipping log for the local laboratory, risk assessment forms).

#### ***e. HIV Test Results and Referrals to Care***

e1. Describe your procedures for returning rapid and, if applicable, laboratory-based test results:

e2. Describe your procedures for anonymously referring HIV-positive participants to care:

e3. Attach a copy of the script you will use to explain the anonymous referral process to participants (please refer to **Section 9.8** of the *NHBS-HET5 Operations Manual* for guidance).

#### ***f. Hepatitis Testing***

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

Yes, HBV and HCV testing

Yes, only HBV testing

Yes, only HCV testing

No

**If No:** Skip to section XIg (STI Testing).

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

f3. Attach your laboratory specimen slip or form.

f4. **If conducting HBV testing**, trade name(s) of HBV screening EIAs:

Trade name of Hepatitis B surface antigen (HBsAg):

\_\_\_\_\_  
(e.g., VITROS system [from Ortho Clinical Diagnostics], Abbott AxSYM and Abbott Prism, Siemens Advia Centaur, ETI-MAK-2 assay by Diasorin)

Trade name of antibody to HBsAg (anti-HBs):

\_\_\_\_\_  
(e.g., VITROS system [from Ortho Clinical Diagnostics], Abbott AxSYM and Abbott Prism, Siemens Advia Centaur, ETI-MAK-2 assay by Diasorin)

Trade name of total antibody to hepatitis B core antigen (anti-HBc):

\_\_\_\_\_  
(e.g., VITROS system [from Ortho Clinical Diagnostics], Abbott AxSYM and Abbott Prism, Siemens Advia Centaur, ETI-MAK-2 assay by Diasorin)

Trade name of IgM antibody to hepatitis B core antigen (IgM anti-HBc):

\_\_\_\_\_  
(e.g., VITROS system [from Ortho Clinical Diagnostics], Abbott AxSYM and Abbott Prism, Siemens Advia Centaur, ETI-MAK-2 assay by Diasorin)

f5. **If conducting HCV testing:**

f5a. Will you use a rapid test?

Yes     No

f5b. Trade name of laboratory-based HCV screening EIA (if applicable):

\_\_\_\_\_  
(e.g., Ortho HCV Version 3.0 ELISA, Abbott HCV EIA 2.0, VITROS Anti-HCV, AxSYM Anti-HCV, Architect Anti-HCV, Advia Centaur HCV)

f5c. Type of laboratory-based HCV confirmatory test:

Nucleic acid test (NAT)

None

f6. Describe your procedures for anonymously referring HBV- or HCV-positive participants to care:

f7. Describe your procedures for anonymously referring participants for hepatitis A and B vaccination:

***g. STI testing***

g1. Will you conduct pharyngeal and vaginal gonorrhea and chlamydia testing in women 18-30 years old?

Yes     No

g2. Will you conduct any other STI testing?

Yes     No

***If Yes:*** What other STI testing will you conduct?

\_\_\_\_\_

\_\_\_\_\_

***If Yes to either XIg1 or XIg2:*** Complete the remainder of section XIg (STI Testing).

g3. Describe your procedures for STI specimen collection:

g4. Describe how STI specimens will be stored at the field site:

g5. *If applicable*, describe how STI specimens will be transported to the project office:

g6. Which laboratory will perform STI testing?

CDC laboratory

Local laboratory

g6a. ***If a local laboratory is performing STI testing***, name and contact information for the local laboratory:

g6b. ***If a local laboratory is performing STI testing***, describe procedures for shipping specimens to the local laboratory:  
(*Include frequency of shipments*)

g6c. ***If a local laboratory is performing STI testing***, describe the system used to run extra-genital gonorrhea and chlamydia tests:

g6d. ***If a local laboratory is performing STI testing***, describe procedures for shipping specimens to the CDC laboratory for storage:  
(*Include frequency of shipments*)

g7. Describe your procedures for anonymously returning STI test results to participants:  
(*Include participants who call outside of scheduled hours and, if applicable, Spanish-speaking participants.*)

g7a. Will you collect participant phone numbers to return STI results by phone?  
(*To do so, local policy must allow the collection of participant phone numbers*)

Yes    No

***If yes***, describe your procedures for keeping participant phone numbers confidential and secure:

g8. Describe your procedures for anonymously referring participants to care:

### ***h. Other Testing***

h1. List any other tests you plan on conducting:

Test: \_\_\_\_\_

Will you return test results to participants?

Yes    No

Test: \_\_\_\_\_

Will you return test results to participants?

Yes    No

h2. Describe how any other tests will be incorporated into NHBS operations:

h3. ***If returning test results to participants***, describe your procedures for anonymously referring participants with positive test results to care:

## XII – Local Questions

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

Yes    No

- a1. *If Yes:* Attach the QDS™ interviewer version of your local use questionnaire. This is an *.rtf* file that you can create with the QDS™ Design Studio [under the “Build” tab, select “Questionnaire (Interviewer)”].

## XIII – Data Management

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

Name	Phone	E-mail

- b. List the name(s) and contact information for the staff member(s) responsible for submitting NHBS data to the DCC data portal. Also indicate the type of data that each will submit (Coupon Manager Program [CMP], surveys, test results, or data edits):

Name	Phone	E-mail	Data Type

- c. Attach the following documents:

c1. Data security policy

c2. Data confidentiality policy

c3. Data transfer protocol (i.e., how data are transferred from the point of collection to the point of upload to the DCC data portal)  
*(Include how forms and computers containing data are securely transported and stored)*

## **XIV – Local Safety and Field Incident Reporting Procedures**

- a. Attach the following documents:
  - a1. Local safety protocol
  - a2. Field incident reporting procedures

## **XV – Prevention and Other Informational Materials**

- a. Attach any written prevention or informational materials that will be distributed to participants.
- b. List any other prevention materials, such as condoms and lube, that will be distributed to participants:

# Appendix B

# Field Supervisor – Project Management Evaluation Form

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

<b>General Instructions:</b> <ul style="list-style-type: none"> <li>To be conducted by the principal investigator or project coordinator.</li> <li>Shaded areas are NHBS performance recommendations.</li> </ul>						
<b>Field Supervisor:</b>		<b>Rating instructions:</b> Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation				
<b>Evaluation Date:</b>						
<b>Evaluator:</b>						
<b>Management of Staff</b>		<b>Rating</b>				
1. Has trained staff members as backups for the field supervisor, coupon manager, and data manager.		1 No	5 Yes			
2. Has adhered to the evaluation schedule for the coupon manager and, if necessary, implemented retraining procedures.		1 No	5 Yes			
3. Has adhered to the evaluation schedule for the interviewers and, if necessary, implemented retraining procedures.		1 No	5 Yes			
4. Has adhered to the evaluation schedule for the HIV test counselors and, if necessary, implemented retraining procedures.		1 No	5 Yes			
5. Has adhered to the evaluation schedule for the STI test facilitators and, if necessary, implemented retraining procedures. <input type="checkbox"/> N/A		1 No	5 Yes			
<b>Field Site Operations Setup</b>						
6. Prepared all supplies and completed tasks per the Field Site Checklist.		1 No	5 Yes			
7. Adequately staffed the field site (the field supervisor plus a minimum of 2 staff members).		1 No	5 Yes			
8. Conducted a staff meeting before opening the field site.		1 No	5 Yes			
<b>Field Site Management</b>						
9. Managed participant flow by monitoring when the coupon manager was available for the next participant.		1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
10. Managed participant flow by monitoring when an interviewer was available for the next participant.		1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
11. Met each potential participant prior to the interview.		1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
12. Checked in with the interviewers after each interview.		1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
13. Managed participant flow by monitoring when the HIV counselor was available for the next participant. <input type="checkbox"/> N/A		1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
14. Ensured participants' privacy was protected at all times.		1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
15. Remained aware of each team member's whereabouts.		1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
16. Maintained the security of staff and study materials.		1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
17. Monitored staff interactions with participants and the general public.		1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well

18. Assisted field staff when necessary. <input type="checkbox"/> N/A	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
19. Treated participants and staff with courtesy and respect.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
20. Ensured staff were knowledgeable of safety procedures.	1 No		5 Yes		
21. Has emergency contact information for each staff member.	1 No		5 Yes		
22. Scheduled and recorded appointments in the Appointment Log. <input type="checkbox"/> N/A	1 No		5 Yes		
23. Maintained the Phone Results Log. <input type="checkbox"/> N/A	1 No		5 Yes		
24. Adhered to established hours of operation.	1 No		5 Yes		
<b>Post Operations Management</b>					
25. Held a debriefing at the completion of field site activities.	1 No		5 Yes		
26. Reviewed Participant Tracking Forms, including data edits.	1 No		5 Yes		
27. Reviewed the consent forms from each participant. <input type="checkbox"/> N/A	1 No		5 Yes		
28. Reviewed the HIV Test Results Log.	1 No		5 Yes		
29. Reviewed the STI Testing Log. <input type="checkbox"/> N/A	1 No		5 Yes		
30. Reviewed the staff evaluation forms from the PI or PC. <input type="checkbox"/> N/A	1 No		5 Yes		
31. Verified that all participants who consented to HIV testing had either an HIV rapid test conducted or a laboratory specimen collected.	1 No		5 Yes		
32. Verified that all participants who consented to STI testing either provided a pharyngeal and vaginal specimen or had a refusal documented. <input type="checkbox"/> N/A	1 No		5 Yes		
33. Ensured that the CMP data were synced to the data portal using the CMP automatic upload function.	1 No		5 Yes		
34. Portable computers and forms that contain confidential information (e.g., HIV Test Results Log, Phone Results Log, and Participant Tracking Forms) were kept in a locked file cabinet.	1 No		5 Yes		
35. Demonstrated adherence to the protocol including RDS methods.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
<b>Criterion #</b>	<b>Skill Description, Recommendations, Accolades, and Additional Comments</b>				
<b>Evaluator: Please ensure that the following steps are completed with the field supervisor.</b>					
<input type="checkbox"/> Reviewed evaluation form with the field supervisor.					
<input type="checkbox"/> Provided time for field supervisor to ask questions.					
<input type="checkbox"/> Provided the field supervisor with recommendations for improvement.					
<input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard.					

