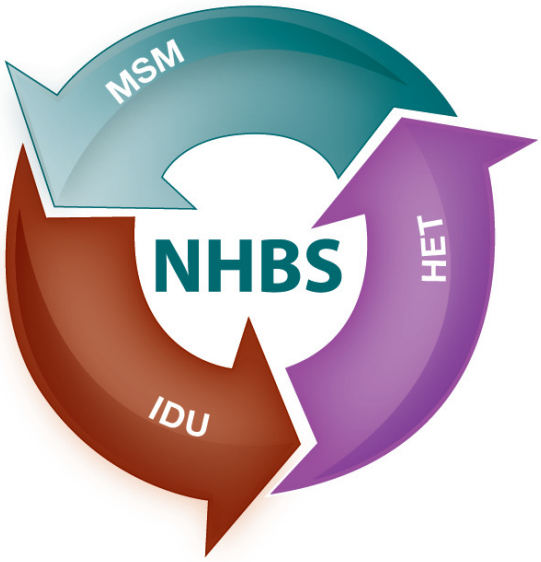
National HIV Behavioral Surveillance: Injection Drug Use – Round 5 (NHBS-IDU5)

OPERATIONS MANUAL



NATIONAL HIV BEHAVIORAL SURVEILLANCE SYSTEM

Behavioral Surveillance Team
NCHHSTP/DHAP/BCSB

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Contacts

Corresponding Author:

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

Contributing Authors:

Dita Broz, PhD, MPH
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

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Acronyms

Acronym:	Definition:
CAPI	Computer Administered 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
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-IDU	National HIV Behavioral Surveillance, Injection Drug Use
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
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

1 Introduction

1.1 Overview

The *NHBS-IDU5 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-IDU5 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.

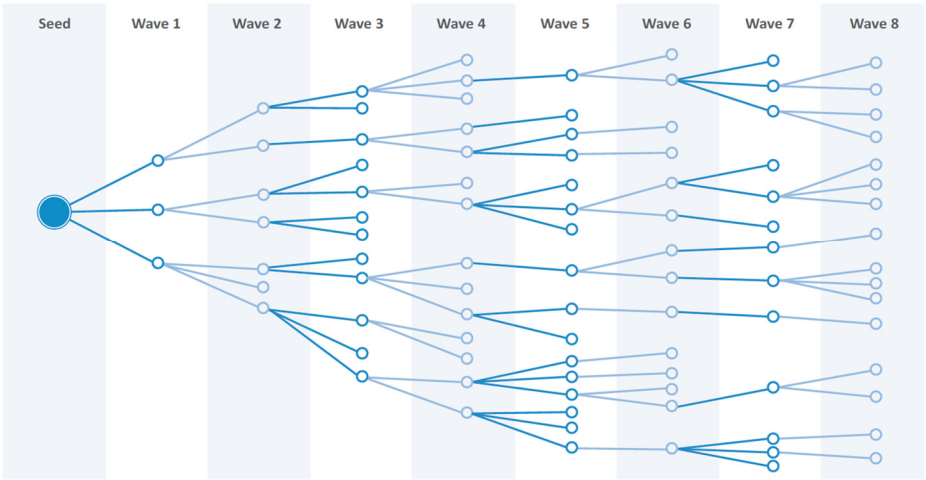
1.4 Respondent-Driven Sampling

The sampling method used during the IDU 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 sub-population 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 sub-populations, like the young, 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
Administrative	• Oversee the hiring and supervision of project staff. • Tailor the *Model Surveillance Protocol* per site-specific needs. • 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. • Ensure that all IRBs providing approval have an active Federalwide Assurance (FWA) number. (Health department only) • Review, monitor, and assure compliance with established Notice of Award guidelines to provide fiscal administration and management of federal funds. This includes administrative supervision to investigate and report financial irregularities. (Health department only) • Oversee preparation and submission of annual cooperative agreement reports, including annual progress reports and financial status reports, to CDC Office of Financial Resources (OFR). (Health department only) • Oversee the development of local use questions. • Respond to CDC's requests for input on revisions to the NHBS questionnaire and other supporting documents. • Participate in CDC site visits, PI meetings, conference calls, and national calls.	• Manage contracts related to the project (if applicable). • Assist PI with the hiring and supervision of project staff. • Assist PI with IRB-related activities, cooperative agreement reports and other key administrative functions. • Participate in CDC site visits, trainings, national calls, and regular conference calls. • Act as the primary point of contact with CDC in matters that relate to the project. • Respond to CDC's requests for input on revisions to the NHBS questionnaire and other supporting documents. • Coordinate the development of local use questions.	• Participate in CDC site visits, trainings, regular conference calls, and, as available, monthly calls.
Project management	• Serve as backup for project coordinator in event of absence or appoint a designee. • Collaborate with local stakeholders and disseminate information and data from the project to garner community support.	• Provide overall project management. • Oversee ongoing formative assessment efforts. • Serve as backup for the field supervisor and data manager. • Maintain inventory of supplies, materials, incentives, and equipment.	• Assist with matters related to field staff (e.g., training and development, scheduling, team building). • Manage operations and data collection at field sites. • Ensure adequate preparations, including supplies, materials, and equipment for field sites. • Coordinate ongoing formative assessment efforts and implement changes based upon findings.

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

Responsibilities	Principal Investigator (PI)	Project Coordinator	Field Supervisor
Training and ongoing evaluations	• Ensure required trainings have been successfully completed by all project staff. • Conduct staff evaluations in collaboration with the project coordinator and field supervisor.	• Coordinate and conduct pre-implementation and ongoing trainings for project staff in collaboration with the field supervisor. • Conduct staff evaluations in collaboration with the PI and field supervisor.	• Coordinate and conduct pre-implementation and ongoing trainings for project staff in collaboration with the project coordinator. • Conduct staff evaluations in collaboration with the PI and project coordinator.
Data collection, management, analysis, and dissemination	• Ensure timely submission and entry of data to the DCC data portal. • Assume responsibility for quality control and data integrity. • Supervise the implementation of recommendations from CDC or the DCC to improve data quality. • Oversee development of policies pertaining to analyses and dissemination of data. (Health department only) • Oversee analyses of site data. • Ensure data is released in accordance with local policy and data use agreements. (Health department only) • Present reports and disseminate study findings. • Use study findings for the development, modification, and evaluation of local prevention programs.	• Ensure daily transfer of data from portable computers to the QDS™ Warehouse. • Ensure that QDS™ Warehouse is maintained. • Ensure that coupon manager information, HIV testing data, and data errors are entered into the DCC data portal daily. • Review Process Monitoring Reports, ensure problems are addressed, and improvement seen. • Coordinate and implement policies pertaining to data analysis and dissemination. • Participate in data analysis and dissemination. • Evaluate need for ongoing formative assessment and make changes based upon findings.	• Schedule field site hours. • Review, tabulate, and reconcile forms and logs used in the field. • Review data errors with the coupon manager, interviewers, and HIV test counselors. • Oversee documentation of data errors. • Supervise entry of coupon manager information, HIV testing data, and data errors into the DCC data portal. • Review Process Monitoring Reports, identify issues of concern, and implement changes for improvement.
HIV testing operations	• Develop local HIV testing protocol and oversee HIV testing activities. • Ensure procedures are developed for making referrals to care and other services.	• Oversee maintenance of HIV testing supplies. • Ship HIV test specimens. • Receive and log HIV test results from lab. • Obtain CLIA waiver (if applicable). • Develop procedures for making referrals to care and other services.	• Ensure proper documentation of HIV testing activities, including consent. • Ensure adherence to HIV testing procedures. • Ensure adherence to procedures for making referrals to care and other services.
Safety, security, and confidentiality	• Responsible for safety, security, and confidentiality of project staff, participants, materials, and data, including the development of local procedures and policies. • Report field incidents and adverse events to CDC within 48 hours of occurrence and to the IRB(s) per local policy.	• Coordinate development of local procedures for incident reporting, safety, and handling participants known to project staff. • Report field incidents and adverse events to CDC within 48 hours of occurrence and to the IRB(s) per local policy.	• Assist in the development of local procedures for incident reporting, safety, and handling participants known to project staff; and ensure adherence to all locally developed procedures. • Report field incidents and adverse events to CDC within 48 hours of occurrence and to the IRB(s) per local policy.

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

Coupon Manager	Interviewer	HIV Test Counselor	Data Manager
• Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately. • 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. • Manage all operational activities related to the coupon manager station and the Coupon Manager Program (CMP). • Upload CMP data to the DCC data portal daily.	• Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately. • Accurately document participant information on the consent form and Participant Tracking Form (if applicable). • Conduct the eligibility screener, consent, and core questionnaire according to the instructions in the *Interviewer Guide*. • Maintain data integrity (i.e., all data collected accurately represent the information provided by participants during the interview). • Provide recruiter training (if applicable). • Assist with ongoing formative assessment as necessary.	• Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately. • Conduct HIV counseling and testing per local and NHBS guidelines. • Have knowledge of information in package insert for rapid testing (if applicable). • Document HIV test results. • Accurately record information on lab slips, HIV Test Result Logs, and Specimen Transport or Shipping Logs. • For sites with separate interviewers and HIV test counselors: Ensure that the participant has consented to HIV testing. • Assist with ongoing formative assessment as necessary.	• Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report adverse events to the field supervisor immediately. • Ensure upload of data from the portable computers to the QDS™ Warehouse. • Ensure daily receipt of forms and logs and review errors or concerns with the field supervisor or project coordinator. • Enter information from forms and logs into the DCC data portal. • Maintain QDS™ Warehouse and submit to the DCC data portal weekly. • Maintain data integrity (i.e., each record in the database represents the data an individual provided to the field team). • Review data reports from the DCC as soon as they are received, and provide requested data edits and explanations to resolve data issues via the DCC data portal. • Perform data analyses as needed.

A successful project coordinator has considerable knowledge of HIV/AIDS and surveillance activities, strong leadership and supervisory skills, and high attention to detail. In addition, the project coordinator should have excellent word processing, spreadsheet, and file management skills, as well as a willingness to learn additional computer programs, such as the Questionnaire Development System™ (QDS™) and the 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 stigmatized 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 Manual	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
Project Coordinator	X	X	X	X	X	X	X	Attend CDC training and view live webinars	X	X	X		X	X
Field Supervisor	X	X	X	X	X	X	X		X	X	X		X	X
Coupon Manager	X	X	X*			X		Attend local training	X	X	X		X	X
Interviewers	X	X	X*	X	X				X	X	X		X	X
HIV Test Counselors	X	X	X*				X		X	X	X		X	X
Data Manager	X	X	X*	X	X	X			X	X	X	X	X	

*If applicable.

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 Collaborative Institutional Training Initiative (CITI) website (https://www.citiprogram.org) or the NIH Protecting Human Research Participants (PHRP) website (https://phrp.nihtraining.com/#!/). 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.	***Project Management:*** 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.
			HIV Testing Operations: 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.	***Minor errors:*** Retrained on any skills that are below standard prior to resuming coupon manager duties.	Successfully completes the ***next*** two check-in/check-out activities using the CMP and, if applicable, the ***next*** two recruiter trainings. If evaluations are unsuccessful, follow the retraining and evaluation recommendations for major errors (see below).
				Major errors: Retrained completely prior to resuming coupon manager duties.	Successfully completes two consecutive ***mock*** 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 10th 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.)	***Minor errors:*** Retrained on any skills that are below standard prior to resuming interviewing.	Successfully completes the ***next*** two full interviews (screening, consent, and interview) and, if applicable, the ***next*** two recruiter trainings. If evaluations are unsuccessful, follow the retraining and evaluation recommendations for major errors (see below).
				Major errors: Retrained completely prior to resuming interviewing.	Successfully completes two consecutive full ***mock*** 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*
HIV Test Counselors	PI, PC, or FS	Successfully completes two consecutive full mock HIV testing sessions. 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).	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.	***Minor errors:*** Retrained on any skills that are below standard prior to resuming HIV testing.	Successfully completes the ***next*** two HIV testing sessions. If evaluations are unsuccessful, follow the retraining and evaluation recommendations for major errors (see below).
				Major errors: Retrained completely prior to resuming HIV testing.	Successfully completes two consecutive ***mock*** HIV testing sessions.
Data Manager	PI or PC	Successfully meets NHBS performance recommendations. Successfully uploads data from the portable computers without any data loss. For new data managers, successfully encrypts and submits QDS™ Warehouse containing mock core interviews to the data portal.	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 or is conducting an interview or HIV counseling session. If an evaluator needs to interrupt, it should be done discreetly, with communication directed to the staff member and not the participant.
- Provide positive feedback and recommendations for improvement to the staff member following each evaluation.
- Maintain pre-implementation and ongoing evaluation schedules.
- Discuss staff evaluations and retraining needs with the field supervisor.

2.6d Project staff

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

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

3.1 Overview

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

As described in **Chapter 11** of this manual, project sites must regularly submit the Questionnaire Development System™ (QDS™) Warehouse with their core surveys to the DCC data portal. They will also use the data portal to enter data into the HIV Test Results Log, the Hepatitis Test Results Log (if applicable), and the Data Error Log. Project staff that need access to the DCC data portal should first receive approval from the principal investigator of the directly funded health department and then apply for access following the instructions in the *NHBS-IDU5 Data Management Training Manual.*

3.4 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 which sites can modify to meet their local needs.

3.4a Portable computers and survey software

NHBS surveys must be conducted using portable computers, such as tablets or laptops. Therefore, project sites should check that their portable computers are functioning properly and ensure that enough are available for use in the field (including at least one backup). 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.

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

Project sites must use QDS version 2.6.1 modules to collect and manage NHBS data. These modules include the Design Studio, Warehouse Manager, and Computer Assisted Personal Interview (CAPI). QDS version 2.6.1 modules may not function properly on computers that also contain earlier or later versions of the modules, such as versions 2.4, 2.5, or 3.0. Only the CAPI module will be supported for NHBS data collection.

3.4b Materials

Project sites should ensure that they have an adequate number of 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.*

3.4c Forms and logs for project management

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

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.

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

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

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

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.

3.4d Prevention and referral materials

All participants who complete at least part of the survey should be provided with HIV prevention and referral materials. Project sites should develop or compile these materials and have them readily available at 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. Also, 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 injection equipment, bleach kits, condoms, and lubricant. If permitted by local policy, project sites may distribute injection equipment, like syringes or cookers, but they cannot use NHBS funds to purchase these items. In addition, sites must obtain approval from their CDC project officer before giving out any injection equipment.

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

3.4e Other supplies and materials

Project sites should obtain any other supplies needed to carry out field operations. 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.

3.5 Local Safety Procedures

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

Project staff must be alert to their own safety and 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. Jewelry, purses, expensive watches, and cameras 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 48 hours. 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 48 hours or earlier if mandated by local IRB requirements (see Chapter 9 of the *NHBS Round 5 Model Surveillance Protocol*).

4 Field Sites

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 sub-populations of persons who inject drugs (PWID) have equal access and would be equally willing to go, such as a location that serves as a "bridge" between the major sub-populations. Similarly, if multiple field sites are used, at least one of the field sites must be readily accessible to all major sub-populations of PWID. Results of formative assessment should be used to determine whether a single field site location is sufficient to reach all the major sub-populations of PWID 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 or near areas where ***large*** numbers of PWID receive services or congregate. This will minimize the likelihood that participants distribute coupons to strangers hanging around the field site rather than to those they know personally.

- Field sites should not be placed in substance use disorder treatment centers or methadone clinics. People attending these facilities may not have injected drugs in the past 12 months, but they would have sufficient knowledge of injection practices to pass the "knowledge" questions in the eligibility screener.

- 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. Another potential problem is that homeless people who do not inject drugs could fraudulently claim to inject drugs in order to participate in the project and collect the incentive.

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.

However, there is an exception to the prohibition on facilities with primary or exclusive services. With approval from their CDC project officer, project sites can place a field site in a facility that provides a specific service if there is ***no*** stigma associated with that service and the field site is able to operate separately from the facility, such as on different days or at different times. For example, if a syringe exchange program operates in a facility Monday thru Friday from 9 am to 5 pm, a field site could operate in the facility on weekends or in the evening.

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 sub-population(s) of PWID because this could also result in a biased sample.

4.2b Additional considerations for vans

Project sites that plan on using 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 PWID or homeless people congregate; near substance use disorder treatment centers or methadone clinics; 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 sub-populations of PWID 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 sub-population of PWID or a sub-population 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 sub-population of PWID operates for too many hours each week, that sub-population may become overrepresented in the sample; whereas if the field site operates for too few hours, the sub-population may become underrepresented. For this reason, field sites which focus on a specific sub-population of PWID should have operating hours that are roughly proportional to the size of the sub-population. For example, if a field site focuses on a sub-population that comprises 20% of PWID, 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 which focus on a specific sub-population of PWID; it does not apply to field sites that all sub-populations 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. 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-recruitment

Cross-recruitment means recruitment between two different groups of participants. In regard to field sites, cross-recruitment occurs when a participant from one field site recruits a person who participates at a different field site, and vice-versa. Cross-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-recruitment is likely to occur among the planned field sites. If cross-recruitment is not likely to occur with a particular field site, that field site should only be used if formative assessment indicates that a sub-population 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 might 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 sub-populations of PWID 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 in the field alone.

4.6 Crowd Control

As the project becomes established in the community and recruitment increases, more and more PWID 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 will 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 sub-population of PWID. Denying available appointment spots to individuals who are not members of the specific sub-population would undermine the RDS sampling method and bias the sample. Nevertheless, sites that are having difficulty enrolling an important sub-population 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 Seeds

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 inject drugs and 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 persons who inject drugs (PWID) in the project area. Examples of key informants include community leaders, individuals doing outreach work among PWID, staff from organizations that provide services to PWID, and persons who currently inject drugs or who formerly injected drugs. 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:

- a person who currently inject drugs,
- at least 18 years old (all initial seeds must also be younger than 30 years of age),
- a resident of the project area, ***and***
- male or female (although transgender persons are eligible to participate in NHBS-IDU, they are not the target population for this cycle and cannot be selected as seeds).

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.

Seeds may also be recruited directly by project staff during outreach activities, or alternatively, key informants who inject drugs 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 PWID 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. In addition, 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 of PWID, and is well respected in the community. These characteristics increase the likelihood that the seed will be able to recruit other PWID to participate in the survey. Moreover, seeds should be diverse with respect to factors such as age, race/ethnicity, drug preference, geography, and any other factors that may create more insular peer networks. For example, if methamphetamine users do not interact with heroin users in a project area, cross-recruitment between these groups would be very limited or non-existent. Accordingly, the project site should select some seeds that are methamphetamine users and some that are heroin users to ensure that both sub-populations are represented. Similarly, if white PWID do not interact with black PWID, the site should select some seeds that are white and some that are black. Nonetheless, selecting seeds by demographic characteristics alone will not guarantee access to diverse peer networks. For example, if a white seed is a member of a black peer network, he may produce a recruitment chain that is racially similar to a chain produced by a black seed.

During previous NHBS-IDU cycles, nearly all project sites experienced difficulty enrolling young PWID. Comparisons of NHBS-IDU data to other sources of data among PWID suggest that young persons have been consistently underrepresented among NHBS-IDU participants. Accordingly, to improve enrollment among young PWID, sites should initially choose seeds that are all less than 30 years old. Because older PWID have demonstrated a greater willingness and ability to participate in the survey in the past, choosing young seeds will decrease the likelihood that recruitment chains become locked in networks of older persons.

Seeds should also reflect those sub-populations which are of greatest importance to the local HIV epidemic among PWID. During formative assessment, sites should identify those sub-populations from which seeds should be chosen to yield a representative sample of at-risk PWID.

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 PWID. 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 sub-populations of PWID are networked in their local community. If two or more sub-populations are ***not*** closely networked, sites will need to select a small number of seeds (2-3) from each of the sub-populations (see **Chapter 4** of this manual for a description of ways to focus on specific sub-populations using field sites). On the other hand, if two or more sub-populations of PWID are closely networked, a small number of seeds from any of the closely-networked sub-populations will be sufficient to start recruitment.

Project sites should not select seeds from every possible network of PWID in their community. Instead, they should focus on those networks that include the sub-populations of PWID at greatest risk of 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 PWID living in the project area. If one imagines a peer network with lines drawn between people to show relationships, a seed is someone with many lines radiating out; that is to say, 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 inject drugs and live in [the project area]?*
- *Are you willing to recruit other people you know who inject drugs and live in [the project area] for the survey?*
- *Of the people you know who inject drugs and 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?*
- *Are you familiar with the injection drug community in [the project area]?*
  - *Do you know where most people buy drugs?*

- *What are the prices of the drugs?*
- *What is the most commonly injected drug?*
- *How do people inject here?*

- *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., Friday, June 1, 2018 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 0888. Project sites should 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 during practice 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.

5.5a Making referral cards

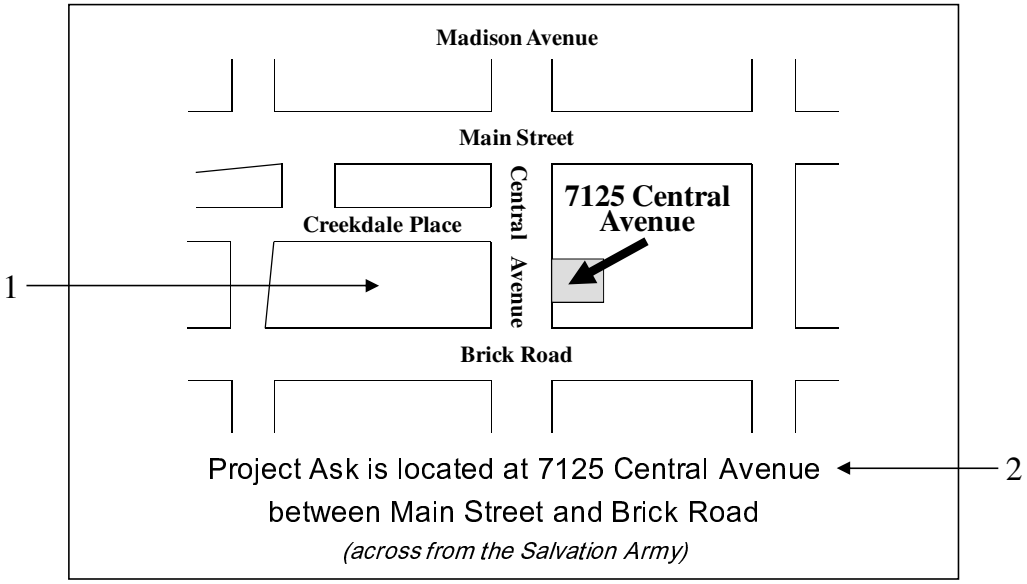
Project sites may have their referral cards professionally printed or they may make the cards themselves by following the instructions in **Appendix S**. Referral cards may be designed however a site wishes, but they must contain specific information on their front and back as illustrated in **Figures 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

1. Referral card number ranging from 0001 to 0888.
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," "AIDS," or "injection drug use" should not be included on the referral card because of the stigma associated with these terms.

6 Coupons

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 8888. 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). 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 during practice 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 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 sub-populations 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 sub-population is less than what is expected based on formative assessment, project sites can increase the number of coupons given to recruiters from the underrepresented sub-population to improve their enrollment. Likewise, to help prevent the sample from becoming biased if a specific sub-population starts to dominate enrollment, sites can decrease the number of coupons given to recruiters from that sub-population 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 sub-populations of greatest importance to the local HIV epidemic without intervention. Before increasing the number of coupons given to a

select sub-population, sites must first conduct ongoing formative assessment to determine why participation by that sub-population 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 sub-population, sites may then distribute more coupons to them. The under- or overrepresentation of a sub-population 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.

Because young persons who inject drugs (PWID) are a priority sub-population for enrollment in NHBS-IDU5, project sites should distribute more coupons to young PWID from the start of data collection. Sites do not have to wait until young PWID are underrepresented in their samples before they begin differential coupon distribution. All sites should start data collection by giving 5 coupons to participants who are less than 30 years old and 2 or 3 coupons to participants who are 30 years old and greater. By giving more coupons to young PWID from the beginning, sites will greatly improve their chances of enrolling this difficult to reach sub-population and obtaining a representative sample of PWID.

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 photo copies. 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, drug injection, 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>."*

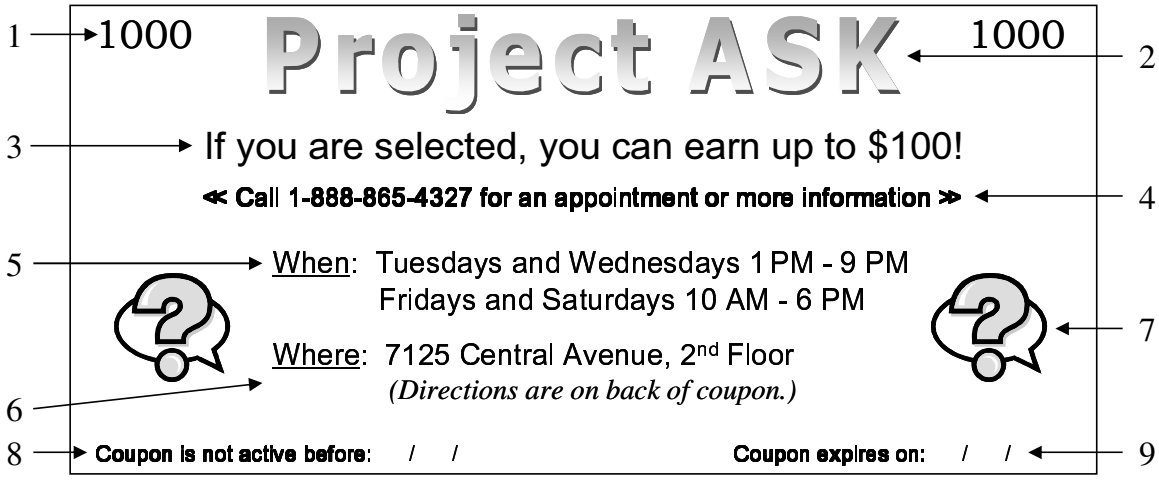
Directions to the field site or other information normally found on the back of a paper coupon could be included in the message as well (alternatively, the participant could include a photograph of the back of the paper coupon). Only one coupon should be shown in each photograph and the coupon number 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 8888.
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," "AIDS," or "injection drug use" 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: 6/1 – 6/7, Week 2: 6/8 – 6/14, 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, Interviewing, 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, interviewing, 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:

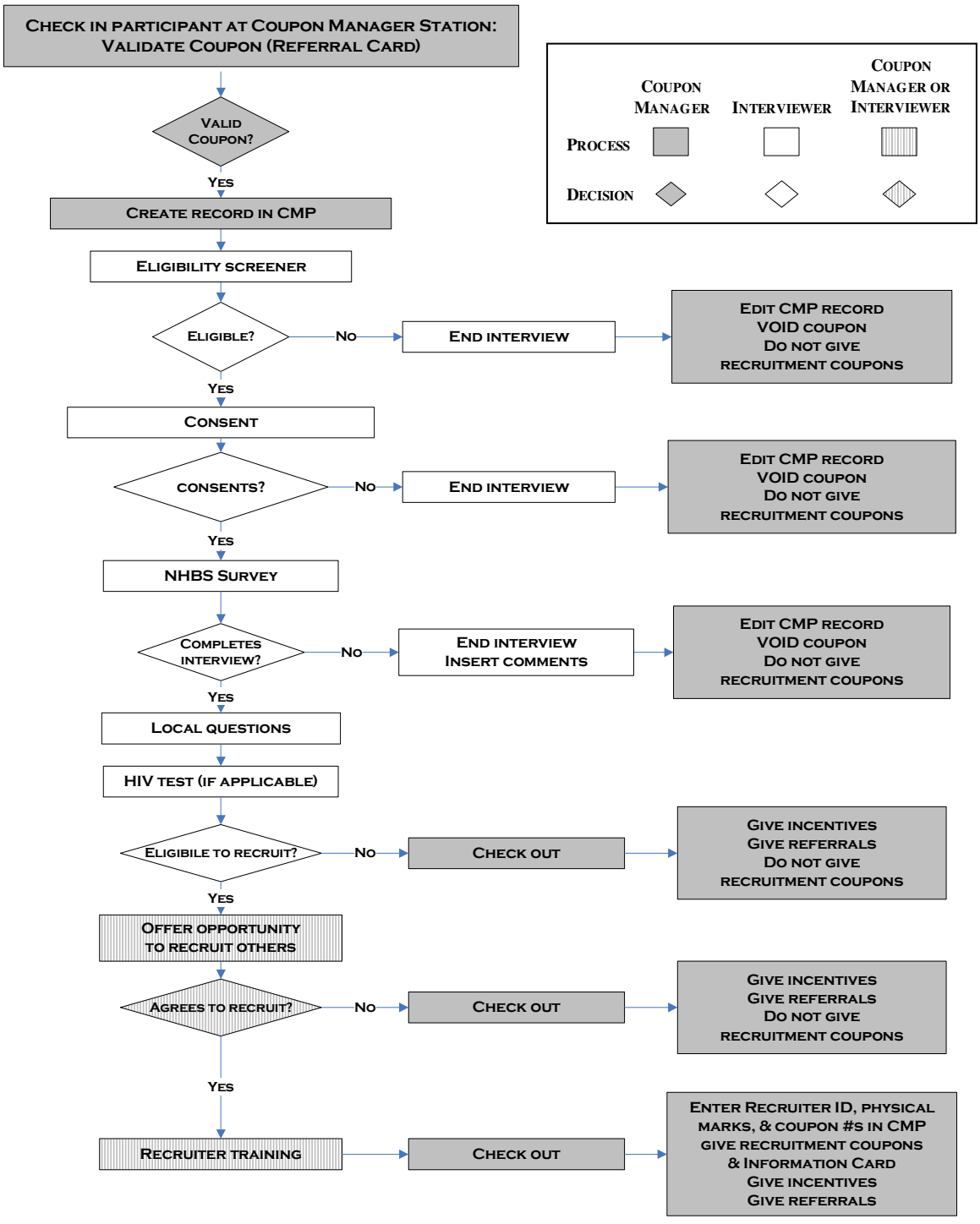
1) **Link recruiters with their recruits:** Each participant's data is linked to that of his recruits by their coupon numbers. This link is necessary to monitor the growth of recruitment chains and to analyze data using specialized RDS software programs, like the RDS Analyst (RDS-A) or the RDS Analysis 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-IDU5 Coupon Manager Training Manual* 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

Figure 7.1 – Check-in, interviewing, and check-out procedures



manager 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.

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 guidelines allow 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 a coupon***, 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 IDU 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

IDU cycle-specific eligibility:

- Has injected drugs that were not prescribed for him in the past 12 months
- Has physical signs of recent drug injection or knows the steps involved in drug injection

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. As with previous participants, the portable computer will automatically make the person ineligible.

Participants thought to be too young (under 18 years)

If project staff suspect that a potential participant is less than 18 years old, they should report their suspicions to the field supervisor. The field supervisor and the project staff should then discuss whether or not the person appears to be too young 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 his interviewer to indicate during eligibility screening that the person cannot complete the survey because his reported age is not plausible. 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 younger than 18 years old; project staff should not decide this on their own.

Project sites that identify a pattern of people less than 18 years old 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 suspected underage individuals.

Injection drug use within the past 12 months

NHBS-IDU participants must have injected drugs within the past 12 months. To meet this eligibility criterion, participants must report that they have injected drugs that were not prescribed for them in the past 12 months ***AND*** they must have physical signs of recent injection (fresh track marks, needle-sized scabs, or abscesses) ***OR*** sufficient knowledge of drug preparation, injection, and syringes. The algorithm for assessing a participant's physical signs and knowledge of drug injection is illustrated in **Figure 7.2**.

Physical signs of injection drug use: If a participant reports that he has injected drugs within the past 12 months, the portable computer will instruct the interviewer to check the participant for physical signs of drug injection. The interviewer should ask "Where on your body do you usually inject?" and have the participant show him all the injection areas on his body. The interviewer should then examine these areas and indicate whether they show:

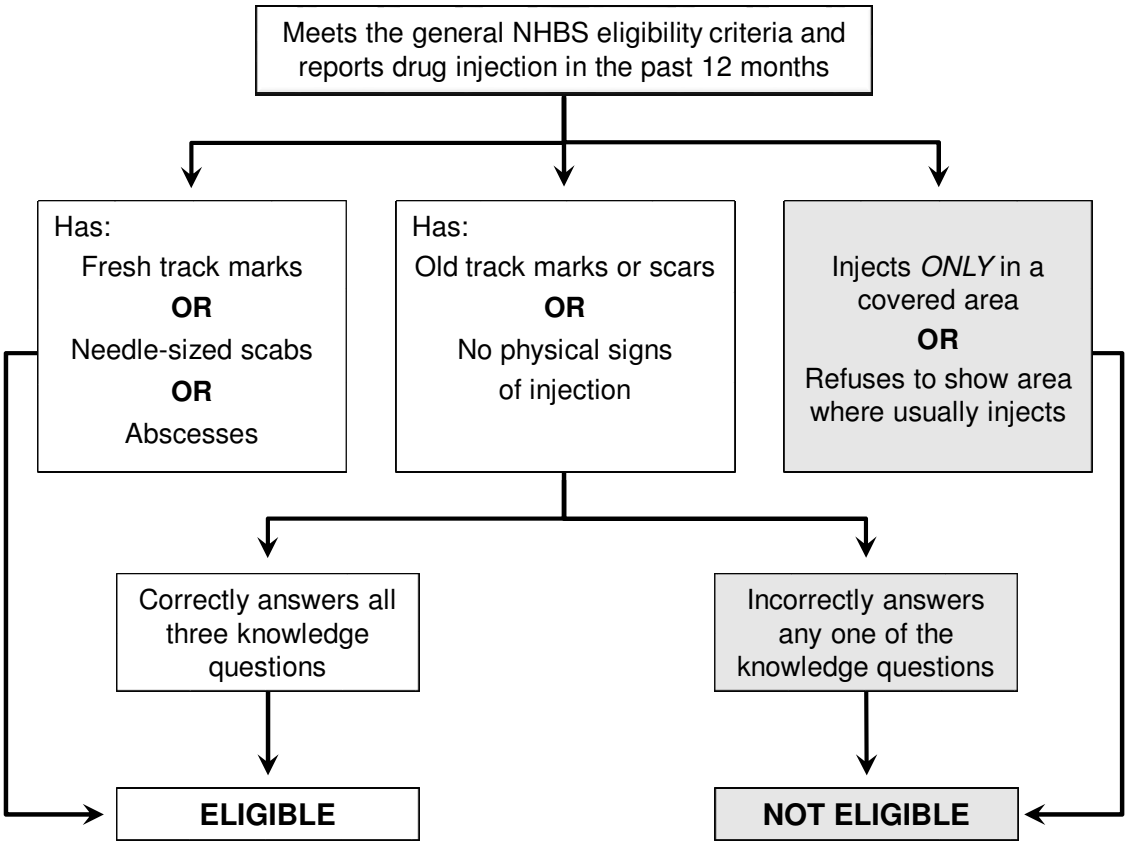
- Fresh track marks
- Needle-sized scabs
- Abscesses
- Old track marks or scars
- No physical signs of injection drug use

If the interviewer does not find physical signs of drug injection in the area where the

participant usually injects, he should ask the participant to show him any areas where he may have injected in the past. Some participants may report that they inject in an area of the body that is covered and considered to be private, like their groin. If a participant reports that he injects in a "private" area of the body, the interviewer should ***not*** view the area to look for signs of drug injection. Instead, the interviewer should ask the participant if he has ever injected in any areas that were not "private," and if so, the interviewer should examine those areas. Persons who inject in covered areas are often heavy or long-time injectors who may have old track marks or scars in areas that are visible.

Photographic examples of the physical signs of drug injection are available at: http://store.samhsa.gov/shin/content//AVD154/AVD154.pdf, and additional examples can readily be found on the internet. Project sites should alert CDC to any new resources they identify so that these can be shared with the other sites.

Figure 7.2 – Algorithm for assessing physical signs and knowledge of drug injection



Based on the responses selected by the interviewer, the portable computer will determine whether the participant has physical evidence of recent drug injection:

- ***If the participant has fresh track marks, needle-sized scabs, or abscesses,*** he has evidence of recent injection and the portable computer will skip the injection knowledge questions.

- ***If the participant has old track marks or scars,*** he does not have evidence of recent injection and the portable computer will instruct the interviewer to ask the injection knowledge questions to further assess whether the participant has recently injected drugs.

- ***If the participant has no physical signs of injection,*** he does not have evidence of recent injection and the portable computer will instruct the interviewer to ask the injection knowledge questions to further assess whether the participant has recently injected drugs.

- ***If the participant injects ONLY in a covered area of his body,*** he does not have evidence of recent injection. However, in this case, if the participant does not report injecting in any visible areas of his body, the portable computer will not instruct the interviewer to ask the injection knowledge questions. Because many people who report that they inject ***only*** in covered areas are fraudulently claiming to be persons who inject drugs (PWID) so that they can participate in the survey and obtain the incentive, the portable computer will automatically make people ineligible if they inject ***only*** in covered areas.

  If a participant injects in both covered and visible areas of his body, the portable computer will instruct the interviewer to ask the injection knowledge questions, even if the participant has no physical signs of injection in a visible area. This participant would be treated like any other participant who has no physical signs of injection in the visible areas of his body where he injects.

- ***If the participant refuses to show where on his body he usually injects,*** the interviewer will not be able to assess whether he has evidence of recent injection. Since the person is not cooperating with the interviewer, the portable computer will not instruct the interviewer to ask the injection knowledge questions and it will automatically make the person ineligible.

Injection knowledge: When participants do not have physical evidence of recent drug injection, they must demonstrate that they have recently injected by providing satisfactory responses to the three injection knowledge questions:

1) "Step-by-step, tell me how you prepare your drugs?"

2) "Step-by-step, tell me how you inject your drugs?"

3) "What type of syringe do you usually inject with?"

Project sites should use the information collected during formative assessment to develop standards for evaluating participants' responses. Not only will this help the interviewers, but it will also ensure that all participants are assessed in a consistent manner. Based on the local standards established by the project site, the interviewer should determine whether the participant has provided an acceptable response to each of the injection knowledge questions. Since a participant who is asked the injection knowledge questions does not have to have recent signs of injection, it is important for the interviewer to carefully assess the suitability of the participant's responses. If the interviewer is not completely satisfied with the participant's initial responses, he should probe with additional questions on drug injection and drug use practices until he can confidently determine whether or not the participant has recently injected. For example, to help differentiate between individuals who recently injected and those who injected in the past, interviewers could ask about current "street" names for drugs, drug packaging and pricing, and locations where drugs are purchased and used.

Whenever an interviewer is not sure how to code a participant's physical signs of drug injection or his responses to the injection knowledge questions, the interviewer should consult the field supervisor or a staff member who has experience working with PWID.

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 critically important 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:

- **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."

- **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 who inject drugs 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.

- **Participants can accurately report their personal network size:** The third *Network Question* automatically sums the number of males and females who inject drugs 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.

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-IDU5 Data Management Training Manual*). 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 or not the participant can receive coupons to recruit others. Participants can recruit others if: 1) they were eligible and completed the core questionnaire and 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"). In addition, while transgender persons who are not seeds can recruit others, transgender persons who are seeds ***cannot*** recruit. Persons who are known to be transgender should therefore not be selected as seeds. This restriction minimizes the likelihood that an initial recruitment chain will become confined to a closed network of transgender persons.

At the end of the core survey, the portable computer will automatically display a message indicating whether or not 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 PWID 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, in this case, PWID.

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 on ending 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
- *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
- *If applicable*, whether dried blood spots (DBS) were collected for the CDC laboratory
- 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 collect the participant's coupon and use the 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 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?

Table 7.2 – Collecting and recording physical marks

The coupon manger 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."

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 PWID than the number of coupons being distributed. For example, a participant may report that in the past 30 days he has only seen 2 PWID he knows, but the project site is giving 3 coupons to each recruiter. Regardless of how many PWID 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 PWID 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 PWID 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 PWID he knows and ***not*** to strangers**.** The coupon manager should also remind the participant of any coupon activation or expiration dates.

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 incentives based on standards in their local communities. In many areas, higher levels of compensation may be more appealing to young PWID who, otherwise, would be less likely to participate in the project than older PWID. Furthermore, if sites are prohibited from providing cash incentives to participants, they may provide an alternative form of remuneration like a gift card or a gift check. Any alternative form of remuneration must protect participant anonymity (e.g., participant names cannot be collected or recorded) and it must have an intrinsic value to members of the community (e.g., gift cards should only be from stores that are locally accessible and well regarded).

When a prospective participant 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.