# Appendix C

# Field Supervisor – HIV Testing Operations Evaluation Form

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

<b>General Instructions</b> <ul style="list-style-type: none"> <li>To be conducted by the principal investigator or project coordinator.</li> <li>Shaded areas are NHBS performance recommendations.</li> </ul>				
<b>Field Supervisor:</b>		<b>Rating instructions:</b> Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box.  <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation		
<b>Evaluation Date:</b>				
<b>Evaluator:</b>				
Specimen Collection, Storage, Shipping, and Disposal			Rating	
1. Maintains a paper log (e.g., HIV Testing Log) with no personal identifying information that links the Survey ID and the Lab ID. <input type="checkbox"/> N/A			1 No	5 Yes
2. Only uses specimen processing and tracking forms approved as part of the Operations Checklist.			1 No	5 Yes
3. Blood tube specimens are stored and transported in coolers that are appropriately labeled according to OSHA regulations. <input type="checkbox"/> N/A			1 No	5 Yes
4. All blood collection devices and personal protective equipment are disposed of in appropriate biohazard containers. <input type="checkbox"/> N/A			1 No	5 Yes
5. Collects all required HIV testing variables per HIV Testing Log, Specimen Transport/Shipping Log, etc.			1 No	5 Yes
6. Ships specimens to the local diagnostic laboratory on a regular basis to ensure a 2-week turnaround for results. <input type="checkbox"/> N/A			1 No	5 Yes
7. Tracks whether participants have obtained their results.			1 No	5 Yes
8. Checks the HIV Testing Log and the Specimen Transport/Shipping Log to ensure that consent for storage has been documented and to identify which specimens must be discarded because consent was not obtained. <input type="checkbox"/> N/A			1 No	5 Yes
Data Security, Confidentiality, and Entry				
9. Stores sensitive information according to the <i>NHBS Model Surveillance Protocol</i> .			1 No	5 Yes
10. Keeps HIV testing forms, logs, lab results, and printouts in a locked file cabinet when not in the immediate possession of a staff member.			1 No	5 Yes
11. Ensures that data from the hard copy of the HIV Testing Log are entered into the HIV Test Results Log on the DCC data portal as soon as the test results are available.			1 No	5 Yes
12. For all HIV-positive and indeterminate test results, verifies that the correct survey IDs have been entered into the HIV Test Results Log on the DCC data portal.			1 No	5 Yes
13. For all HIV-positive <u>rapid</u> test results, ensures that confirmatory test data have been entered into the HIV Test Results Log on the DCC data portal. <input type="checkbox"/> N/A			1 No	5 Yes
Rapid Testing <input type="checkbox"/> N/A				
14. HIV test package inserts are available for reference at the field site.			1 No	5 Yes
15. Monitors the temperature at which test kits are stored and records the temperature on quality assurance logs.			1 No	5 Yes
16. Monitors the temperature at which testing is conducted and records the temperature on quality assurance logs.			1 No	5 Yes

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

# Appendix D

# Coupon Manager Evaluation Form

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

<b>General Instructions:</b>		
<ul style="list-style-type: none"> <li>To be conducted by the principal investigator, project coordinator, or, if necessary, field supervisor.</li> <li>Shaded areas are NHBS performance recommendations.</li> </ul>		
<b>Coupon Manager:</b>	<b>Rating instructions:</b> Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box.	
<b>Evaluation Date:</b>	<input type="checkbox"/> <b>Pre-implementation Evaluation</b> <input type="checkbox"/> <b>Ongoing Evaluation</b>	
<b>Evaluator:</b>		
<b>Check-In</b>	<b>Rating</b>	
1. Greeted potential participant appropriately.	1 No	5 Yes
2. Established rapport with potential participant.	1 No	5 Yes
3. Checked the validity of the potential participant's coupon (including activation/expiration dates).	1 No	5 Yes
4. If potential participant had a valid coupon, created a record in Coupon Manager Program (CMP). <input type="checkbox"/> N/A	1 No	5 Yes
5. If potential participant had a valid coupon, transferred potential participant to interviewer and gave coupon to interviewer. <input type="checkbox"/> N/A	1 No	5 Yes
6. If potential participant did <u>not</u> have a valid coupon, handled him in a professional manner. <input type="checkbox"/> N/A	1 No	5 Yes
7. Voided and filed invalid coupons appropriately. <input type="checkbox"/> N/A	1 No	5 Yes
<b>Recruiter Training</b> <input type="checkbox"/> N/A		
8. Ensured participant was eligible to receive recruitment coupons.	1 No	5 Yes
9. Successfully trained recruiter: <i>Instructions were given regarding whom to recruit.</i>		
a. Friends, relatives, and people you associate with.	1 No	5 Yes
b. People who are between 18 and 60 years old.	1 No	5 Yes
c. People you know. Do <u>not</u> give coupons to strangers.	1 No	5 Yes
d. People who live in the project area.	1 No	5 Yes
e. People who have <u>not</u> already participated in the study.	1 No	5 Yes
10. Successfully trained recruiter: <i>Instructions were given on how to use photo coupons.</i> <input type="checkbox"/> N/A		
a. Can text or email a photo of a coupon to someone you want to recruit.	1 No	5 Yes
b. Message sent should be general to protect the person's privacy.	1 No	5 Yes
c. Coupon number must be clearly visible in photo.	1 No	5 Yes
d. Only the first person using each photo coupon will be allowed to participate in the study.	1 No	5 Yes
11. Successfully trained recruiter: <i>Instructions were given on what to say to person receiving the coupon.</i>		
a. Call for an appointment or visit the field site before the expiration date.	1 No	5 Yes
b. The process will take about an hour.	1 No	5 Yes
c. Children can't sit in on the interview.	1 No	5 Yes
d. Coupons can't be replaced if lost or stolen. <input type="checkbox"/> N/A	1 No	5 Yes

12. Successfully trained recruiter: <i>Rewards</i> .			
a. Rewards will be paid for each person recruited who is selected to participate and completes the interview.		1 No	5 Yes
b. Rewards will not be paid for someone who is not selected to participate.		1 No	5 Yes
c. Rewards will not be paid for recruiting someone who has already participated.		1 No	5 Yes
d. Rewards will not be paid for someone who does not complete the interview.		1 No	5 Yes
e. Each coupon can only be given to one person.		1 No	5 Yes
f. A unique identification number will link the recruiter, coupon(s), and reward(s).		1 No	5 Yes
g. Recruiter can call the office to check on any rewards due.		1 No	5 Yes
13. Asked the recruiter if he had any questions.		1 No	5 Yes
<b>Check-Out</b>			
14. Ensured participant had completed all applicable steps of the enrollment process (i.e., eligible, provided consent for interview/HIV testing, completed interview/HIV testing, and, if applicable, eligible and willing to recruit).		1 No	5 Yes
15. Collected participant's coupon and, if applicable, Participant Tracking Form from interviewer.		1 No	5 Yes
16. Marked and filed the coupon and, if applicable, the Participant Tracking Form appropriately.		1 No	5 Yes
17. Created Recruiter ID and collected physical marks. <input type="checkbox"/> N/A		1 No	5 Yes
18. Distributed correct number of coupons and recorded coupon numbers. <input type="checkbox"/> N/A		1 No	5 Yes
19. Reinforced recruiter training by asking the recruiter questions to ensure that he understands whom to recruit and what to do with coupons.		1 No	5 Yes
20. Gave incentives. <input type="checkbox"/> N/A		1 No	5 Yes
21. Provided local HIV prevention materials and referrals. <input type="checkbox"/> N/A		1 No	5 Yes
<b>General</b>			
22. Demonstrated adherence to the <i>NHBS Model Surveillance Protocol</i> , including RDS methods.		1 No	5 Yes
23. Maintained an organized Coupon Manager Station (i.e., CMP hard copy, coupons, referral cards, information cards, and incentives).		1 No	5 Yes
24. CMP was never left open or unattended.		1 No	5 Yes
25. Ensured participant was never able to view the CMP on the computer screen.		1 No	5 Yes
26. Was knowledgeable of safety procedures.		1 No	5 Yes
<b>Criterion #</b>	<b>Skill Description, Recommendations, Accolades, and Additional Comments</b>		
<b>Evaluator: Please ensure that the following steps are completed with the coupon manager.</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Reviewed evaluation form with the coupon manager.</li> <li><input type="checkbox"/> Provided time for coupon manager to ask questions.</li> <li><input type="checkbox"/> Provided the coupon manager with recommendations for improvement.</li> <li><input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard.</li> </ul>			