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 PWID community. Project sites should provide participants with prevention materials such as informational pamphlets on safe drug injection practices and HIV, STI, and hepatitis prevention, as well as hygiene kits, condoms, and lubricants.

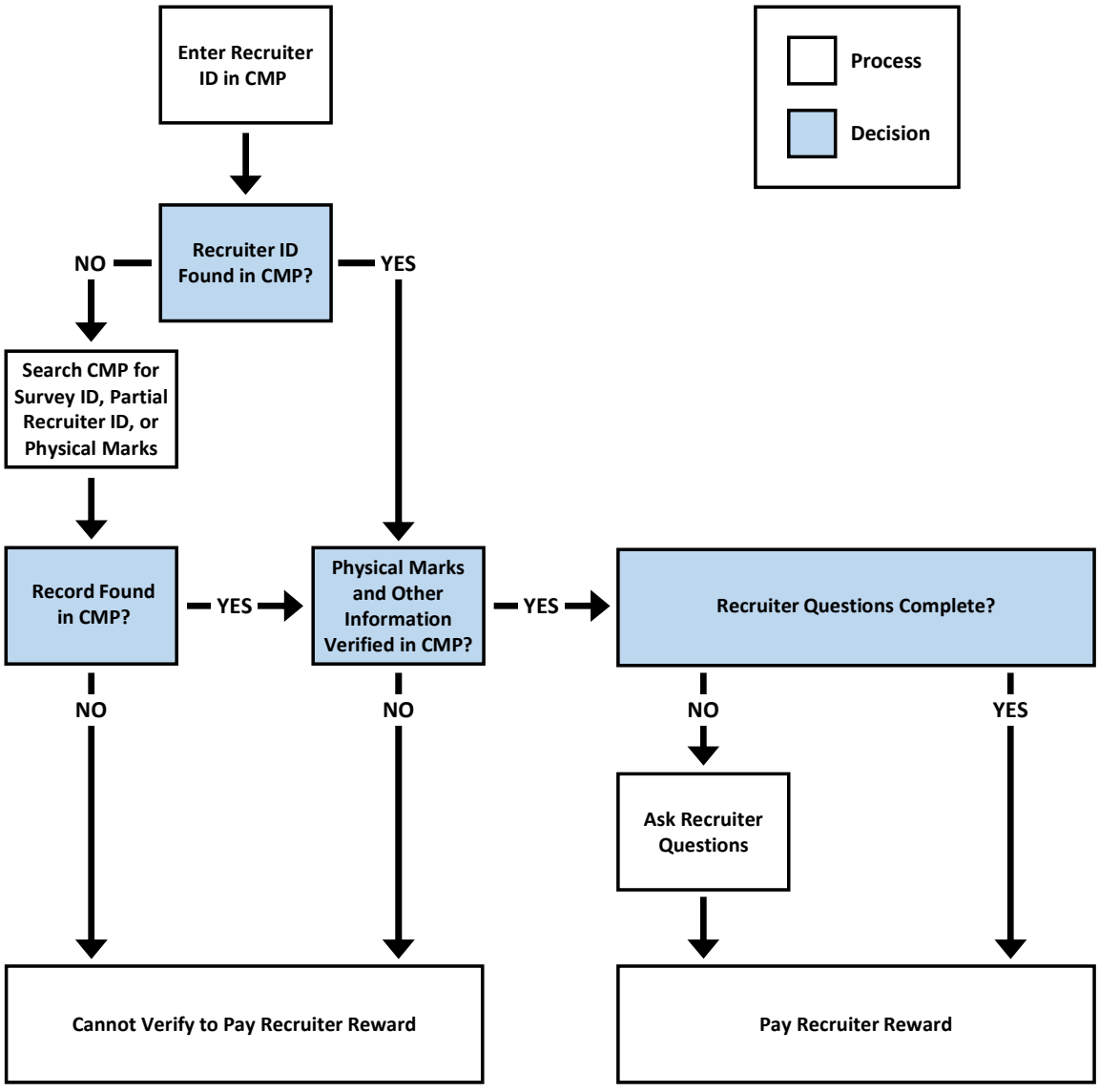
Participants in need of health care or social services should be offered referrals to the appropriate local providers. Based on their formative assessment, project sites should identify those health care and social service providers most commonly used by PWID in their localities. Sites should maintain 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 Recruiter Reward Process

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? *(Read each one, check all that apply)* • They didn't have time • They didn't live in the area • They didn't trust you (recruiter) • They don't like research/surveys • They already participated in this survey • They didn't want to be identified as IDU • Some other reason (please specify): _____

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 or for lost or stolen coupons.

- 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 HIV and Other Testing

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, or 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 HIV care must also be given anonymously. Participants cannot be asked to provide a name or any other personal identifiers to receive their test results or a referral to care. Prior to the start of data collection, 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. Guidance for sending specimens to the CDC laboratory is included in **Sections 9.5a** and **9.6a** (below).

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., 4th generation immunoassays, 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: Alere Determine, Chembio DPP, Chembio SURE CHECK (formerly Clearview COMPLETE), Clearview STAT-PAK, Insti, OraQuick, and 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 work space.

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

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. All

participants with at least 1 reactive rapid test should be referred to care (see **Section 9.8**). As described below, counseling messages for participants 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).

Counseling message for participants with 2 reactive rapid tests:

> *"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."*

Counseling message for participants with 2 discordant rapid tests:

> *"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."*

Participants who self-report being HIV-positive should receive only 1 rapid test. However, if that rapid test is non-reactive, the participant should receive a second rapid test with a different type of test. For example, consider a project site that is using the Insti and Determine tests for the rapid-rapid algorithm. If a participant enrolled at this project site self-reports being HIV-positive but has a non-reactive Insti test, the participant would receive a second rapid test using Determine.

Project sites are required to send DBS to the CDC laboratory for ***all*** HIV-positive participants who consent to blood storage. This includes participants who have discordant rapid test results, as well as those who self-report being HIV-positive yet have a non-reactive rapid test. Accordingly, if a participant self-reports being HIV-positive, DBS should be collected when the specimen is obtained for the first rapid test; and if a participant does not self-report being HIV-positive, DBS should be collected when the specimen is obtained for the second (confirmatory) rapid test.

Project sites using the rapid-rapid algorithm may use any 2 rapid tests that they choose, in any order. That being said, it may be most efficient to choose a rapid test with a shorter run time for the second test to minimize how long the participant has to wait for his test results (**Table 9.1** lists the run 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 will impact field operations. To ensure the standardization of operations, sites should use the same order of rapid tests for every participant. Nonetheless, sites may vary this order for participants who self-report being HIV-positive. For example, a site may use the rapid test with a shorter run time as ***test 2*** for participants who ***do not*** self-report being HIV-positive, but use it as ***test 1*** for those who ***do*** self-report being HIV-positive. Sites should discuss these logistical considerations with their CDC project officer before choosing which rapid tests to use in the algorithm.

Table 9.1 – Run times for CLIA-waived rapid tests

Trade Name	Run Time
Insti HIV-1/HIV-2 Antibody Test	< 1 minute
Uni-Gold Recombigen HIV-1/2	10 minutes
Chembio SURE CHECK HIV 1/2 Assay *(formerly Clearview COMPLETE)*	15 minutes
Clearview HIV 1/2 STAT-PAK	15 minutes
Determine HIV-1/2 Ag/Ab Combo Test	20 minutes
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	20 minutes
Chembio DPP HIV-1/2	10-25 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 site protocols and the test package insert. It is important to note that external rapid test controls should be run in the environment in which testing will occur to ensure the tests are working and conditions are appropriate (e.g., 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**). A reference guide for Rapid Testing Quality Assurance can be found at http://www.cdc.gov/hiv/pdf/testing_QA_Guidlines.pdf and additional guidance for 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.

Project sites that would like to offer hepatitis 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 CDC funding to conduct HCV testing must follow the guidance outlined in the *NHBS-IDU5 Operations Manual – HCV Testing Supplement*.

9.2c STI testing

Project sites may offer testing for STIs, such as gonorrhea, chlamydia, or herpes simplex virus, 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, rectal, or urethral). If project sites wish to conduct STI testing, they must use local funds for the collection, processing, and testing of any STI specimens; they are not permitted to use core 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.

9.2d Future testing

Project sites should ask participants to store their blood at CDC or, if applicable, locally

for future testing. Test results will not be returned to participants for any future testing conducted. Sites should notify their laboratory whenever specimens are to be stored locally for future testing. Participants will be asked to consent to storage of their blood specimen if they consent to HIV testing or hepatitis testing.

Consent for specimen storage must be documented to permit any 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 in these standards, and may be able to get training support from health departments, hospitals, and community-based organizations that perform HIV testing.

In addition to training local staff 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

Manufactures 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 3rd (middle) or 4th (ring) finger of the non-dominant hand. These fingers tend to be used less often and are thus less likely to have calluses or tough skin.

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) Wipe away the first drop of blood, which tends to contain excess tissue fluid, with a sterile gauze or cotton ball. Allow a new drop of blood to form before collecting the blood specimen.

6) If collecting a fingerstick specimen for rapid testing, follow the instructions provided by the rapid test manufacturer; and if collecting a fingerstick specimen for dried blood spots, follow the guidance provided below.

Dried blood spots from fingersticks

A reference guide for fingerstick blood collection for dried blood spots (DBS) can be found in **Appendix U**. DBS should be collected with 903 filter paper cards and, to obtain a sufficient quantity of blood, the lancets used for fingersticks should be blades rather than needles (see **Appendix T** for required cards and lancets). Following the fingerstick blood collection process described in steps 1 through 6 above, hold the finger downward, below the heart. If necessary, the finger can be massaged at the base or pressure can be applied next to the puncture point to increase blood flow. When massaging the base of the finger, provide intermittent pressure rather than constant pressure; apply pressure in a "squeeze, release, squeeze, release" pattern. Massaging the whole hand is also effective for increasing blood flow.

After making the fingerstick, place the blood collection card close to the puncture site but ***DO NOT*** touch it to the puncture site at any time during the collection process. Approach the first circle and allow a large drop of blood to form on the tip of the finger. Without touching the tip of the finger to the card, allow the large drop of blood to barely touch the card inside the first circle; the filter paper will wick the drop of blood away from the finger. Allow the blood to completely fill the circle before moving on to the next circle. If the circle is not completely filled with 1 drop, allow a second large drop to fall onto the same circle before moving to the next circle. Moving from 1 circle to the next, fill the remaining circles in the same way. Project sites should try to fill all the circles on the cards that will be sent to the CDC laboratory. Those sites using DBS for

laboratory-based HIV testing should check with their local laboratory to find out how many full circles the laboratory will need on its cards. When finished, apply cotton to the puncture site until bleeding stops.

It is very important that a circle be filled completely before moving onto the next circle. If the participant does not bleed for very long and there is only enough blood to fill 1 circle, then only 1 circle should be completely filled instead of partially filling multiple circles.

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

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

A list of supplies needed to collect DBS and tips for storing some of the supplies can be found in **Appendix T**. Project sites using DBS for laboratory-based HIV testing should prepare 2 DBS cards: 1 for the local laboratory and 1 for the CDC laboratory. Project sites should begin the DBS collection process by recording the collection date and the participant's survey ID number on the DBS card. If the local laboratory uses a separate laboratory ID, that ID should also be included on the card. The local laboratory ID should not be written on the card that will be sent to the CDC laboratory.

To enable the CDC laboratory to distinguish between the same survey ID numbers from different project sites, a 2-letter code indicating the project site must be added to the beginning of the survey ID. The 2-letter codes that have been assigned to each site are shown in **Table 9.2**.

9.4b Venipuncture specimens

Using standard venipuncture procedures, specimens should be collected in blood collection tubes appropriate for the type of testing that will be performed. Project sites conducting laboratory-based testing 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.

Dried blood spots from blood tubes

Project sites collecting venipuncture specimens can prepare DBS cards from the blood in a collection tube that contains the anticoagulant EDTA, which prevents blood from clotting. The DBS can be made by either the project staff or the laboratory staff before the blood specimen is spun down and separated into plasma. Prior to making the DBS, the blood collection tube should be inverted several times to ensure adequate mixing of the EDTA. A disposable, non-sterile transfer pipette should then be used to remove the blood from the tube. As with making DBS from a fingerstick, place the pipette tip close to the blood collection card but ***DO NOT*** touch the tip to the card at any time during the collection process. Gently squeeze the pipette bulb to allow a drop of blood to fall onto the surface of the card inside the circle. Allow the blood to completely fill the circle before moving on to the next circle. If the circle is not completely filled with 1 drop, allow a second large drop to fall onto the same circle. After the needed circles on the card have been filled, the card should be dried as described above in the "DBS from fingerstick" section. Project sites should try to fill all circles on the cards that will be sent to the CDC laboratory. Those sites using DBS for laboratory-based HIV testing should check with their local laboratory to find out how many full circles the laboratory will need on its cards.

Table 9.2 – 2-letter project site codes

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

For example, survey ID "2475" from Chicago would be labeled as "CH2475" on the

DBS card.

9.5 Specimen Storage and Processing

9.5a Dried blood spots

The DBS cards should be dry or close to dry before packaging. Once they do become dry (which should not exceed 24 hours), the flaps on the 903 cards can be closed. The cards should then be placed in low-gas permeable zip-lock bags. If DBS are being used locally for laboratory-based testing, the cards for the local laboratory should be packaged separately from the cards that will be sent to the CDC laboratory. The DBS from each day of operations should be packaged together in the same zip-lock bag, with the site name, date of packaging, and "HIV+" written on the bag.