# Appendix E

# Interviewer Evaluation Form

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

<b>General Instructions</b> <ul style="list-style-type: none"> <li>To be conducted by the principal investigator, project coordinator, or, if necessary, field supervisor.</li> <li><b>Permission must be obtained from the potential participant before an evaluator joins an interview.</b></li> <li>The evaluator should follow along during the interview by using a separate portable computer or by observing the interviewer's portable computer.</li> <li>The evaluator should be seated close enough to hear and observe both the interviewer and the participant, without being a distraction.</li> <li>The evaluator should only interrupt the interview for major issues, be discreet when doing so, and direct questions to the interviewer.</li> <li>Shaded areas are NHBS performance recommendations.</li> </ul>					
<b>Interviewer:</b>	<b>Rating instructions:</b> Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation				
<b>Evaluation Date:</b>					
<b>Evaluator:</b>					
<b>Time to Complete Survey</b>	<b>Time</b>				
1. Eligibility screener	<b>Start:</b> _____	<b>End:</b> _____	<b>Length:</b> _____		
2. Consent process	<b>Start:</b> _____	<b>End:</b> _____	<b>Length:</b> _____		
3. Core questionnaire	<b>Start:</b> _____	<b>End:</b> _____	<b>Length:</b> _____		
4. Local questionnaire <input type="checkbox"/> N/A	<b>Start:</b> _____	<b>End:</b> _____	<b>Length:</b> _____		
<b>Set-up</b>	<b>Rating</b>				
5. Checked date and time on portable computer before starting.	1 No	5 Yes			
6. All materials needed were prepared and organized before starting (flashcards, consent forms, prevention materials, referral information, pens, etc.).	1 No	5 Yes			
7. Was knowledgeable of safety procedures.	1 No	5 Yes			
<b>Consent Process</b>					
8. No personal identifiers (e.g., name, address) were recorded.	1 Recorded	5 Not recorded			
9. <u>All</u> aspects of informed consent were followed per local IRB requirements (i.e., read as written if required; covered all relevant points if summarized).	1 No	5 Yes			
10. Determined whether the participant was eligible for STI testing and if so, conducted the STI consent process. <input type="checkbox"/> N/A	1 No	5 Yes			
11. Provided the participant with a copy of the consent form to follow along.	1 No	5 Yes			
12. Offered the participant a copy of the consent form to keep.	1 No	5 Yes			
13. Provided an opportunity for questions about the project and consent process.	1 No	5 Yes			
14. Ensured participant understood anonymous nature of NHBS (i.e. will NOT ask for participant's name; participant names NEVER linked to interviews or test results).	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
15. Obtained a <u>separate</u> consent for the interview.	1 No	5 Yes			
16. Obtained a <u>separate</u> consent for HIV testing.	1 No	5 Yes			
17. Obtained a <u>separate</u> consent for hepatitis testing. <input type="checkbox"/> N/A	1 No	5 Yes			
18. Obtained a <u>separate</u> consent for STI testing. <input type="checkbox"/> N/A	1 No	5 Yes			
19. Obtained a <u>separate</u> consent for specimen storage. <input type="checkbox"/> N/A	1 No	5 Yes			
20. The pace of reading the consent was...	1 Too slow	1 Too fast	5 Just right		

Survey Administration					
21. Oriented the participant by reading the introductory statement for the core survey.	1 No		5 Yes		
22. Read the questions, definitions, and transition statements as written.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
23. Followed the survey instructions to read or not read response options.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
24. When needed, reread and clarified instructions, questions, and responses. <input type="checkbox"/> N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
25. Recognized inconsistent responses, clarified with participant, and corrected data in the portable computer. <input type="checkbox"/> N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
26. Probed incomplete, unclear, and, if necessary, "don't know" responses. <input type="checkbox"/> N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
27. Used <u>neutral</u> probes (i.e., probed without influencing response).	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
28. Ensured that the participant was never able to view the portable computer screen.	1 No		5 Yes		
29. The pace of reading the screener was...	1 Too short		1 Too long		5 Just right
30. The pace of reading the questionnaire was...	1 Too slow		1 Too fast		5 Just right
31. The amount of time given for responses was...	1 Too slow		1 Too fast		5 Just right
Flashcards					
32. Used flashcards when instructed.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
33. 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
34. Read the flashcards as written.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
Establishing and Maintaining Rapport					
35. 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
36. Maintained eye contact with the participant throughout interview.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
37. Provided neutral feedback throughout the interview.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
38. Remained engaged with the participant and his responses throughout the survey.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
39. Demonstrated a professional demeanor.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
Recruiter Training <input type="checkbox"/> N/A					
40. Ensured participant was eligible to receive recruitment coupons.	1 No		5 Yes		
41. Successfully trained recruiter: <i>Instructions were given regarding whom to recruit.</i>					
a. Friends, relatives, and people you associate with.	1 No		5 Yes		
b. People who are between 18 and 60 years old.	1 No		5 Yes		
c. People you know. Do <u>not</u> give coupons to strangers.	1 No		5 Yes		
d. People who live in the project area.	1 No		5 Yes		
e. People who have <u>not</u> already participated in the study.	1 No		5 Yes		

42. Successfully trained recruiter: <i>Instructions were given on how to use photo coupons.</i> <input type="checkbox"/> N/A			
a. Can text or email a photo of a coupon to someone you want to recruit.	1 No	5 Yes	
b. Message sent should be general to protect the person's privacy.	1 No	5 Yes	
c. Coupon number must be clearly visible in photo.	1 No	5 Yes	
d. Only the first person using each photo coupon will be allowed to participate in the study.	1 No	5 Yes	
43. Successfully trained recruiter: <i>Instructions were given on what to say to person receiving the coupon.</i>			
a. Call for an appointment or visit the field site before the expiration date.	1 No	5 Yes	
b. The process will take about an hour.	1 No	5 Yes	
c. Children can't sit in on the interview.	1 No	5 Yes	
d. Coupons can't be replaced if lost or stolen. <input type="checkbox"/> N/A	1 No	5 Yes	
44. Successfully trained recruiter: <i>Rewards.</i>			
a. Rewards will be paid for each person recruited who is selected to participate and completes the interview.	1 No	5 Yes	
b. Rewards will not be paid for someone who is not selected to participate.	1 No	5 Yes	
c. Rewards will not be paid for recruiting someone who has already participated.	1 No	5 Yes	
d. Rewards will not be paid for someone who does not complete the interview.	1 No	5 Yes	
e. Each coupon can only be given to one person.	1 No	5 Yes	
f. A unique identification number will link the recruiter, coupon(s), and reward(s).	1 No	5 Yes	
g. Recruiter can call the office to check on any rewards due.	1 No	5 Yes	
45. Asked the recruiter questions to ensure that he understands whom to recruit and what to do with coupons.	1 No	5 Yes	
46. Asked the recruiter if he had any questions.	1 No	5 Yes	
<b>Criterion #</b>	<b>Skill Description, Recommendations, Accolades, and Additional Comments</b>		
<b>Evaluator: Please ensure that the following steps are completed with the interviewer.</b>			
<input type="checkbox"/> Asked the interviewer how any unclear responses were entered into the portable computer.			
<input type="checkbox"/> Reviewed how the interviewer coded the question regarding the validity of answers.			
<input type="checkbox"/> Reviewed evaluation form with the interviewer.			
<input type="checkbox"/> Provided time for interviewer to ask questions.			
<input type="checkbox"/> Provided the interviewer with recommendations for improvement.			
<input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard.			

# Appendix F

# HIV Counseling and Testing Evaluation Form

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

<b>General Instructions</b> <ul style="list-style-type: none"> <li>To be conducted by the principal investigator, project coordinator, or, if necessary, the field supervisor.</li> <li><b>Permission must be obtained from the participant before an evaluator joins the HIV testing session.</b></li> <li>The evaluator should only interrupt the session for major issues, be discreet when doing so, and only direct questions to the counselor.</li> <li>Shaded areas are NHBS performance recommendations.</li> <li>This form may be modified to reflect local counseling and testing regulations.</li> </ul>					
<b>HIV Test Counselor:</b>		<b>Rating instructions:</b> Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> <b>Pre-implementation Evaluation</b> <input type="checkbox"/> <b>Ongoing Evaluation</b>			
<b>Evaluation Date:</b>					
<b>Evaluator:</b>					
<b>Test Preparation</b>		<b>Rating</b>			
1. Prepared all necessary materials prior to starting (HIV testing kit, phlebotomy materials, HIV Testing Log, referrals, information handouts, personal protective equipment, etc.).	1 Not at all	2	3 Some	4	5 Fully
2. Verified on Participant Tracking Form that consent for HIV testing was provided.	1 No		5 Yes		
3. Verified with participant that he is interested in getting tested and has provided appropriate consent(s), including other tests and specimen storage if applicable.	1 No		5 Yes		
4. Discreetly obtained relevant behavioral risk information from interviewer. <input type="checkbox"/> N/A	1 No		5 Yes		
<b>Testing Procedures</b>					
5. Conducted the test in an appropriate environment (temperature, lighting, adequate work space, etc.).	1 No		5 Yes		
6. Labeled all specimens or test devices with the survey ID or lab ID.	1 No		5 Yes		
7. Did not record any personal identifiers.	1 Collected identifiable info		5 Did not collect identifiable info		
8. Adequately counseled participant on what to expect during specimen collection.	1 No		5 Yes		
9. Adhered to OSHA regulations for universal precautions (gloves) and for proper waste disposal in approved biohazard and sharps containers.	1 No		5 Yes		
10. Scheduled an appointment for the participant to obtain his HIV test result. <input type="checkbox"/> N/A	1 No		5 Yes		
11. Provided an appointment card and counseled the participant that the ID number on the card must be presented to obtain his HIV test result. <input type="checkbox"/> N/A	1 No		5 Yes		
12. Provided a phone results card and counseled the participant that the ID number on the card is necessary to obtain his HIV test result. <input type="checkbox"/> N/A	1 No		5 Yes		
<b>Rapid Testing</b> <input type="checkbox"/> N/A					
13. When opening the pouch with the test cassette, checked for desiccant pack and discarded the test cassette if no desiccant pack was present.	1 No		5 Yes		
14. Had a comprehensive knowledge of the information listed in the package insert, including critical elements such as the temperature ranges for storage and testing.	1 No		5 Yes		
15. Performed the test <u>exactly as directed by the package insert</u> . ( <b>Critical element:</b> To ensure consistency, evaluator must use the package insert for every evaluation of tester's performance.)	1 No		5 Yes		