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

Each zip-lock bag should also contain a handful (a minimum of 10) desiccant packs to remove any residual moisture from the cards and 1 humidity indicator card to monitor the humidity in the bag. If the humidity level is high in a project area, more desiccant packs should be added to the zip-lock bag. Press as much air out of the bag as possible and seal it shut. Humidity indicator cards and desiccant packs have a color indicator which changes from blue to pink as humidity within the bag becomes unacceptably high. To ensure that the humidity in the bags remains low, it is important to monitor the humidity indicator cards in the bags on a ***daily*** basis and to replace the desiccant packs if the indicator cards change from blue to pink. The used desiccant packs and indicator card should be discarded, and a new indicator card should be added to the bag along with new desiccants.

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

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

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 Shipping DBS

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

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

Shipping DBS to CDC

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

The DBS must be shipped to the CDC on a ***weekly*** basis and no more than 10 days after the spots are made. The DBS should be packaged as mentioned above. A Specimen Shipping Log should be exported from the HIV Testing Log on the DCC data portal and included in the envelope sent to the CDC. On the day project sites ship the DBS to the CDC, they should send an email to Silvina Masciotra (svm6@cdc.gov), Shamaya Whitby (lvi3@cdc.gov), and their CDC project officer notifying them of the shipment. Sites should include the UPS or FedEx tracking number in the notification email. Overnight mailing should be used and the packages should be timed to arrive at CDC Monday through Thursday. Shipments should be sent to the attention of Shamaya Whitby:

ATTN: Shamaya Whitby
Centers for Disease Control and Prevention
1600 Clifton Rd NE MS A-25 Room 3015
Atlanta, GA 30329
Phone: 404-718-1093

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

9.6b 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 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). If the participant consented to blood specimen storage, DBS should be collected too.

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, DBS for storage and future testing. In situations where the participant declines receipt of his rapid test result after a specimen for rapid testing has been collected, project sites should request that the participant provide a specimen for laboratory-based testing so 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). If the participant consented to blood specimen storage, DBS should be collected too.

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 rapid tests so that participants will at least get a preliminary positive test result and a referral to care. 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 the 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 call an agency to schedule a medical appointment for a participant. 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 contact with the referral agency (either in-person or by phone) cannot occur until after the participant has checked out of NHBS. To maintain the anonymity of NHBS participants, all activities involving the referral agency 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-IDU5 Data Management Training Manual* 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 V**.

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. While in the field, sites should record hepatitis test results on a hard copy of the Hepatitis Testing Log (see Appendix J of the *NHBS Round 5 Model Surveillance Protocol*). The hard copy of the Hepatitis Testing Log, as well as any other hepatitis testing forms or

logs, must be secure and in the possession of project staff at all times when in use in the field; otherwise, the forms and logs should be kept locked in a file cabinet or file box.

Those project sites that received CDC funding to conduct HCV testing should enter the data from the hard copy of the Hepatitis Testing Log into the online Hepatitis Test Results Log on the DCC data portal on a ***daily basis*****.** It is important for project sites to enter these data daily so that the process monitoring reports generated by the DCC are up-to-date and reflect each project site's latest data. If they wish, project sites that conduct hepatitis testing without CDC funding may also enter hepatitis test results into the DCC data portal. At data closeout, the DCC will then be able to include the site's hepatitis test results in the site's final NHBS dataset.

9.9c STI testing

The online STI Test Results Log on the DCC data portal was designed for the CDC laboratory to return STI test results to the project sites. Accordingly, project sites that are using local funds to conduct STI testing will not be able to enter their results into this log or have their results processed by the DCC.

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 persons who injected drugs in the previous year. 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 persons who injected drugs in the past 12 months.
- The proportion of young persons who inject drugs (PWID) meets the project site's enrollment goal for this sub-population. (The enrollment goal for young PWID is the expected proportion of persons completing an interview who are less than 30 years old. Sites should establish their own specific goal based on their formative assessment findings and they should document their goal in the Operations Checklist [**Appendix A**].)

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 W**.

10.3a Recruitment Monitoring Report

The *Recruitment Monitoring Report* (**Section W.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 other testing (e.g., hepatitis or STI 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, other 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 W.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 sub-populations 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 W.3** of this manual) shows the characteristics of participants who were screened for eligibility stratified by whether or not they were eligible to take the survey. The characteristics examined are:

- 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
- Injection Drug Use in the Past 12 Months
- Signs of Drug Injection
- Drug Injection Knowledge
- Type of Drug Injected Most Often

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 participate, and injection drug use). Particular attention should be paid to the drug injection tables. If the proportion of participants who injected drugs in the past 12 months is low, sites may need to improve their recruiter training so that participants only recruit persons who currently inject drugs. An extremely low proportion of participants who have signs or knowledge of drug injection may indicate that interviewers do not recognize the signs of recent injection or the steps involved in injection, whereas an extremely high proportion may mean that interviewers are not adequately screening out participants who do not currently inject. In either case, additional interviewer training may be needed.

Project sites should always remain vigilant for potential participants who do not currently inject drugs. People who formerly injected drugs or those who never injected may fraudulently claim to currently inject so that they can participate in the survey and obtain the incentive. A high proportion of participants who do not have signs of recent drug injection, especially a high proportion of those who only inject in a covered area, should serve as a warning that people may be fraudulently trying to enroll in the survey.

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 W.4** of this manual) shows the characteristics of participants who completed the interview. The characteristics listed are:

- Age
- Gender
- Race/Ethnicity
- Education
- Homeless in Past 12 Months
- Income
- Type of Drug Injected Most Often
- Zip Code

Project sites should review the tables in this report to monitor the demographic characteristics of participants who successfully completed the interview. The characteristics of these participants should reflect those of local PWID, as described in the project site's formative assessment reports. Sites should also ensure that there is representation of those sub-populations of greatest importance to the local HIV epidemic, like young PWID.

10.3e Test Results Report

The *Test Results Report* (**Section W.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). Sites can use the Specimen Sent to CDC Lab Report to determine whether the proper specimens are being sent to the CDC lab. Depending on circumstances, sites may need to send all specimens to the CDC lab or they may only need to send specimens from participants who do not test HIV-negative.

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 W.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, age, drug of choice, and zip code 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 sub-populations, 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 W.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 report 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 kick-backs 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.

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 recruitment among field sites occurs when a participant is enrolled at a different field site than his recruiter was. A lack of cross recruitment may indicate that participants are not members of a single social network, which may impact the interpretation of NHBS results. In some cases, however, the absence of cross recruitment among field sites may be necessary to ensure adequate representation of all the major sub-populations of PWID.

Ideally, field site locations should be accessible to all major sub-populations of PWID (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 sub-populations 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 sub-population, project sites can use these tables to monitor how successful the field site is at reaching that sub-population.

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 recruiter) 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 W.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 sites 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 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 W.9** of this manual) consists of the following tables:

- Interview Length
- Signs and Knowledge of Drug Injection
- 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 eligible men fully understand NHBS procedures and their options for participation.

The Signs and Knowledge of Drug Injection table will help project sites identify interviewers who may not be properly screening potential participants for indicators of recent drug injection. For each interviewer, the table shows the proportion of potential participants who were found to be eligible based on physical signs of recent drug injection, knowledge of injection practices with old signs of drug injection, or knowledge of injection practices with no signs of drug injection. Again, sites should compare each interviewer's data to the overall data to look for any outliers. In addition, a high proportion of participants who are eligible based solely on their knowledge of injection practices should alert sites to the possibility that persons who formerly injected drugs or

those who never injected may be fraudulently claiming to currently inject so that they can participate in the survey and obtain the incentive.

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 or hepatitis testing even though the site is not offering those tests. These interviewers 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 PWID in the community 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 sub-population, 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
Low or declining enrollment	***Quantitative:*** Project sites should review the Coupon Tracking table in the *Coupon Manager Program Report* 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, a measure of how many potential participants there are in the community. 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 *Coupon Manager Program Report*. The Recruitment Chains table in the *Respondent-Driven Sampling Report* will also help sites monitor the progress of recruitment and enrollment. ***Qualitative:*** 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.
A large proportion of ineligible participants	***Quantitative*** Project sites should review the *Sample Characteristics – Screened Report* to determine if there are any particular eligibility criteria that potential participants are failing or if certain demographic sub-populations are more likely to be ineligible. If a high proportion of participants are ineligible based on their signs or knowledge of drug injection, sites should check the Signs and Knowledge of Drug Injection table in the *Interviewer Report* to determine whether a particular interviewer is responsible. ***Qualitative*** If a large proportion of participants are ineligible because they have not injected drugs within the past 12 months, project sites should observe the recruiter training provided by

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

Operational Problem	Potential Evaluation Methods
A large proportion of ineligible participants *(continued)*	project staff and they should conduct exit interviews with participants to see if the participants know that they should only recruit persons who ***currently*** inject drugs. If a high proportion of participants are ineligible based on their signs or knowledge of drug injection, project sites should observe their interviewers while they assess the signs of recent injection and the steps involved in injection. They should also conduct observations, informal conversations with participants, street intercept surveys, or key informant interviews to find out if people in the community are fraudulently claiming to currently inject so that they can participate in the survey.
Demographic characteristics of participants do not match those of the local PWID population	***Quantitative*** Project sites should review the *Sample Characteristics – Screened Report* to determine whether members of the underrepresented sub-population are more likely to be ineligible, and they should check the "coupon refusals" tables in the *Coupon Manager Program Report* to find out if members of the underrepresented sub-population are more likely to refuse coupons. They should also review the Seed Characteristics table in the *Seed Report* 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 sub-population (e.g., examine "age" if young PWID are underrepresented). They should check the affiliation matrix in the RDSAT output to see if members of the underrepresented sub-population are substantially less likely to be recruited by members of other sub-populations and they should check the recruitment count in the output to see if members of the underrepresented sub-population are less effective recruiters (i.e., are less likely to recruit other participants). ***Qualitative*** If members of the underrepresented sub-population are more likely to be ineligible, project sites should observe the

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

Operational Problem	Potential Evaluation Methods
Demographic characteristics of participants do not match those of the local PWID population *(continued)*	recruiter training provided by project staff and conduct exit interviews with participants from the underrepresented sub-population to 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. If members of the underrepresented sub-population are less likely to recruit others or more likely to refuse coupons, project sites should have informal conversations with participants or community members from the underrepresented sub-population 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. If members of the underrepresented sub-population are substantially less likely to be recruited by members of other sub-populations, project sites should conduct informal conversations with participants, street intercept surveys, key informant interviews, or focus groups to see if members of the underrepresented sub-population are less likely to mix socially with members of other sub-populations.
Stranger recruitment	***Quantitative*** Project sites should review the *Respondent-Driven Sampling Report* 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 sub-populations are more likely to recruit people who are strangers. ***Qualitative*** 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

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

Operational Problem	Potential Evaluation Methods
Stranger recruitment *(continued)*	stranger. Project sites should conduct observations in the area around the field site to determine whether people are 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 kick-backs 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-IDU5 Data Management Training Manual*. The DCC will also provide training via webinar that the data manager from each project site is required to attend.

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 (required from sites that received CDC funding for hepatitis testing; optional from all others)
- 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-IDU5 Data Management Training Manual* 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) (and backups) who will sync the CMP data; submit the QDS™ Warehouse; enter HIV and, if applicable, hepatitis 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. Project 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. Project sites should always review and process their data in accordance with their local plan and the *NHBS Round 5 Model Surveillance Protocol.* Moreover, project 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

Data	Action	Frequency
CMP data	Sync to the data portal	***Daily***, at the end of field site operations
QDS™ Warehouse	Submit through the data portal	***Weekly***
HIV test results	Enter in the HIV Test Results Log	***Daily***, after rapid or laboratory test results are obtained
Hepatitis test results (if applicable*)	Enter in the Hepatitis Test Results Log	***Daily***, after rapid or laboratory test results are obtained
Data corrections	Enter in the Data Error Log	***Daily***, as soon as errors are identified

*Required from project sites that received CDC funding for hepatitis testing; optional from all others.

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.

Appendix A NHBS-IDU5 Operations Checklist

A model Operations Checklist is shown below. The actual checklist can be completed using the Word file named **Appendix A – NHBS-IDU5 Operations Checklist.**

Initial Version Date: ____ / ____ / _____ (mm / dd / yyyy) **Updated Version Date:** ____ / ____ / _____ (mm / dd / yyyy)

Project sites should send the FINAL completed checklist to their CDC Project Officer at least two weeks before the planned start of data collection. They may want to send a draft of the checklist earlier in case revisions need to be made. They may also send draft sections of the checklist as each is completed.

Project sites must complete all applicable sections of the checklist. If any information in the checklist changes after it has been submitted (e.g., new staff added), project sites must update the checklist and resubmit it to their CDC Project Officer. Updated versions of the checklist should be tracked using the "Updated Version Date" (see field above).

Once a project site's CDC Project Officer has approved their checklist, they will receive an email stating that they can begin data collection. They cannot begin data collection until they receive this email.

Project sites should contact their CDC Project Officer if they have any questions about the checklist.

I – IRB Review

a. What type of review did you obtain from your local Institutional Review Board(s) (IRBs)?

☐ Full ☐ Expedited ☐ Exempt

b. Complete the following table on your IRB submission for NHBS-IDU5:

	Funded Health Department IRB	**Other Local IRB** *(if applicable)*	**Other Local IRB** *(if applicable)*
Name of IRB			
IRB FWA Number			

FWA Expiration Date			
Date IRB Package Submitted			
Date IRB Approval Received			
Date Amendment Approval Received *(if applicable)*			

Instructions for completing the table:

Name of IRB: List the name of each IRB that reviewed your NHBS-IDU5 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-IDU5 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-IDU5.