16. The participant could not view rapid test during test development.	1 No	5 Yes			
17. Read test result within the appropriate time frame for rapid test performed (INSTI: < 5 min, Unigold: 10-20 min, Chembio DPP: 10-25 min, Chembio SURE CHECK or STAT-PAK: 15-20 min, Determine: 20-30 min, Oraquick: 20-40 min).	1 No	5 Yes			
18. Read test result under adequate lighting.	1 No	5 Yes			
19. Knew how to read a positive, negative, or invalid test result; and knew what steps to take when returning these test results.	1 No	5 Yes			
20. Recorded test result and properly completed all steps for returning the result.	1 No	5 Yes			
21. Gave the participant the subject information pamphlet from the test kit.	1 No	5 Yes			
<b>Test Counseling</b>					
22. Conducted pre-test counseling <i>after</i> the survey was completed. <input type="checkbox"/> N/A	1 No	5 Yes			
23. Provided HIV information regarding transmission, risk factors, etc.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
24. Clarified misconceptions of HIV and corrected false information. <input type="checkbox"/> N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
25. Assessed barriers to risk reduction and explored methods to reduce or remove those barriers.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
26. Developed risk reduction steps that were participant-driven, appropriate for participant's situation, explicit, and achievable.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
27. Targeted prevention messages to specific risks identified during the survey and risk assessment.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
28. Returned test result in a manner that preserved participant's privacy. <input type="checkbox"/> N/A	1 No	5 Yes			
29. Ensured participant fully understood the HIV test result. <input type="checkbox"/> N/A	1 No	5 Yes			
30. Discussed disclosure of HIV status to partner(s) and discussed how to ask partner's HIV status.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
31. Provided and explained referral to medical care and case management. <input type="checkbox"/> N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
32. Provided informational materials on prevention, testing resources, medical services, and other support services; and when necessary, provided referrals to those services.	1 No	5 Yes			
33. Allowed participant to ask questions and raise concerns, and provided appropriate answers.	1 No	5 Yes			
<b>Criterion #</b>	<b>Skill Description, Recommendations, Accolades, and Additional Comments</b>				
<b>Evaluator: Please ensure that the following steps are completed with the HIV test counselor.</b>					
<input type="checkbox"/> Reviewed evaluation form with the HIV test counselor.					
<input type="checkbox"/> Provided time for HIV test counselor to ask questions.					
<input type="checkbox"/> Provided the HIV test counselor with recommendations for improvement.					
<input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard.					

# Appendix G

# Data Manager Evaluation Form

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

<b>General Instructions</b> <ul style="list-style-type: none"> <li>To be conducted by the principal investigator or project coordinator.</li> <li>Shaded areas are NHBS performance recommendations.</li> </ul>			
<b>Data Manager:</b>	<b>Rating instructions:</b> Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box.  <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation		
<b>Evaluation Date:</b>			
<b>Evaluator:</b>			
<b>Data Management</b>		<b>Rating</b>	
1. Ensured receipt of the Participant Tracking Forms (including data edits), HIV Testing Log, and, if applicable, other data management forms.		1 No	5 Yes
2. Reviewed data discrepancies and concerns with the field supervisor or project coordinator to determine resolutions. <input type="checkbox"/> N/A		1 No	5 Yes
3. Documented data discrepancies and their resolutions on the Participant Tracking Forms. <input type="checkbox"/> N/A		1 No	5 Yes
4. Entered data edits from the Participant Tracking Forms into the online Data Error Log on the DCC data portal or demonstrated how to do so.		1 No	5 Yes
5. Successfully uploaded data from each portable computer to the desktop computer.		1 No	5 Yes
6. Reviewed QDS™ data files from each portable computer and compared the Survey IDs with the Survey IDs recorded on the Participant Tracking Forms or similar forms.		1 No	5 Yes
7. Transferred records from QDS™ data files (i.e., files with a ".QAD" extension) to the QDS™ Warehouse successfully.		1 No	5 Yes
8. Did not delete QDS™ data files from the portable computers until after confirming the records were added to the QDS™ Warehouse.		1 No	5 Yes
9. Successfully encrypted NHBS data using PGP software.		1 No	5 Yes
10. Submitted the QDS™ Warehouse containing core interview files to the DCC data portal or demonstrated how to do so.		1 No	5 Yes
11. Successfully entered HIV testing data, including laboratory test results, into the online HIV Test Results Log on the DCC data portal or demonstrated how to do so.		1 No	5 Yes
12. Successfully entered hepatitis testing data into the online Hepatitis Test Results Log on the DCC data portal or demonstrated how to do so. <input type="checkbox"/> N/A		1 No	5 Yes
13. Successfully submitted the Local STI Test Results Log to CDC through the secure file transfer program on the DCC data portal or demonstrated how to do so. <input type="checkbox"/> N/A		1 No	5 Yes
14. Successfully submitted the STI Results Returned Monitoring Log to CDC through the secure file transfer program on the DCC data portal or demonstrated how to do so. <input type="checkbox"/> N/A		1 No	5 Yes
<b>Ongoing Activities</b>			
15. Enters data edits into the online Data Error Log on the DCC data portal <b>daily</b> .		1 No	5 Yes
16. Submits the QDS™ Warehouse to the DCC data portal <b>weekly</b> .		1 No	5 Yes
17. Enters HIV testing data into the online HIV Test Results Log on the DCC data portal <b>daily</b> (after final rapid or laboratory test results are obtained).		1 No	5 Yes

18. Enters hepatitis testing data into the online Hepatitis Test Results Log on the DCC data portal <b>daily</b> (after final test results are obtained). <input type="checkbox"/> N/A	1 No	5 Yes
19. Completes the Local STI Test Results Log and submits it to CDC through the secure file transfer program on the DCC data portal <b>monthly</b> (after final test results are obtained). <input type="checkbox"/> N/A	1 No	5 Yes
20. Completes the STI Results Returned Monitoring Log and submits it to CDC through the secure file transfer program on the DCC data portal <b>at the end of data collection</b> (after final test results are returned). <input type="checkbox"/> N/A	1 No	5 Yes
21. Reviews Process Monitoring Reports <b>weekly</b> and, if necessary, communicates discrepancies to the DCC.	1 No	5 Yes
22. Reviews DCC Data Management Reports <b>monthly</b> .	1 No	5 Yes
23. Responds to DCC inquiries and communications on a timely basis.	1 No	5 Yes
24. Knows how to ask the DCC questions and understands how to access information on the DCC data portal.	1 No	5 Yes
<b>Criterion #</b>	<b>Skill Description, Recommendations, Accolades, and Additional Comments (continued)</b>	
<b>Evaluator: Please ensure that the following steps are completed with the data manager.</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Reviewed evaluation form with the data manager.</li> <li><input type="checkbox"/> Provided time for the data manager to ask questions.</li> <li><input type="checkbox"/> Provided the data manager with recommendations for improvement.</li> <li><input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard.</li> </ul>		

# Appendix H

# Field Site Checklist

A model Field Site Checklist is outlined below. This checklist can be printed or modified using the Word file named **Appendix H - Field Site Checklist**.