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-IDU5 project name:

b. Insert or attach your NHBS-IDU5 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 sub-populations of persons who inject drugs (PWID) 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 – Enrollment Goal for Young PWID

Based on their formative assessment findings, each project site should establish a specific goal for enrolling young PWID. This goal should be expressed as the expected proportion of persons completing an interview who are less than 30 years old.

a. Enrollment goal for young PWID: _____ %

V – 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	Drug of Choice	Geographic Area*
1					
2					
3					

**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.)*

VI – 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.)*

VII – Recruiter Training

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

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

VIII – 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:

IX – 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:

X – 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: _____

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

Local compensation provided for:	**Amount**	**Type**
Ineligibles		
Participant who passed the eligibility screener but completed only part of the interview		
Recruiter whose recruit passed the eligibility screener but completed only part of the interview		
Returning for HIV test result ***(NOTE: only non-NHBS funds can be used)***		
HCV testing *(if applicable)*		
Other activity or test *(specify)*:		

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

XI – Project Staff Training and Evaluation

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

Name of Staff Member			
Position			
ID Code *(if applicable)*			
Received Confidentiality Training?			
Date Signed Confidentiality Agreement			
Read *NHBS-IDU5 Operations Manual*?			
Read *NHBS Round 5 Interviewer Guide*? *(for field supervisor and interviewers)*			
Read Package Insert for Rapid HIV Test (*for test counselors conducting rapid tests*)			
Date HIV Counseling and Testing Certification Expires *(for test counselors)*			
Viewed NHBS-IDU5 Formative Research Webinar			
Viewed NHBS-IDU5 Human Subjects and Field Safety Webinar			
Attended NHBS-IDU5 Field Operations Training			
Viewed NHBS-IDU5 Data Management Webinar			
Viewed NHBS-IDU5 Coupon Manager Webinar			
Other Training (*specify type and dates*):			
Other Training (*specify type and dates*):			
Evaluated and Met Performance Criteria for Position(s)?			

Instructions for completing the table:

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

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

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

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

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

Read the *NHBS-IDU5 Operations Manual:* Prior to the start of data collection, all project staff must read the *NHBS-IDU5 Operations Manual*. 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-IDU5 Formative Research Webinar: Record *Yes* to indicate that a staff member viewed this webinar.

Viewed NHBS-IDU5 Human Subjects and Field Safety Webinar: Record *Yes* to indicate that a staff member viewed this webinar.

Attended NHBS-IDU5 Field Operations Training: Record *Yes* to indicate that a staff member attended this training.

Viewed NHBS-IDU5 Data Management Webinar: Record *Yes* to indicate that a staff member viewed this webinar.

Viewed NHBS-IDU5 Coupon Manager Webinar: Record *Yes* to indicate that a staff member viewed this webinar.

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-IDU5 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-IDU5 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)

XII – 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 a7.

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 IXc (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 1st 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 2nd 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 3rd 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 4th 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. Specimen Storage, Transport, and Processing

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

c2. Describe how and where specimens (including DBS) will be stored before they are sent to CDC or 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. 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-IDU5 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 IXg (Other 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? ***(required by sites that received CDC funding for HCV testing)***

☐ 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) ***(required by sites that received CDC funding for HCV testing)***

☐ 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. Other Testing

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

Test: _____

Will you return test results to participants?

☐ Yes ☐ No

Test: _____

Will you return test results to participants?

☐ Yes ☐ No

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

g3. *If returning test results to participants,* describe your procedures for anonymously referring participants with positive test results to care:

XIII – 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)"].

XIV – 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)

XV – Local Safety and Field Incident Reporting Procedures

a. Attach the following documents:

a1. Local safety protocol

a2. Field incident reporting procedures

XVI – Prevention and Other Informational Materials

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

XVII – Public Health Insurance Plans

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

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

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

Instructions for completing the table:

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

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

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

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

Appendix B Field Supervisor – Project Management Evaluation Form

A model Field Supervisor Project Management Evaluation Form is shown below and on the 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**.

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

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

Management of Staff	**Rating**				
1. 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
Field Site Operations Setup					
5. Prepared all supplies and completed tasks per the Field Site Checklist.	1 No				5 Yes
6. Adequately staffed the field site (the field supervisor plus a minimum of 2 staff members).	1 No				5 Yes
7. Conducted a staff meeting before opening the field site.	1 No				5 Yes
Field Site Management					
8. 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
9. 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
10. Met each potential participant prior to the interview.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
11. Checked in with the interviewers after each interview.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
12. Managed participant flow by monitoring when the HIV counselor was available for the next participant. ☐ N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
13. Ensured participants' privacy was protected at all times.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
14. Remained aware of each team member's whereabouts.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
15. Maintained the security of staff and study materials.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
16. Monitored staff interactions with participants and the general public.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
17. Assisted field staff when necessary. ☐ N/A	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always
18. Treated participants and staff with courtesy and respect.	1 Never	2 Rarely	3 Sometime	4 Usually	5 Always

19. Ensured staff were knowledgeable of safety procedures.		1 No			5 Yes	
20. Has emergency contact information for each staff member.		1 No			5 Yes	
21. Scheduled and recorded appointments in the Appointment Log.	☐ N/A	1 No			5 Yes	
22. Maintained the Phone Results Log.	☐ N/A	1 No			5 Yes	
23. Adhered to established hours of operation.		1 No			5 Yes	
Post Operations Management						
24. Held a debriefing at the completion of field site activities.		1 No			5 Yes	
25. Reviewed Participant Tracking Forms, including data edits.		1 No			5 Yes	
26. Reviewed the consent forms from each participant.	☐ N/A	1 No			5 Yes	
27. Reviewed the HIV Test Results Log.		1 No			5 Yes	
28. Reviewed the staff evaluation forms from the PI or PC.	☐ N/A	1 No			5 Yes	
29. 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	
30. Ensured that the CMP data were synced to the data portal using the CMP automatic upload function.		1 No			5 Yes	
31. Portable computers and forms that contain confidential information (i.e., HIV Test Results Log, Phone Results Log, and Participant Tracking Forms) were kept in a locked file cabinet.		1 No			5 Yes	
32. Demonstrated adherence to the protocol including RDS methods.		1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well

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

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

☐ Reviewed evaluation form with the field supervisor.

☐ Provided time for field supervisor to ask questions.

☐ Provided the field supervisor with recommendations for improvement.

☐ 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**.

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

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

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.	☐ 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.	☐ N/A	1 No	5 Yes
4. DBS collection and packaging supplies are properly stored per the *Operations Manual.*	☐ N/A	1 No	5 Yes
5. DBS collection and packaging supplies are available and meet the specifications listed in the *Operations Manual*.	☐ N/A	1 No	5 Yes
6. DBS are handled, transported to the main office, packaged, and stored per the *Operations Manual*.	☐ N/A	1 No	5 Yes
7. All blood collection devices and personal protective equipment are disposed of in appropriate biohazard containers.	☐ N/A	1 No	5 Yes
8. Collects all required HIV testing variables per HIV Testing Log, Specimen Transport/Shipping Log, etc.		1 No	5 Yes
9. Ships specimens to the local diagnostic laboratory on a regular basis to ensure a 2-week turnaround for results.	☐ N/A	1 No	5 Yes
10. Tracks whether participants have obtained their results.		1 No	5 Yes
11. 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.	☐ N/A	1 No	5 Yes
Data Security, Confidentiality, and Entry			
12. Stores sensitive information according to the *NHBS Model Surveillance Protocol*.		1 No	5 Yes
13. 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
14. 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
15. 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
16. For all HIV-positive rapid test results, ensures that confirmatory test data have been entered into the HIV Test Results Log on the DCC data portal.	☐ N/A	1 No	5 Yes

Rapid Testing ☐ N/A		
17. HIV test package inserts are available for reference at the field site.	1 No	5 Yes
18. Monitors the temperature at which test kits are stored and records the temperature on quality assurance logs.	1 No	5 Yes
19. Monitors the temperature at which testing is conducted and records the temperature on quality assurance logs.	1 No	5 Yes
20. Runs controls in accordance with the test package insert and records results on quality assurance logs.	1 No	5 Yes
21. Monitors data for discordant test results (i.e., reactive rapid test and non-reactive confirmatory test).	1 No	5 Yes
22. Conducts evaluations for all new testing staff and then every 2 weeks thereafter.	1 No	5 Yes

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

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

☐ Reviewed evaluation form with the field supervisor.

☐ Provided time for the field supervisor to ask questions.

☐ Provided the field supervisor with recommendations for improvement.

☐ If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard.

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**.

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

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

Check-In	**Rating**	
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). ☐ N/A	1 No	5 Yes
5. If potential participant had a valid coupon, transferred potential participant to interviewer and gave coupon to interviewer. ☐ N/A	1 No	5 Yes
6. If potential participant did <u>not</u> have a valid coupon, handled him in a professional manner. ☐ N/A	1 No	5 Yes
7. Voided and filed invalid coupons appropriately. ☐ N/A	1 No	5 Yes
Recruiter Training ☐ N/A		
8. Ensured participant was eligible to receive recruitment coupons.	1 No	5 Yes
9. Successfully trained recruiter: *Instructions were given regarding whom to recruit.*		
a. People who inject drugs.	1 No	5 Yes
b. People you know. Do <u>not</u> give coupons to strangers.	1 No	5 Yes
c. People who live in the project area.	1 No	5 Yes
d. People who have <u>not</u> already participated in the study.	1 No	5 Yes
10. Successfully trained recruiter: *Instructions were given on how to use photo coupons.* ☐ 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: *Instructions were given on what to say to person receiving the coupon.*		
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.	1 No	5 Yes

12. Successfully trained recruiter: *Rewards*.		
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
Check-Out		
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. ☐ N/A	1 No	5 Yes
18. Distributed correct number of coupons and recorded coupon numbers. ☐ 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. ☐ N/A	1 No	5 Yes
21. Provided local HIV prevention materials and referrals. ☐ N/A	1 No	5 Yes
General		
22. Demonstrated adherence to the *NHBS Model Surveillance Protocol,* 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

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

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

☐ Reviewed evaluation form with the coupon manager.

☐ Provided time for coupon manager to ask questions.

☐ Provided the coupon manager with recommendations for improvement.

☐ If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard.

Appendix E Interviewer Evaluation Form

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

General Instructions

- To be conducted by the principal investigator, project coordinator, or, if necessary, field supervisor.
- **Permission must be obtained from the potential participant before an evaluator joins an interview**.
- The evaluator should follow along during the interview by using a separate portable computer or by observing the interviewer's portable computer.
- The evaluator should be seated close enough to hear and observe both the interviewer and the participant, without being a distraction.
- The evaluator should only interrupt the interview for major issues, be discreet when doing so, and direct questions to the interviewer**.**
- Shaded areas are NHBS performance recommendations.

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

Time to Complete Survey	**Time**
1. Eligibility screener	**Start:** _____ **End:** _____ **Length:** _____
2. Consent process	**Start:** _____ **End:** _____ **Length:** _____
3. Core questionnaire	**Start:** _____ **End:** _____ **Length:** _____
4. Local questionnaire ☐ N/A	**Start:** _____ **End:** _____ **Length:** _____

Set-up	**Rating**				
5. Checked date and time on portable computer before starting.	1 No				5 Yes
6. All materials needed were prepared 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
Consent Process					
8. No personal identifiers (e.g., name, address) were recorded.	1 Recorded				5 Not recorded
9. <u>All</u> aspects of informed consent were followed per local IRB requirements (i.e., read as written if required; covered all relevant points if summarized).	1 No				5 Yes
10. Provided the participant with a copy of the consent form to follow along.	1 No				5 Yes
11. Offered the participant a copy of the consent form to keep.	1 No				5 Yes
12. Provided an opportunity for questions about the project and consent process.	1 No				5 Yes
13. Ensured participant understood anonymous nature of NHBS (i.e. will NOT ask for participant's name; participant names NEVER linked to interviews or test results).	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
14. Obtained a <u>separate</u> consent for the interview.	1 No				5 Yes
15. Obtained a <u>separate</u> consent for HIV testing.	1 No				5 Yes
16. Obtained a <u>separate</u> consent for hepatitis testing. ☐ N/A	1 No				5 Yes
17. Obtained a <u>separate</u> consent for STI testing. ☐ N/A	1 No				5 Yes
18. Obtained a <u>separate</u> consent for specimen storage. ☐ N/A	1 No				5 Yes
19. The pace of reading the consent was…	1 Too slow		1 Too fast		5 Just right

Survey Administration					
20. Oriented the participant by reading the introductory statement for the core survey.	1 No			5 Yes	
21. Read the questions, definitions, and transition statements as written.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
22. Followed the survey instructions to read or not read response options.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
23. When needed, reread and clarified instructions, questions, and responses. ☐ N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
24. Recognized inconsistent responses, clarified with participant, and corrected data in the portable computer. ☐ N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
25. Probed incomplete, unclear, and, if necessary, "don't know" responses. ☐ N/A	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
26. Used <u>neutral</u> probes (i.e., probed without influencing response).	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
27. Ensured that the participant was never able to view the portable computer screen.	1 No			5 Yes	
28. The pace of reading the screener was…	1 Too short		1 Too long		5 Just right
29. The pace of reading the questionnaire was…	1 Too slow		1 Too fast		5 Just right
30. The amount of time given for responses was…	1 Too slow		1 Too fast		5 Just right
Flashcards					
31. Used flashcards when instructed.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
32. 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
33. Read the flashcards as written.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
Establishing and Maintaining Rapport					
34. 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
35. Maintained eye contact with the participant throughout interview.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
36. Provided neutral feedback throughout the interview.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
37. Remained engaged with the participant and his responses throughout the survey.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
38. Demonstrated a professional demeanor.	1 Never	2 Rarely	3 Sometimes	4 Usually	5 Always
Recruiter Training ☐ N/A					
39. Ensured participant was eligible to receive recruitment coupons.	1 No			5 Yes	
40. Successfully trained recruiter: *Instructions were given regarding whom to recruit.*					
a. People who inject drugs.	1 No			5 Yes	
b. People you know. Do <u>not</u> give coupons to strangers.	1 No			5 Yes	
c. People who live in the project area.	1 No			5 Yes	
d. People who have <u>not</u> already participated in the study.	1 No			5 Yes	
41. Successfully trained recruiter: *Instructions were given on how to use photo coupons.* ☐ 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
42. Successfully trained recruiter: *Instructions were given on what to say to person receiving the coupon.*		
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.	1 No	5 Yes
43. Successfully trained recruiter: *Rewards.*		
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
44. Asked the recruiter questions to ensure that he understands whom to recruit and what to do with coupons.	1 No	5 Yes
45. Asked the recruiter if he had any questions.	1 No	5 Yes

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

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

☐ Asked the interviewer how any unclear responses were entered into the portable computer.