## 1. General Supplies

### ***Equipment:***

- Portable computers (1 for each interviewer and backups)
- Laptop or desktop computer for the CMP
- AC adaptors for portable and laptop computers
- Communications equipment (e.g., 2-way radios or cell phones)
- Other office equipment (e.g., telephone, printer): \_\_\_\_\_

### ***Blank forms or logs:***

- Appointment book or log (if applicable)
- Appointment Cards (if applicable)
- Consent forms (including copies for participants)
- Participant Tracking Forms
- HIV Testing Log (**Appendix L** of *NHBS Round 4 Model Surveillance Protocol*)
- Rapid Testing Quality Control Log (if applicable)
- Rapid Testing Temperature Log (if applicable)
- Lab slips (if applicable)
- Local specimen transport or shipping log (if applicable)
- Phone Results Log (if applicable)
- Phone Results Cards (if applicable)
- CMP Log
- Seed Referral Cards
- Coupons
- Information Cards
- Recruiter training scripts or talking points
- Incentive log or receipt book for recording incentive payments
- Other forms or logs: \_\_\_\_\_

### ***Staff evaluation forms:***

- Field Supervisor- Project Management Evaluation Form
- Field Supervisor- HIV Testing Operations Evaluation Form
- Coupon Manager Evaluation Form
- Interviewer Evaluation Form(s)
- HIV Counseling and Testing Evaluation Form(s)
- Data Manager Evaluation Form

**Guidance documents:**

- NHBS Round 5 Model Surveillance Protocol*
- NHBS-IDU5/HET5 Formative Assessment Manual*
- NHBS-HET5 Operations Manual*
- NHBS Round 5 Interviewer Guide*
- Other documents: \_\_\_\_\_

**Miscellaneous items:**

- Flashcards for each interviewer
- Interview and test incentives to cover the expected number of participants
- Recruiter rewards
- Envelopes or file folders to store used, voided, and expired coupons
- Signed memorandums of understanding (MOUs) (if applicable)
- Informational pamphlets on HIV and other medical conditions
- Referral information for HIV medical care and case management
- Referral information for other health care and social services
- HIV risk reduction supplies (e.g., condoms and lubricant)
- Other items: \_\_\_\_\_

**2. HIV Testing Supplies**

***Rapid testing supplies (if applicable):***

- Rapid tests
- Lancets
- Fingertick blood collection devices (i.e., pipettes or loops)
- Test reagents (i.e., developer solution, wash solution, and running buffer)
- Package inserts for the specific rapid test being used
- Subject information pamphlets for each participant who receives a rapid test
- Other rapid testing supplies: \_\_\_\_\_

***Laboratory-based testing supplies (if applicable):***

- Whole blood specimen collection tubes (if applicable)
- Phlebotomy equipment (e.g., butterfly needles, tube stopper, tourniquet) (if applicable)
- DBS collection cards (if applicable)
- DBS collection devices (i.e., blade lancets if DBS from fingertick or transfer pipettes if DBS from blood tube) (if applicable)
- Equipment to transfer DBS (e.g., test tube racks, binder clips, transport box) (if applicable)
- Other laboratory-based testing supplies: \_\_\_\_\_

**Miscellaneous testing supplies:**

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

**3. Daily Closeout Activities**

**Field supervisor with coupon manager:**

- Collect and file coupons returned
- Collect and review the CMP Log
- Review the Coupon Manager Evaluation Form or note if the scheduled evaluation did not occur and needs to be re-scheduled (if applicable)

**Field supervisor with interviewers:**

- Collect the portable computers
- Determine if any problems occurred with the portable computers
- Collect and review the Participant Tracking Forms (including data edits)
- Determine if any unusual events occurred (e.g., participant ended the interview early, participant consented to an HIV test but then changed his mind)
- Review the Interviewer Evaluation Form(s) or note if the scheduled evaluation(s) did not occur and need to be re-scheduled (if applicable)

**Field supervisor with HIV test counselors:**

- Collect and review the HIV Testing Log and any other HIV test forms (ensure that the survey and laboratory IDs are accurate)
- Check HIV Testing Log to ensure that appointments have been scheduled for HIV test results (if applicable)
- Cross-check that there is a specimen for each entry on the HIV Testing Log (if applicable)
- Cross-check that there is a lab slip for each laboratory-based test specimen (if applicable)
- Collect and review the lab slips (ensure that the laboratory IDs are accurate) (if applicable)
- Collect and review the local specimen transport or shipping log (if applicable)
- Collect and review the Phone Results Log (if applicable)
- While waiting to ship HIV test specimens, store them at the appropriate

- temperature indicated by the local laboratory (if applicable)
- Transport or ship HIV test specimens to the local laboratory (if applicable)
- Review the HIV Counseling and Testing Evaluation Form(s) or note if the scheduled evaluation(s) did not occur and need to be re-scheduled (if applicable)

***Data manager:***

- Upload data from the portable computers
- Charge and lock up the portable computers
- Back up CMP data
- Enter data edits into the Data Error Log on the DCC data portal
- Enter HIV test results into the HIV Test Results Log on the DCC data portal
- Lock up completed forms and logs
- The field supervisor should review the Data Manager Evaluation Form with data manager or note if the scheduled evaluation did not occur and needs to be re-scheduled (if applicable)
- Other daily data management activities: \_\_\_\_\_

# Appendix I

# Participant Tracking Form

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

### Participant Tracking Form

Date

Portable Computer #

*Data Manager Use Only:*

Interview Start Time

Interviewer ID

Survey ID (Coupon #)

Seed?      Y      N

Field Site ID

INTERVIEWER	NOTES
1. Passed the screener?                      Y      N	
2. Consented to the interview?            Y      N	
3. Consented to the HIV test?             Y      N	
4. Consented to <other> test?            Y      N	
5. Consented to specimen storage?       Y      N	
6. SRP during interview?                  Y      N	
7. Completed the interview?              Y      N	
8. Selected to recruit?                    Y      N	
<i>If yes, agreed to recruit?</i> Y      N	
<i>If yes, number of coupons due:</i> _____	
9. Received recruiter training?          Y      N	

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

**DATA EDITS:**

Variable Name	Old Value	New Value



# Appendix K

# Rapid Testing Quality Control Log

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

Rapid Testing Quality Control Log NHBS-HET5: 2019							
Date Controls Ran	Name of Person Running Controls	Date Controls Opened	Reason for Running Controls		Negative Control Result	HIV-1/HIV-2 Positive Control Result(s)	Notes
					Indicate if Controls Ran Successfully		
			<input type="checkbox"/> Routine	<input type="checkbox"/> New Lot Opened	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	
			<input type="checkbox"/> New Operator	<input type="checkbox"/> Storage Temp Irregularity	<input type="checkbox"/> No	<input type="checkbox"/> No	
			<input type="checkbox"/> New Shipment	<input type="checkbox"/> Test Area Temp Irregularity			
			<input type="checkbox"/> Routine	<input type="checkbox"/> New Lot Opened	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	
			<input type="checkbox"/> New Operator	<input type="checkbox"/> Storage Temp Irregularity	<input type="checkbox"/> No	<input type="checkbox"/> No	
			<input type="checkbox"/> New Shipment	<input type="checkbox"/> Test Area Temp Irregularity			
			<input type="checkbox"/> Routine	<input type="checkbox"/> New Lot Opened	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	
			<input type="checkbox"/> New Operator	<input type="checkbox"/> Storage Temp Irregularity	<input type="checkbox"/> No	<input type="checkbox"/> No	
			<input type="checkbox"/> New Shipment	<input type="checkbox"/> Test Area Temp Irregularity			
			<input type="checkbox"/> Routine	<input type="checkbox"/> New Lot Opened	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	
			<input type="checkbox"/> New Operator	<input type="checkbox"/> Storage Temp Irregularity	<input type="checkbox"/> No	<input type="checkbox"/> No	
			<input type="checkbox"/> New Shipment	<input type="checkbox"/> Test Area Temp Irregularity			
			<input type="checkbox"/> Routine	<input type="checkbox"/> New Lot Opened	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	
			<input type="checkbox"/> New Operator	<input type="checkbox"/> Storage Temp Irregularity	<input type="checkbox"/> No	<input type="checkbox"/> No	
			<input type="checkbox"/> New Shipment	<input type="checkbox"/> Test Area Temp Irregularity			

*Field Supervisor Signature:* \_\_\_\_\_







## Appendix N Phone Results Procedures and Log

Project sites conducting laboratory-based HIV testing can give participants their test results in person or, if permitted by local policies, over the phone. Sites planning to provide HIV test results over the phone should follow the guidance outlined in the steps below and they should record the information needed for returning test results on the Phone Results Log (**Figure N.1**). A model log can be printed or modified using the Excel file named **Appendix N - Phone Results Log**. Sites providing HIV test results by phone should never collect any personally identifiable information (PII) from participants, such as their names, nicknames, or phone numbers. Furthermore, the project phone number that participants call for their results should not have voice mail activated to prevent them from leaving any PII.

### ***Step 1 – Explaining the Process***

During HIV counseling, participants should be offered the option of receiving their HIV test results in person or by phone. A participant who would like to obtain his test result by phone should be required to identify a least one friend or relative from whom he can seek support if his test result is positive or indeterminate.



A participant should not be offered the option of receiving his test result by phone if the HIV test counselor believes that he is not psychologically able to handle a positive test result over the phone.

### ***Step 2 – Completing the Phone Results Card and Log***

If a participant chooses to obtain his HIV test result by phone, the HIV test counselor should give him a Phone Results Card (**Appendix M**) listing the phone number to call to obtain his result, the date his result will be available, the days and hours that results are provided, and an ID linked to his result, like the laboratory ID or Survey ID. To verify the participant's identity when he calls for his test result, the HIV test counselor should ask the participant to provide a password question, such as his mother's date of birth or his favorite sports team, along with the answer to this question. The HIV test counselor should then record the participant's test information on the Phone Results Log.

### ***Step 3 – Returning the HIV Test Result***

When a participant calls for his HIV test result, the HIV test counselor should ask him for his ID (e.g., laboratory ID or Survey ID) to locate his test information on the Phone Results Log and to locate his test results on the HIV Testing Log (Appendix L of the *NHBS Round 5 Model Surveillance Protocol*). Once the participant's test information and results have been found, the HIV test counselor should ask him his password question to verify his identity. If the participant's identity is verified, the HIV test counselor should give him his test result and the counselor should record the date the test result was given on the Phone Results Log. Participants with positive test results should





Information cards should be given to recruiters so that they know where and when to return for their recruiter rewards. Examples of the front and back of a card are illustrated in **Figures P.1** and **P.2**. Instructions on how to create cards from a Microsoft Power Point template are provided in **Appendix S** of this manual.

The color and size of the information cards should differ from those of the seed referral cards and coupons to help participants and project staff distinguish among them.

**Figure P.1 – Example of the front of an information card**

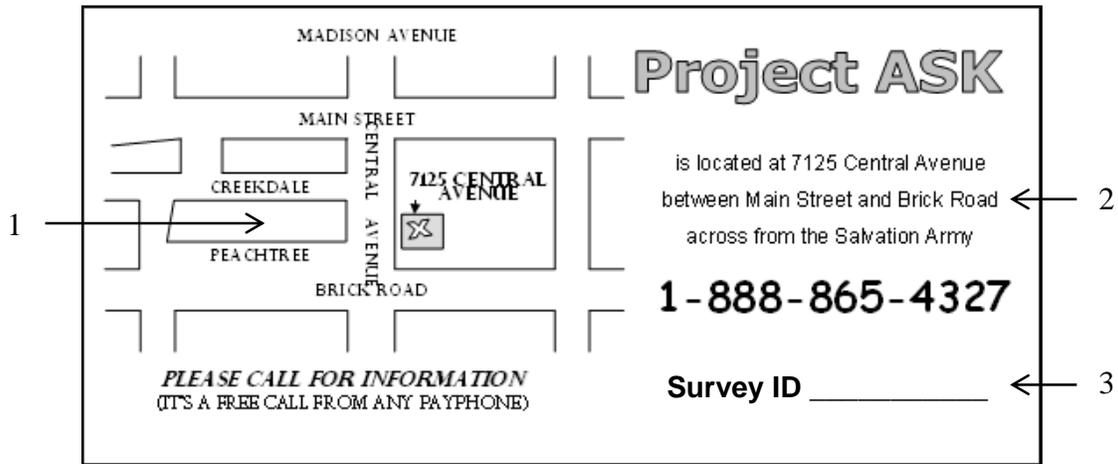


1. Name of the local NHBS project.
2. Description of the type of recruiter reward and the amount.
3. Phone number to call for project information (preferably toll-free).
4. Days and hours of field site operations.
5. Address of the field site.



If the days, times, and addresses of multiple field site locations cannot fit on the front of the information card, they can be included on the back of the card. The maps and directions normally printed on the back of the card can then be placed on a separate flyer that is distributed with the card.

**Figure P.2 – Example of the back of an information card**



1. Map showing the location of the field site.
2. Directions to the field site.
3. Space to record the participant's survey ID to search for his record in the Coupon Manager Program (CMP).

## Appendix Q

## Recruiter Training Script

A model Recruiter Training Script is outlined below. This script can be printed or modified using the Word file named **Appendix Q - Recruiter Training Script**.

### ***Who to Recruit***

We're going to give you *[insert #]* coupons to give to friends, relatives, or people you associate with so that they can be in the study too. You should give the coupons to people you know and who are between 18 and 60 years old; you should NOT give the coupons to strangers. You should only give the coupons to friends, relatives, or people you associate with who live in *[insert project area]*. Since people can just be in the study once, don't give the coupons to anyone who has already participated. Most importantly, the people you recruit will have to bring in their coupons and answer questions to determine if they are selected for the study.

### ***Coupons***

To be in the study, everyone has to have a coupon. Be sure to tell the people you give a coupon to that they need to have the coupon with them when they come in or when they call to make an appointment. The first thing we'll do is check to see if their coupon is valid.

***If a project site chooses to replace lost or stolen coupons when the numbers on the lost or stolen coupons can be identified and voided in the CMP:*** Your coupons cannot be replaced if the people you recruited are not selected for the study. A coupon cannot be used more than once. Each coupon has a date when it expires, and after that date, it can't be used anymore. So, you should tell people you give the coupon to that they need to come in or call to make an appointment before the expiration date written on the coupon.

***If a project site chooses not to replace lost or stolen coupons:*** Your coupons cannot be replaced if they are lost or stolen or if the people you recruited are not selected for the study. A coupon cannot be used more than once. Each coupon has a date when it expires, and after that date, it can't be used anymore. So, you should tell people you give the coupon to that they need to come in or call to make an appointment before the expiration date written on the coupon.

***If a project site is using photo coupons:*** Instead of handing out your coupons, you can take a photo of each one and text or email it to someone you want to recruit. If you do this, keep the message you send with the coupon general to protect the person's privacy. For example, you could say:

*You can use this coupon to take a health survey and earn up to \$[insert total incentive amount].*

You can also include directions to the field site in your message or you can send a photo

of the directions from the back of the coupon. We will not accept the coupon photo if the coupon number cannot be clearly seen or if the photo shows more than one coupon. Only one person can use each coupon. Therefore, if more than one person tries to use the same coupon photo, only the first person using it will be allowed to participate in the study.

### ***Process***

***If a project site is conducting STI testing:*** Be sure to tell the people you recruit to come in or make an appointment at a time when they are able to complete the whole survey process, which takes about 1 hour. Children aren't allowed to sit in on the interview, so ask your recruits to have someone watch their children if they have any. People you give coupons to who complete the interview will be given *[\$insert survey incentive]*. They will get an additional *[\$insert HIV testing incentive]* for taking an HIV test and an additional *[\$insert STI testing incentive]* for completing STI testing. We won't do an interview with anyone who is under the influence of drugs or alcohol; people who are not capable of completing the interview will not be allowed to participate in the study.

***If a project site is not conducting STI testing:*** Be sure to tell the people you recruit to come in or make an appointment at a time when they are able to complete the whole survey process, which takes about 1 hour. Children aren't allowed to sit in on the interview, so ask your recruits to have someone watch their children if they have any. People you give coupons to who complete the interview will be given *[\$insert survey incentive]*. They will get an additional *[\$insert HIV testing incentive]* for taking an HIV test. We won't do an interview with anyone who is under the influence of drugs or alcohol; people who are not capable of completing the interview will not be allowed to participate in the study.

### ***Reward***

You will get paid *[\$insert recruiter reward]* for each person you recruit who is selected for the study and who completes the interview. But you are not guaranteed to get the *[\$insert recruiter reward]* just for recruiting someone:

- You will not be paid for someone who is not selected for the study.
- You will not be paid for recruiting someone who has already participated in the study.
- You will not be paid for someone who does not complete an interview.

Not everyone in this study gets the opportunity to recruit others, and not everyone gets the same number of coupons. The computer determines who gets to recruit other people for the study and how many coupons they get. If someone you recruit participates in the study, they might get a different number of coupons than you did. The study is time-limited, so eventually no more coupons will be given out and no more interviews will be conducted.

### ***Recruiter Information***

In order for us to be sure that we give the reward to the right person, we're going to ask you a few questions and enter the information into the computer to create an identification number that is unique to you. When you come in to get paid, we'll ask you those same questions again to create the number and check it in the computer. The coupons we give you are linked to you so we'll know which ones to pay you for.

You can call our office to see if the people you gave coupons to were selected for the study and completed an interview, so that you can come in to get your reward. We can't tell you who came in or not, but we can tell you whether you can get a reward. We will only pay you, so do not send someone else in to get paid.

### ***Wrap-up***

Do you have any questions?

Thanks for helping us, and remember, give the coupons to people you know and who are between the ages of 18 and 60.

## Appendix R

## Recruiter Training Talking Points

Model Recruiter Training Talking Points are outlined below. These talking points can be printed or modified using the Word file named **Appendix R - Recruiter Training Talking Points**.

### ***Who to Recruit***

- We're going to give you *[insert #]* coupons to give to friends, relatives, or people you associate with so that they can be in the study too.
- Give the coupons to people you know and who are between 18 and 60 years old.
- Do NOT give the coupons to **strangers**.
- Give the coupons to people who live in *[insert project area]*.
- Give the coupons to people who have not already participated in the study.

### ***Coupons***

- Everyone has to have a coupon to be in the study.
- Tell people you recruit to have the coupon with them when they come in or when they call to make an appointment.
- ***If a project site chooses to replace lost or stolen coupons when the numbers on the lost or stolen coupons can be identified and voided in the CMP:*** Your coupons cannot be replaced if the people you recruited are not selected for the study.
- ***If a project site chooses not to replace lost or stolen coupons:*** Your coupons cannot be replaced if they are lost or stolen or the people you recruited are not selected for the study.
- ***If a project site is using photo coupons:*** Instead of handing out your coupons, you can take a photo of each one and text or email it to someone you want to recruit.
- ***If a project site is using photo coupons:*** Keep the message you send general to protect the person's privacy. For example: *You can use this coupon to take a health survey and earn up to \$[insert total incentive amount]*.
- ***If a project site is using photo coupons:*** Coupon photos will not be accepted if the coupon number cannot be clearly seen or if the photo shows more than one coupon.
- ***If a project site is using photo coupons:*** If more than one person tries to use the same coupon photo, only the first person using it will be allowed to participate in the study.

### ***Process***

- The whole process for the survey takes about 1 hour.

- Children aren't allowed to sit in on the interview, so ask the people you recruit to have someone watch their children if they have any.
- ***If a project site is conducting STI testing:*** Everyone who completes an interview will get *[\$insert survey incentive]*. Everyone who also does an HIV test will get an additional *[\$insert HIV testing incentive]* and everyone who completes STI testing will get an additional *[\$insert STI testing incentive]*.
- ***If a project site is not conducting STI testing:*** Everyone who completes an interview will get *[\$insert survey incentive]*. Everyone who also does an HIV test will get an additional *[\$insert HIV testing incentive]*.
- People who aren't capable of completing the interview won't be allowed to participate in the study. This includes people who are too drunk or high to complete the interview.