☐ Reviewed how the interviewer coded the question regarding the validity of answers.

☐ Reviewed evaluation form with the interviewer.

☐ Provided time for interviewer to ask questions.

☐ Provided the interviewer with recommendations for improvement.

☐ If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard.

Appendix F HIV Counseling and Testing Evaluation Form

A model HIV Counseling and Testing Evaluation Form is shown below and on the 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**.

General Instructions

- To be conducted by the principal investigator, project coordinator, or, if necessary, the field supervisor.
- **Permission must be obtained from the participant before an evaluator joins the HIV testing session**.
- The evaluator should only interrupt the session for major issues, be discreet when doing so, and only direct questions to the counselor**.**
- Shaded areas are NHBS performance recommendations.
- This form may be modified to reflect local counseling and testing regulations.

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

Test Preparation	**Rating**				
1. Prepared all necessary materials prior to starting (HIV testing kit, phlebotomy or DBS materials, HIV Testing Log, referrals, information handouts, personal protective equipment, etc.).	1 Not at all	2	3 Some	4	5 Fully
2. Verified on Participant Tracking Form that consent for HIV testing was provided.	1 No				5 Yes
3. Verified with participant that he is interested in getting tested and has provided appropriate consent(s), including other tests and specimen storage if applicable.	1 No				5 Yes
4. Discreetly obtained relevant behavioral risk information from interviewer. ☐ N/A	1 No				5 Yes
Testing Procedures					
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. Collected DBS from fingerstick according to procedures in the *NHBS Operations Manual*. ☐ N/A	1 No				5 Yes
10. Adhered to OSHA regulations for universal precautions (gloves) and for proper waste disposal in approved biohazard and sharps containers.	1 No				5 Yes
11. Scheduled an appointment for the participant to obtain his HIV test result. ☐ N/A	1 No				5 Yes
12. Provided an appointment card and counseled the participant that the ID number on the card must be presented to obtain his HIV test result. ☐ N/A	1 No				5 Yes
13. Provided a phone results card and counseled the participant that the ID number on the card is necessary to obtain his HIV test result. ☐ N/A	1 No				5 Yes
Rapid Testing ☐ N/A					
14. 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
15. 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

16. Performed the test exactly as directed by the package insert. (***Critical element:*** To ensure consistency, evaluator must use the package insert for every evaluation of tester's performance.)	1 No			5 Yes	
17. The participant could not view rapid test during test development.	1 No			5 Yes	
18. Read test result within the appropriate time frame for rapid test performed (INSTI: < 5 min, Unigold: 10-20 min, Chembio (blood): 10-25 min, Chembio (oral): 25-40 min, Clearview: 15-20 min, Determine: 20-30 min, Oraquick: 20-40 min).	1 No			5 Yes	
19. Read test result under adequate lighting.	1 No			5 Yes	
20. Knew how to read a positive, negative, or invalid test result; and knew what steps to take when returning these test results.	1 No			5 Yes	
21. Recorded test result and properly completed all steps for returning the result.	1 No			5 Yes	
22. Gave the participant the subject information pamphlet from the test kit.	1 No			5 Yes	
Test Counseling					
23. Conducted pre-test counseling *after* the survey was completed. ☐ N/A	1 No			5 Yes	
24. Provided HIV information regarding transmission, risk factors, etc.	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
25. Clarified misconceptions of HIV and corrected false information. ☐ N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
26. 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
27. 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
28. 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
29. Returned test result in a manner that preserved participant's privacy. ☐ N/A	1 No			5 Yes	
30. Ensured participant fully understood the HIV test result. ☐ N/A	1 No			5 Yes	
31. 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
32. Provided and explained referral to medical care and case management. ☐ N/A	1 Not at all	2 Poorly	3 Okay	4 Well	5 Very well
33. 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	
34. Allowed participant to ask questions and raise concerns, and provided appropriate answers.	1 No			5 Yes	

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

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

☐ Reviewed evaluation form with the HIV test counselor.

☐ Provided time for HIV test counselor to ask questions.

☐ Provided the HIV test counselor with recommendations for improvement.

☐ 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**.

General Instructions

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

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

Data Management	**Rating**	
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. ☐ N/A	1 No	5 Yes
3. Documented data discrepancies and their resolutions on the Participant Tracking Forms. ☐ 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 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
6. Successfully entered hepatitis testing data into the online Hepatitis Test Results Log on the DCC data portal or demonstrated how to do so. ☐ N/A	1 No	5 Yes
7. Successfully uploaded data from each portable computer to the desktop computer.	1 No	5 Yes
8. 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
9. Transferred records from QDS™ data files (i.e., files with a ".QAD" extension) to the QDS™ Warehouse successfully.	1 No	5 Yes
10. 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
11. Successfully encrypted NHBS data using PGP software.	1 No	5 Yes
12. Submitted QDS™ Warehouse containing core interview files to the DCC data portal or demonstrated how to do so.	1 No	5 Yes
Ongoing Activities		
13. Submits QDS™ Warehouse to the DCC data portal ***weekly***.	1 No	5 Yes
14. Enters data edits into the online Data Error Log on the DCC data portal ***daily***.	1 No	5 Yes
15. Enters HIV testing data into the online HIV Test Results Log on the DCC data portal ***daily*** (after rapid or laboratory test results are obtained).	1 No	5 Yes
16. Enters hepatitis testing data into the online Hepatitis Test Results Log on the DCC data portal ***daily*** (after final test results are obtained). ☐ N/A	1 No	5 Yes
17. Reviews Process Monitoring Reports ***weekly*** and, if necessary, communicates discrepancies to the DCC.	1 No	5 Yes

18. Reviews DCC Data Management Reports ***monthly***.	1 No	5 Yes
19. Responds to DCC inquiries and communications on a timely basis.	1 No	5 Yes
20. Knows how to ask the DCC questions and understands how to access information on the DCC data portal.	1 No	5 Yes

Criterion #	Skill Description, Recommendations, Accolades, and Additional Comments (continued)

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

☐ Reviewed evaluation form with the data manager.

☐ Provided time for the data manager to ask questions.

☐ Provided the data manager with recommendations for improvement.

☐ If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard.

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-IDU5 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, lubricant, hygiene kits)
- ☐ Other items: _____

2. HIV Testing Supplies

Rapid testing supplies (if applicable):

- ☐ Rapid tests
- ☐ Lancets
- ☐ Fingerstick 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)
- ☐ Other laboratory-based testing supplies: _____

DBS collection supplies:

- ☐ DBS collection cards
- ☐ DBS collection devices (i.e., blade lancets if DBS from fingerstick or transfer pipettes if DBS from blood tube)
- ☐ Equipment to transfer DBS (e.g., test tube racks, binder clips, transport box)
- ☐ Other DBS collection 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 _____ Interviewer ID _____

Portable Computer # _____ Survey ID (Coupon #) _____

Seed? Y N

Data Manager Use Only:

Interview Start Time _____ 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	
If yes, agreed to recruit?	Y	N	
If yes, number of coupons due: ____			
9. Received recruiter training?	Y	N	

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

DATA EDITS:

Variable Name	Old Value	New Value

Appendix J CMP Log

A model CMP Log is shown below. The actual log can be printed or modified using the Excel file named **Appendix J - CMP Log**.

CMP Log

Date of Interview	Survey ID (Coupon #)	Interviewer ID	Coupons Distributed to Participant				
			# on 1st Coupon	# on 2nd Coupon	# on 3rd Coupon	# on 4th Coupon	# on 5th Coupon

Page _____

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-IDU5: 2018

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		
			☐ Routine ☐ New Lot Opened ☐ New Operator ☐ Storage Temp Irregularity ☐ New Shipment ☐ Test Area Temp Irregularity	☐ Yes ☐ No	☐ Yes ☐ No	
			☐ Routine ☐ New Lot Opened ☐ New Operator ☐ Storage Temp Irregularity ☐ New Shipment ☐ Test Area Temp Irregularity	☐ Yes ☐ No	☐ Yes ☐ No	
			☐ Routine ☐ New Lot Opened ☐ New Operator ☐ Storage Temp Irregularity ☐ New Shipment ☐ Test Area Temp Irregularity	☐ Yes ☐ No	☐ Yes ☐ No	
			☐ Routine ☐ New Lot Opened ☐ New Operator ☐ Storage Temp Irregularity ☐ New Shipment ☐ Test Area Temp Irregularity	☐ Yes ☐ No	☐ Yes ☐ No	
			☐ Routine ☐ New Lot Opened ☐ New Operator ☐ Storage Temp Irregularity ☐ New Shipment ☐ Test Area Temp Irregularity	☐ Yes ☐ No	☐ Yes ☐ No	
			☐ Routine ☐ New Lot Opened ☐ New Operator ☐ Storage Temp Irregularity ☐ New Shipment ☐ Test Area Temp Irregularity	☐ Yes ☐ No	☐ Yes ☐ No	

Field Supervisor Signature: ______________________________

Appendix L Rapid Testing Temperature Log

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

Rapid Testing Temperature Log
NHBS-IDU5: 2018

Area Monitored (check one): ☐ Control Storage ☐ Test Kit Storage ☐ Testing

Date	Temperature	Initials	*If there is a problem:*		
			Corrective Action Taken	**Test Kit Lot Number**	**Notes**

One temperature log should be kept for each area: Control Storage, Test Kit Storage, and Testing. If the temperature for any area falls outside the range indicated as appropriate on the test kit package insert, corrective actions should be taken and documented on the temperature log.

Field Supervisor Signature: _____

Appendix M Appointment and Phone Results Cards

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

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

Figure M.1 – Model Appointment Card

[PROJECT NAME]

Your appointment is scheduled for:

_____ , _____ at _____ AM PM
day date time

If you need to reschedule your appointment or have any questions, please call us at ***[project phone number]***.

Our office is located at:
[address of project office]

and is open ***[days of operation]*** from ***[opening time]*** to ***[closing time]***.

ID Number: _____

Figure M.2 – Model Phone Results Card

[PROJECT NAME]

Please call us at ***[project phone number]*** on or after:

_____ , _____
day date

Our office is open ***[days of operation]*** from ***[opening time]*** to ***[closing time]***.

ID Number: _____

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

be referred to care and to any other necessary services, and those with indeterminate test results should be referred for follow-up testing. If local policies require participants with positive or indeterminate test results to receive in-person counseling, an appointment should be scheduled for this counseling session and the date of the appointment should be recorded on the Phone Results Log.

A participant who becomes upset or angry when he learns his HIV test result should be kept on the phone. The HIV test counselor should listen to the participant's concerns and remain on the phone with him until he becomes calm. The HIV test counselor should also refer the participant to follow-up counseling and advise him to seek immediate support from a friend or relative.

The HIV test counselor should not give a participant his test result over the phone if the counselor believes that he is not psychologically able to handle a positive test result by phone. Instead, the HIV test counselor should ask the participant to schedule an appointment to obtain his test result in person.

Figure N.1 – Phone Results Log

Phone Results Log

Test Date	Lab or Survey ID	Password Question	Password Answer	Date Result Given	Counseling Date*	Notes

*After their test results have been given over the phone, all participants with positive or indeterminate results should be scheduled to receive in-person counseling.

Page _____

The Counseling Date should only be included on the Phone Results Log if local policies require participants with positive or indeterminate test results to receive in-person counseling

Appendix O Field Incident Report

A model Field Incident Report is shown below. The actual report can be printed or modified using the Word file named **Appendix O - Field Incident Report.**

NHBS Field Incident Report

Project Site: _____

Name of Person Filing Report:_____

Position of Person Filing Report (check all that apply):

___ Interviewer
___ Field Supervisor
___ Project Coordinator
___ Other (Specify):_____

Location of Incident (name and address):

_____

_____

_____

Date of Incident: ____ / ____ / ____

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

Description of Incident and Actions Taken (include actions taken to prevent future incidents):

_____

_____

_____

_____

_____

Reported Locally to (check all that apply):

___ Supervisor Date: ____ / ____ / ____ Time: ____ : ____ am pm (circle one)
___ Police Date: ____ / ____ / ____ Time: ____ : ____ am pm (circle one)
___ IRB Date: ____ / ____ / ____ (attach report)
___ Other (specify): _____
Date: ____ / ____ / ____ Time: ____ : ____ am pm (circle one)

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

Name of Contact at CDC:_____

Comments (other information relevant to the incident):

_____

_____

_____

Appendix P Information Cards

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.

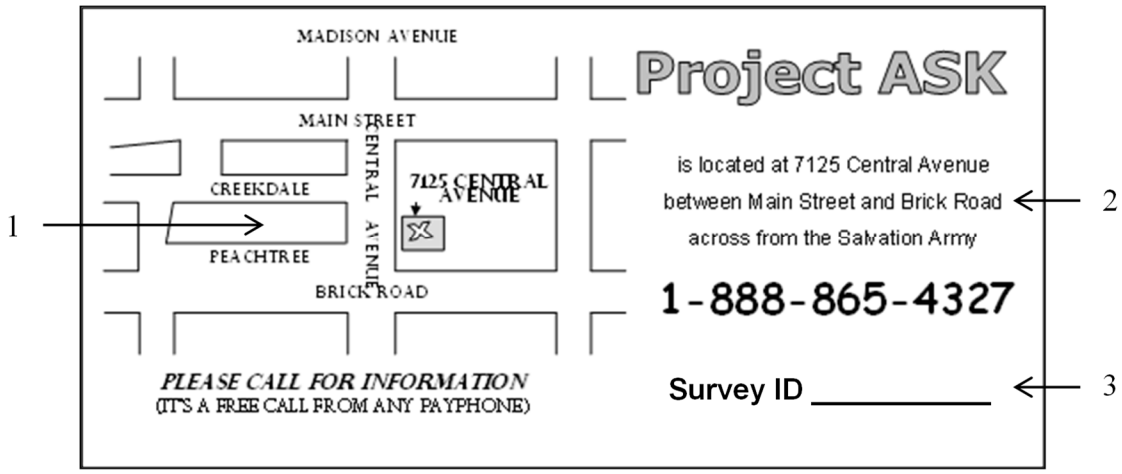
The color and size of the information cards should differ from those of the seed referral cards and coupons to help participants and project staff distinguish among them.

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 other people who inject drugs so that they can be in the study too. You should give the coupons to people you know; you should NOT give the coupons to strangers. You should only give the coupons to people 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.

Your coupons cannot be replaced if they are lost or stolen or if the person you recruited is 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

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 inject drugs.

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 other people who inject drugs so that they can be in the study too.
- Give the coupons to people you know. Do NOT give the coupons to **strangers**.
- Give the coupons to people who live in ***[insert project area]***.
- Give the coupons to people who have not already participated in the study.

Coupons

- Everyone has to have a coupon to be in the study.
- Tell people you recruit to have the coupon with them when they come in or when they call to make an appointment.
- Your coupons cannot be replaced if they are lost or the person you recruited is not selected for the study.
- ***If a project site is using photo coupons:*** Instead of handing out your coupons, you can take a photo of each one and text or email it to someone you want to recruit.
- ***If a project site is using photo coupons:*** Keep the message you send general to protect the person's privacy. For example: *You can use this coupon to take a health survey and earn up to* $***[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.
- 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 inject drugs.

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.

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 and ensure that the template is in the "Normal" view.
2. Select the ***Design*** tab.
3. Select ***Slide Size***.
4. Select ***Custom Slide Size***. The "Slide Size" window will open.
5. In the "Number slides from" field, enter the desired start number.
6. 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 DBS Supplies

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

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

T.1 Supplies for Specimen Collection

Lancets

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

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

DBS Cards

Product: Item # 10534612
903 Protein Saver Card (US)

Vendor: GE Healthcare Life Sciences
(800) 526-3593
http://www.gelifesciences.com/webapp/wcs/stores/servlet/catalog/en/GELifeSciences-us/products/AlternativeProductStructure_21577/28416778

Transfer Pipets *(Only required if preparing DBS from tubes of blood)*

Product: Item # 13-711-9BM
Sterile Disposable Graduated Transfer Pipettes
Draws 3.5mL per squeeze
Capacity: 5.8mL; 0.25mL graduations

Vendor: Fisher Scientific
(800) 766-7000
https://www.fishersci.com/shop/products/fisherbrand-disposable-graduated-transfer-pipettes-5/137119bm?keyword=true

T.2 Supplies for Specimen Drying, Storage, and Shipping

Bitran Specimen Storage Bags (low-gas permeable zip closure)

Product: Item # 19240200 (7 x 8 in.)

Vendor: Fisher Scientific
(800) 766-7000
https://www.fishersci.com/shop/products/fisherbrand-bitran-specimen-storage-bags-15/19240200?searchHijack=true&searchTerm=19240200&searchType=RAPID

Desiccant Packets

New desiccant packs should be purchased every year just before the start of data collection. The new desiccant packs should be stored in air-tight containers, with a humidity indicator placed in each container.

Product: 1 gram desiccant packs with blue indicator that turns pink in high humidity (02-00039AG105)

Vendor: Multisorb Technologies
+1-716-824-8900
http://www.multisorb.com/products-and-systems/minipax-sorbent-packets/

Humidity Indicator Cards

Humidity indicator cards should be stored in air-tight containers, with a few desiccant packs placed in each container.

Product: 3-Spot Humidity Indicator Cards, Indicates: 30, 40, 50% (3HIC125)

Vendor: VWR
1-800-932-5000
https://us.vwr.com/store/catalog/product.jsp?product_id=17963415

Envelopes

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

Vendor: Staples
http://www.staples.com/

Office Depot
http://www.officedepot.com/

Miscellaneous Supplies for Drying, Storage, and Shipping

Product: Binder clips

Test tube racks

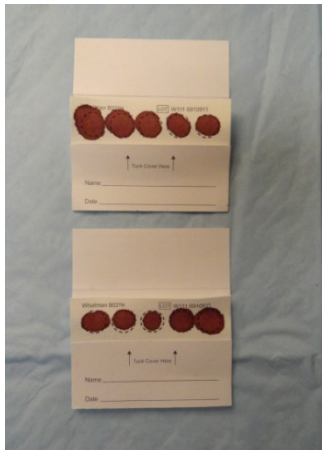
FedEx or UPS mailing envelopes

Vendor: These products can be purchased or obtained from a variety of local vendors.

Appendix U Fingerstick Quick Reference Guide

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

Valid DBS Specimens…



Supply list…

- Band aids
- Cotton balls
- Alcohol prep pads
- Lancets
- Absorbent paper (i.e., "chucks")
- DBS cards
- Biohazard waste containers
- Gloves
- Disinfectant cleaner

Biohazard reminders….

- Gloves must be worn at all times
- Gloves should fit appropriately; DO NOT begin collection until you have gloves that fit snug
- Blood collection should occur over absorbent paper in case of spillage
- Always have a disinfectant cleaner on hand

POCKET GUIDE

TO

FINGERSTICK BLOOD

COLLECTION

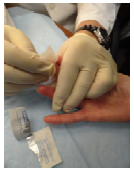
FOR

DRIED BLOOD SPOTS

Before sticking the finger…

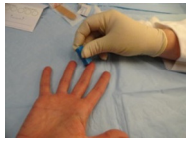
- Set out all supplies needed to collect blood; open band aid and alcohol pad
- Ask the participant which is his non-dominant hand
- Assess positioning of you and the participant to decide the easiest way to collect blood for the rapid test and DBS

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

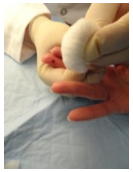


The stick…

- Lay the hand against a hard, flat surface



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



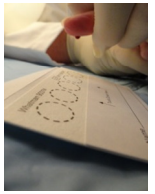
- Wipe away the first drop of blood with a cotton ball

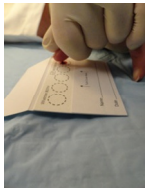
If blood is not readily flowing:

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

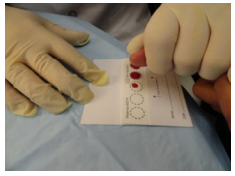
Specimen collection…

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





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



- Upon completion, the circles should be full

Appendix V 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 V.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 V.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	DCC 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 Clearview 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 *Any viral load assay* (e.g., Abbott m2000, Roche COBAS v2.0, Hologic HIV-1 RNA quant)	Nucleic Acid Test
Bio-Rad Genetic Systems HIV-1 Western Blot Cambridge Biotech HIV-1 Serum Western Blot	Western Blot

Appendix W 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.

W.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
Total								

No. Consented to Other Tests	% Consented to Other Tests	No. Agreed to Blood Storage	% Agreed to Blood Storage	No. Eligible to Recruit	% Eligible to Recruit

W.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
Total										

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		
Didn't want to be identified as IDU		
Other		
Unknown		
Total		

W.3 Sample Characteristics – Screened Report

1. QUESTIONNAIRE VERSION

Questionnaire Version	N	%
Total		

2. ELIGIBLE

Eligible	N	%
Yes		
No		
Total		

3. AGE

	Eligible		Not Eligible		Total	
Age	N	%	N	%	N	%
< 18						
18 – 29						
30 – 39						
40 – 49						
50 – 60						
> 60						
Unknown						
Total						

4. GENDER

	Eligible		Not Eligible		Total	
Gender	N	%	N	%	N	%
Male						
Female						
Other (Includes Transgender)						
Total						

5. RACE/ETHNICITY

	Eligible		Not Eligible		Total	
Race/Ethnicity	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

	Eligible		Not Eligible		Total	
MSA Resident	N	%	N	%	N	%
Yes						
No						
Unknown						
Total						

7. KNOWN PREVIOUS PARTICIPANT

	Eligible		Not Eligible		Total	
Known Previous Participant	N	%	N	%	N	%
Yes						
No						
Unknown						
Total						

8. ABLE TO PARTICIPATE

	Eligible		Not Eligible		Total	
Able to Participate	N	%	N	%	N	%
Yes						
No						
Unknown						
Total						

9. TOO YOUNG TO PARTICIPATE

	Eligible		Not Eligible		Total	
Too Young to Participate	N	%	N	%	N	%
Yes						
No						
Unknown						
Total						

10. IDU IN PAST 12 MONTHS

	Eligible		Not Eligible		Total	
IDU in Past 12 Months	N	%	N	%	N	%
Yes						
No						
Unknown						
Total						

11. SIGNS OF DRUG INJECTION

	Eligible		Not Eligible		Total	
Signs of Injection	N	%	N	%	N	%
Covered Area Only						
No signs						
Old signs						
Recent signs						
Refused						
Unknown						
Total						

12. DRUG INJECTION KNOWLEDGE

	Eligible		Not Eligible		Total	
Drug Injection Knowledge	N	%	N	%	N	%
Yes						
No						
Not asked						
Unknown						
Total						

13. TYPE OF DRUG INJECTED MOST OFTEN

	Eligible		Not Eligible		Total	
Type of Drug Injected Most Often	N	%	N	%	N	%
Heroin						
Cocaine						
Speedball – Heroin and cocaine together						
Crack						
Methampthetamine (i.e., crystal, speed, crank)						
Painkillers (e.g., Oxycontin, Dilaudid, Percocet)						
Something else						
Unknown						
Total						

W.4 Sample Characteristics – Interviewed Report

1. AGE

Age	N	%
18 – 29		
30 – 39		
40 – 49		
≥ 50		
Unknown		
Total		

2. GENDER

Gender	N	%
Male		
Female		
Other (Includes Transgender)		
Unknown		
Total		

3. RACE/ETHNICITY

Race/Ethnicity	N	%
American Indian or Alaska Native		
Asian		
Black or African American		
Hispanic		
Native Hawaiian or Other Pacific Islander		
White		
Multiple Races		
Unknown		
Total		

4. EDUCATION

Education	N	%
Less Than High School		
High School		
Vocational/Tech School or Some College		
College Graduate or Graduate School		
Unknown		
Total		

5. HOMELESS IN PAST 12 MONTHS

Homeless in Past 12 Months	N	%
Yes, currently		
Yes, not currently		
No		
Unknown		
Total		

6. INCOME

	Total	
Income	**N**	**%**
0 – $9,999		
$10,000 – $19,999		
$20,000 – $29,999		
$30,000 – $39,999		
$40,000 – $49,999		
≥ $50,000		
Unknown		
Total		

7. TYPE OF DRUG INJECTED MOST OFTEN

Type of Drug Injected Most Often	N	%
Heroin		
Cocaine		
Speedball – Heroin and cocaine together		
Crack		
Methampthetamine (i.e., crystal, speed, crank)		
Painkillers (e.g., Oxycontin, Dilaudid, Percocet)		
Something else		
Unknown		
Total		

8. ZIP CODE

Zip Code	N	%
Total		

W.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									

W.6 Seed Report

1. SEED MONITORING

Week No.	Date	No. Screened	No. Eligible	No. Completed Interview	No. Eligible to Recruit
Total					

2. SEED CHARACTERISTICS

Date	Survey ID	Gender	Race/Ethnicity	Age	Drug of Choice	Zip Code	Eligible to Recruit

W.7 Respondent Driven Sampling Report

1. RECRUITMENT BY STRANGER

Recruitment by Stranger	N	%
Yes		
No		
Unknown		
Total		

2. FIELD SITE ENROLLMENT

	No. of Interviews				Total
Day of Week	*Field Site ID 1*	*Field Site ID 2*	*Field Site ID 3*	*Field Site ID 4*	
Sunday					
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Total					

3. CROSS RECRUITMENT

	Recruit's Field Site				Total
Recruiter's Field Site	*Field Site ID 1*	*Field Site ID 2*	*Field Site ID 3*	*Field Site ID 4*	
Field Site ID 1					
Field Site ID 2					
Field Site ID 3					
Field Site ID 4					
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

W.8 Possible Previous Participant Report

1. POSSIBLE PREVIOUS PARTICIPANTS

Date of Birth	Gender	Race/Ethnicity	No. of Records

W.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.
TOTAL																

2. SIGNS AND KNOWLEDGE OF DRUG INJECTION

Interviewer ID	Recent Signs of Injection		Injection Knowledge with Old signs of Injection		Injection Knowledge with No Signs of Injection		No Signs or Knowledge of Injection		Unknown		Total
	N	%	N	%	N	%	N	%	N	%	N
Total											

3. INTERVIEWER CONFIDENCE IN RESPONSES

Interviewer ID	Confident		Some Doubts		Not Confident at All		Unknown		Total
	N	%	N	%	N	%	N	%	N
Total									

4. 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	%	N
Total									

5. CODING OF OTHER INSURANCE

Interviewer ID	Survey ID	Private	Medicaid	Medicare	Other Government	Tricare (Champus)	VA Coverage	Text for Other Insurance Specified