### ***Reward***

- You will get paid *[\$insert recruiter reward]* for each person you recruit who is selected for the study and who completes the interview; the *[\$insert recruiter reward]* is not guaranteed just for recruiting someone.
- You will not be paid for someone who is not selected for the study.
- You will not be paid for someone who has already participated.
- You will not be paid for someone who does not complete an interview.
- The computer determines who gets to recruit other people for the study and how many coupons they will get.
- Coupons will expire and the study will end at some point.

### ***Recruiter Information***

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

Do you have any questions? Thanks for helping us, and remember, give the coupons to people you know and who are between the ages of 18 and 60.

## **Appendix S    Instructions for Creating Referral Cards, Coupons, and Information Cards**

Project sites that wish to create their own referral cards, coupons, or information cards can use the Microsoft PowerPoint templates\* that were sent electronically with this manual. These templates are compatible with the most recent versions of PowerPoint. Sites using earlier versions of PowerPoint should contact their CDC Project Officer to request templates compatible with those versions and instructions for editing the templates. The template files are named:

Appendix S - Model Referral Card - Front  
Appendix S - Model Referral Card - Back  
  
Appendix S - Model Coupon - Front  
Appendix S - Model Coupon - Back  
  
Appendix S - Model Information Card - Front  
Appendix S - Model Information Card - Back

Project sites should edit the templates to create their own unique designs. Those sites that are in close proximity to one another should share their coupon designs to ensure that they are sufficiently different. This will help alleviate participant confusion if coupons from a neighboring project site become introduced locally.

To minimize the chance of damage to the cards or coupons, they should be printed on heavy stock paper. It is also helpful to use a different color paper for each of the three types of printouts so that they can be easily distinguished from one another.

### ***S.1    Using PowerPoint Templates***

The Microsoft PowerPoint templates can be edited, copied, and printed as described in the steps below.

#### ***S.1a    Editing***

The template files will automatically open in the “Slide Master” view for editing. While the templates are in the “Slide Master” view, you can use PowerPoint’s editing, inserting, and formatting functions to make any necessary changes. When you are finished, remember to save the changes.

#### ***Auto-numbering***

The front templates for the referral cards and coupons include auto-numbering (indicated by “<#>”) to automatically number the cards and coupons in sequence. The auto-numbering functions can be changed while in the “Slide Master” view and the “Normal”

view:

1. Select the **View** tab.
2. Select **Slide Master** or **Normal** as indicated in the steps below.

Auto-numbering can be removed from the templates in the “Slide Master” view:

1. Place the cursor on the “<#>” symbol and left click the mouse. The “<#>” symbol will become highlighted.
2. Press the **Delete** key.

Auto-numbering can be added to the templates in the “Slide Master” view:

1. Select the **Insert** tab.
2. Select **Text Box**.
3. Place the cursor where the number should appear and left click the mouse. A text box will open with the cursor inside (make sure the cursor is inside the text box before proceeding to the next step).
4. Select the **Insert** tab.
5. Select **Slide Number**. The “<#>” symbol will appear in the text box.

Auto-numbering on the referral cards begins with “1” and on the coupons, “1000.” To change these start numbers:

1. Close the “Slide Master” view or, as described above, use the **View** tab to change from the “Slide Master” view to the “Normal” view.
2. Confirm that the template is in the “Normal” view.
3. Select the **Design** tab.
4. Select **Slide Size**.
5. Select **Custom Slide Size**. The “Slide Size” window will open.
6. In the “Number slides from” field, enter the desired start number.
7. Select **OK**.



On the referral cards, the auto-numbering symbols are preceded by three zeros (“000<#>”) to automatically create the numbers “0001” to “0009.” If more than nine referral cards are printed, one of the zeros should be deleted so that the auto-numbering symbols are preceded by two zeros (“00<#>”). This will allow the numbers “0010” to “0099” to be automatically created.

### **S.1b Copying**

If the referral card or coupon templates include auto-numbering, they must be duplicated

before printing to automatically generate sequential numbers. This function must be performed in the “Slide Sorter” view:

1. Select the **View** tab.
2. Select **Slide Sorter**.
3. Copy the template by pressing the **Ctrl** key and the letter **C** key simultaneously.
4. Paste the template by pressing the **Ctrl** key and the letter **V** key simultaneously. The template can be pasted multiple times by holding the **Ctrl** key down and pressing the letter **V** key as many times as needed (holding both keys down simultaneously will generate multiple copies rapidly).

### **S.1c Printing**

To print the front templates:

1. Select the **File** tab.
2. Select **Print**. The “Print” window will open.
3. Change “Full Page Slides” to “Handouts (2 slides per page).” This will print cards approximately the size of an index card and coupons, the size of a dollar bill.
4. Select **Print**.

After the front templates are printed, the back templates can be printed on the reverse side of the printouts by following the steps outlined above.



Check the orientation of the printer’s paper feed before attempting to print the back templates. Otherwise, the back templates may be inadvertently printed upside-down or over the front templates.

---

\* The Microsoft PowerPoint referral card and coupon templates were originally provided by Douglas Heckathorn and Robert Broadhead. These templates were further modified by the Detroit project site during the NHBS-HET1 pilot.

## Appendix T

## Data Entry for Laboratory-based HIV Testing

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

- Ag/Ab Combo Immunoassay
- Antibody Immunoassay
- Laboratory Screening Rapid Test
- Laboratory Supplemental Rapid Test
- IFA
- Nucleic Acid Test
- Western Blot

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

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

Trade Name of Laboratory-based HIV Test	HIV Test Results Log Response Option
Abbott Architect HIV Ag/Ab Combo Assay ADVIA Centaur HIV Ag/Ab Combo (CHIV) BioPlex 2200 HIV Ag-Ab Bio-Rad GS HIV Combo Ag/Ab EIA Ortho VITROS HIV Combo Test Roche Elecsys HIV combi PT	Ag/Ab Combo Immunoassay
ADVIA Centaur HIV 1/O/2 Enhanced (EHIV) Bio-Rad GS HIV-1/2 Plus O Ortho VITROS ECi/ECiQ Anti-HIV 1 + 2 Reagent pack Avioq HIV-1 Microelisa System	Antibody Immunoassay
Chembio DPP HIV-1/2 Chembio SURE CHECK HIV 1/2 Assay Chembio HIV 1/2 STAT-PAK Determine HIV-1/2 Ag/Ab Combo Test INSTI HIV-1/HIV-2 Rapid Antibody Test MedMira Reveal G4Rapid HIV-1 Antibody Test OraQuick Advance Rapid HIV-1/2 Antibody Test Uni-Gold Recombigen HIV	Laboratory Screening Rapid Test
Geenius HIV-1/2 Supplemental System	Laboratory Supplemental Rapid Test
Flourognost HIV-1 IFA	IFA
Aptima HIV-1 RNA Qualitative Assay <i>Any viral load assay (e.g., Abbott m2000, Roche COBAS v2.0, Hologic HIV-1 RNA quant)</i>	Nucleic Acid Test
Bio-Rad Genetic Systems HIV-1 Western Blot Cambridge Biotech HIV-1 Serum Western Blot	Western Blot

## Appendix U

## Process Monitoring Reports

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

### ***U.1 Recruitment Monitoring Report***

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

#### **1. RECRUITMENT MONITORING**

Week No.	Date	No. Screened	No. Eligible	% Eligible	No. Completed Interview	% Completed Interview	No. Consented to HIV Test	% Consented to HIV Test
<b>Total</b>								

No. Consented to STI Tests	% Consented to STI Tests	No. Consented to Hepatitis Tests	% Consented to Hepatitis Tests	No. Agreed to Blood Storage	% Agreed to Blood Storage	No. Eligible to Recruit	% Eligible to Recruit

### ***U.2 Coupon Manager Program Report***

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

#### **1. COUPON TRACKING**

Week No.	Date	No. Interviewed	No. Agreed to Recruit	% Agreed to Recruit	No. of Participants who Received Coupons by No. of Coupons Distributed					
					0	1	2	3	4	5
<b>Total</b>										

*Coupon Tracking Report* continued:

No. Coupons Distributed	No. Coupons Returned	% Coupons Returned	No. Photo Coupons Returned	% Photo Coupons Returned

## 2. NUMBER OF COUPONS DISTRIBUTED TO RECRUITERS

Recruiter Type	No. of coupons	Date Implemented	No. Recruiters

## 3. NUMBER WHO REPORTED COUPON REFUSALS

Coupon Refusals	N	%
Reported coupon refusals		
Reported no coupon refusals		
Not asked		
Total		

## 4. GENDER OF COUPON REFUSALS

Gender	N	%
Male		
Female		
Total		

## 5. RACE/ETHNICITY OF COUPON REFUSALS

Race/Ethnicity	N	%
Asian		
Black		
Hispanic		
Other		
White		
Total		

## 6. REASONS FOR COUPON REFUSALS

Reasons for refusal	N	%
Already participated in the survey		
Didn't have time		
Didn't live in the area		
Didn't trust you (recruiter)		
Don't like research/surveys		
Other		
Unknown		
Total		

## U.3 Sample Characteristics – Screened Report

### 1. QUESTIONNAIRE VERSION

Questionnaire Version	N	%
Total		

### 2. ELIGIBLE

Eligible	N	%
Yes		
No		
Total		

### 3. AGE

Age	Eligible		Not Eligible		Total	
	N	%	N	%	N	%
< 18						
18 – 29						
30 – 39						
40 – 49						
50 – 60						
> 60						
Unknown						
Total						

#### 4. GENDER

Gender	Eligible		Not Eligible		Total	
	N	%	N	%	N	%
Male						
Female						
Other (Includes Transgender)						
Total						

#### 5. RACE/ETHNICITY

Race/Ethnicity	Eligible		Not Eligible		Total	
	N	%	N	%	N	%
American Indian or Alaska Native						
Asian						
Black or African American						
Hispanic						
Native Hawaiian or Other Pacific Islander						
White						
Multiple Races						
Unknown						
Total						

#### 6. MSA RESIDENT

MSA Resident	Eligible		Not Eligible		Total	
	N	%	N	%	N	%
Yes						
No						
Unknown						
Total						

#### 7. KNOWN PREVIOUS PARTICIPANT

Known Previous Participant	Eligible		Not Eligible		Total	
	N	%	N	%	N	%
Yes						
No						
Unknown						
Total						

**8. ABLE TO PARTICIPATE**

	Eligible		Not Eligible		Total	
	N	%	N	%	N	%
Able to Participate						
Yes						
No						
Unknown						
Total						

**9. TOO YOUNG TO PARTICIPATE**

	Eligible		Not Eligible		Total	
	N	%	N	%	N	%
Too Young to Participate						
Yes						
No						
Unknown						
Total						

**10. TOO OLD TO PARTICIPATE**

	Eligible		Not Eligible		Total	
	N	%	N	%	N	%
Too Old to Participate						
Yes						
No						
Unknown						
Total						

**11. HETEROSEXUAL SEX IN PAST 12 MONTHS**

	Eligible		Not Eligible		Total	
	N	%	N	%	N	%
Heterosexual Sex in Past 12 Months						
Yes						
No						
Unknown						
Total						

## ***U.4 Sample Characteristics – Interviewed Report***

### **1. AGE**

Age	HETDEF		Not HETDEF		Total	
	N	%	N	%	N	%
18 – 29						
30 – 39						
40 – 49						
≥ 50						
Unknown						
<b>Total</b>						

### **2. GENDER**

Gender	HETDEF		Not HETDEF		Total	
	N	%	N	%	N	%
Male						
Female						
Unknown						
<b>Total</b>						

### **3. RACE/ETHNICITY**

Race/Ethnicity	HETDEF		Not HETDEF		Total	
	N	%	N	%	N	%
American Indian or Alaska Native						
Asian						
Black or African American						
Hispanic						
Native Hawaiian or Other Pacific Islander						
White						
Multiple Races						
Unknown						
<b>Total</b>						

#### 4. EDUCATION

Education	HETDEF		Not HETDEF		Total	
	N	%	N	%	N	%
Less Than High School						
High School						
Vocational/Tech School or Some College						
College Graduate or Graduate School						
Unknown						
<b>Total</b>						

#### 5. HOMELESS IN PAST 12 MONTHS

Homeless in Past 12 Months	HETDEF		Not HETDEF		Total	
	N	%	N	%	N	%
Yes, currently						
Yes, not currently						
No						
Unknown						
<b>Total</b>						

#### 6. INCOME

Income	HETDEF		Not HETDEF		Total	
	N	%	N	%	N	%
0 – \$9,999						
\$10,000 – \$19,999						
\$20,000 – \$ 29,999						
\$30,000 – \$39,999						
\$40,000 – \$49,999						
≥ \$50,000						
Unknown						
<b>Total</b>						

## 7. LOW INCOME

	HETDEF		Not HETDEF		Total	
	N	%	N	%	N	%
Low Income						
Yes						
No						
Unknown						
Total						

## 8. INJECTION HISTORY

	HETDEF		Not HETDEF		Total	
	N	%	N	%	N	%
Injection Drug Use						
Never						
Not Recent (> 12 months)						
Recent ( $\leq$ 12 months)						
Unknown						
Total						

## 9. ZIP CODE

	HETDEF		Not HETDEF		Total	
	N	%	N	%	N	%
Zip Code						
Total						

## U.5 Test Results Report

### 1. HIV RAPID TEST RESULT

	Rapid HIV Test Result #2										Total
	Preliminary Positive		Negative		Invalid		Not Done		Unknown		
Rapid HIV Test Result #1	N	%	N	%	N	%	N	%	N	%	N
Preliminary Positive											
Negative											
Invalid											
Not Done											
Unknown											
Total											

### 2. HIV SELF-REPORTED TEST RESULT

	Final HIV Test Results										Total
	Positive		Negative		Indeterminate		Discordant Rapid Test Results		Unknown		
Self-Reported HIV Status	N	%	N	%	N	%	N	%	N	%	N
Self-reported Positive											
Not Self-reported Positive											
Unknown											
Total											

### 3. SPECIMEN SENT TO CDC LAB

	Final HIV Test Results										Total
	Positive		Negative		Indeterminate		Discordant Rapid Test Results		Unknown		
Specimen Sent To CDC Lab	N	%	N	%	N	%	N	%	N	%	N
Yes											
No											
Total											

#### 4. HEPATITIS B TEST RESULT

	Interpretation of HBV Tests by DCC										Total	
	Susceptible		Immune Due to Infection		Immune Due to Vaccination		Infected		Unknown			
Interpretation of HBV Tests by Project Staff	N	%	N	%	N	%	N	%	N	%	N	%
Susceptible												
Immune Due to Infection												
Immune Due to Vaccination												
Infected												
Unknown												
Not done												
Total												

#### 5. HEPATITIS C TEST RESULT

	RNA Test Result								Total
	Positive		Negative		Unknown		Not Done		
Rapid HCV Test Result	N	%	N	%	N	%	N	%	N
Reactive									
Non-reactive									
Invalid									
Unknown									
Not Done									
Total									

### ***U.6 Seed Report***

#### 1. SEED MONITORING

No. Screened	No. Eligible	No. Completed Interview	No. Eligible to Recruit

## 2. SEED CHARACTERISTICS

Date	Survey ID	Gender	Race/Ethnicity	Age	Eligible to Recruit

## *U.7 Respondent-Driven Sampling Report*

### 1. RECRUITMENT BY STRANGER

Recruitment by Stranger	N	%
Yes		
No		
Total		

### 2. FIELD SITE ENROLLMENT

Day of Week	No. of Interviews				Total
	<i>Field Site ID 1</i>	<i>Field Site ID 2</i>	<i>Field Site ID 3</i>	<i>Field Site ID 4</i>	
Sunday					
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Total					

### 3. CROSS RECRUITMENT

Recruiter's Field Site	Recruit's Field Site				Total
	<i>Field Site ID 1</i>	<i>Field Site ID 2</i>	<i>Field Site ID 3</i>	<i>Field Site ID 4</i>	
<i>Field Site ID 1</i>					
<i>Field Site ID 2</i>					
<i>Field Site ID 3</i>					
<i>Field Site ID 4</i>					
Total					

#### 4. RACE/ETHNICITY BY FIELD SITE

Race/Ethnicity	Recruit's Field Site				Total
	Field Site ID 1	Field Site ID 2	Field Site ID 3	Field Site ID 4	
American Indian or Alaska Native					
Asian					
Black or African American					
Hispanic					
Multiple Races					
Native Hawaiian or Other Pacific Islander					
White					
Unknown					
Total					

#### 5. AGE BY FIELD SITE

Age	Recruit's Field Site				Total
	Field Site ID 1	Field Site ID 2	Field Site ID 3	Field Site ID 4	
18 – 29					
30 – 39					
40 – 49					
≥ 50					
Unknown					
Total					

#### 6. RECRUITMENT CHAINS

Chain	Wave	Frequency	Percent	Cumulative Frequency	Cumulative Percent

*Note:* The Recruitment Chains table is an Excel spreadsheet that can be downloaded from a link in the Respondent-Driven Sampling Report.

## ***U.8 Possible Previous Participant Report***

### **1. POSSIBLE PREVIOUS PARTICIPANTS**

Date of Birth	Gender	Race/Ethnicity	No. of Records

## ***U.9 Interviewer Report***

### **1. INTERVIEW LENGTH**

Interviewer ID	No. of Completed Interviews	Length of Eligibility Screener					Length of Consent Process					Length of Core Survey				
		Med	Mean	Min	Max	No.	Med	Mean	Min	Max	No.	Med	Mean	Min	Max	No.
<b>TOTAL</b>																

### **2. INTERVIEWER CONFIDENCE IN RESPONSES**

Interviewer ID	Confident		Some Doubts		Not Confident at All		Unknown		Total
	N	%	N	%	N	%	N	%	
<b>Total</b>									

### **3. TESTING CONSENT**

Interviewer ID	Consented to HIV Test		Consented to STI Tests		Consented to Hepatitis Tests		Consented to Specimen Storage		Total
	N	%	N	%	N	%	N	%	
<b>Total</b>									

#### 4. CODING OF OTHER INSURANCE

Interviewer ID	Survey ID	Private	Medicaid	Medicare	Other Government	Tricare (Champus)	VA Coverage	Text for Other Insurance Specified