

**National HIV Behavioral Surveillance:
Persons Who Inject Drugs – 2024
(NHBS-PWID2024)**

OPERATIONS MANUAL



**Behavioral Surveillance Team
NCHHSTP/DHP/BCSB**

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Abbreviations

Abbreviation:	Definition:
CAPI	Computer-assisted Personal Interview
CBO	Community-based Organization
CDC	Centers for Disease Control and Prevention
CITI	Collaborative Institutional Training Initiative
CLIA	Clinical Laboratory Improvement Amendments
CMP	Coupon Manager (software) Program
DBS	Dried Blood Spot
DCC	NHBS Data Coordinating Center
DHP	Division of HIV 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
IRB	Institutional Review Board
MOU	Memorandum of Understanding
MSA	Metropolitan Statistical Area
NAT	Nucleic Acid Test
NCCC	National Center for Cultural Competence
NGA	Notice of Grant Award
NHBS	National HIV Behavioral Surveillance
NHBS-PWID	National HIV Behavioral Surveillance (among) Persons Who Inject Drugs
NIH	National Institutes of Health
OFR	Office of Financial Resources
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
PHRP	(National Institutes of Health) Protecting Human Research Participants
PI	Principal Investigator
PII	Personally Identifiable Information

Abbreviation:	Definition:
PPE	Personal Protective Equipment
PRA	Paperwork Reduction Act
PrEP	Pre-exposure Prophylaxis
PWID	Person Who Injects Drugs
QR	Quick Response
RDS	Respondent-driven Sampling
RDS-A	Respondent-driven Sampling Analyst (software)
RDSAT	Respondent-driven Sampling Analysis Tool (software)
RNA	Ribonucleic Acid
SAMS	Secure Access Management Services
SRP	Self-reported (HIV) Positive
SSP	Syringe Services Program
STI	Sexually Transmitted Infection
TAC	(NHBS Data Coordinating Center) Technical Assistance Coordinator
TAMS	Training Asset Management System

1.1 Chapter Overview

The *NHBS-PWID2024 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 7 Model Surveillance Protocol* to prepare for data collection activities. Copies of the operations manual and the protocol should also be readily 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). These procedures include:

- Staffing the project ([Chapter 2](#))
- Preparing materials ([Chapter 3](#))
- Selecting field sites and scheduling appointments ([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 document the procedures and guidelines to be followed for conducting NHBS. The manual ensures operational standardization of NHBS activities across all project areas.

1.3 Staff Responsibilities

CDC staff are responsible for writing the *NHBS-PWID2024 Operations Manual* and providing technical assistance to project areas during implementation. Local NHBS staff are responsible for conducting the project using the procedures described in the manual

and for submitting all required data and laboratory specimens to CDC in a timely manner.

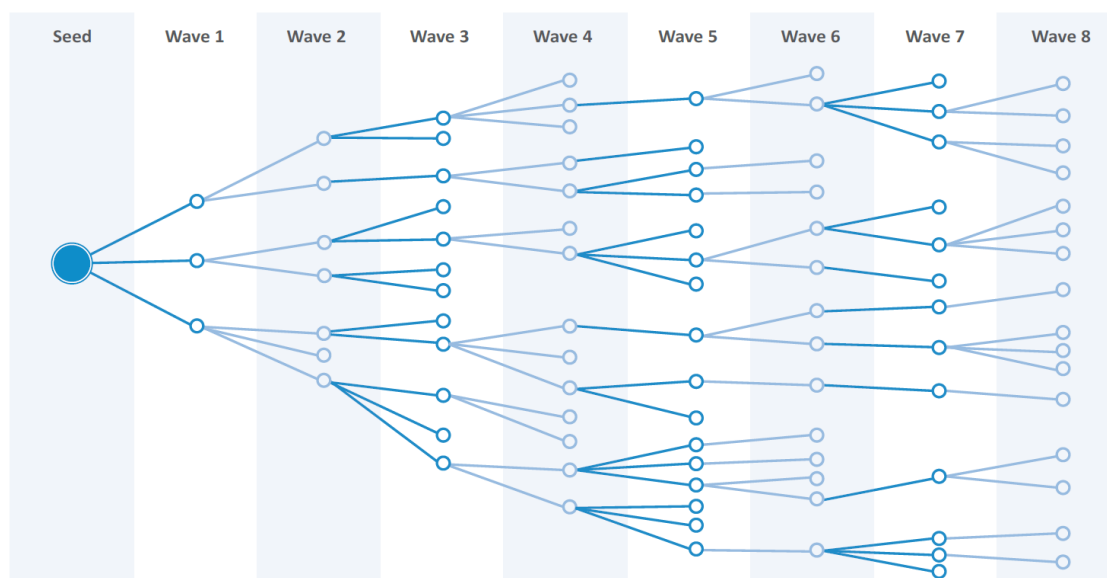
1.4 Respondent-Driven Sampling

The sampling method used during the PWID 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 5.

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

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

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

RDS has to be implemented correctly so that its underlying assumptions are not violated and bias is minimized. For instance, seeds should not be chosen from networks that are so sparse and disconnected that peer-recruitment would be unsuccessful. Hours of operation and locations of field sites should be considered carefully so that certain subpopulations, like young PWID, are not underrepresented in the sample because they are limited in their ability to participate in the survey. Recruiters should not give coupons to strangers. Project areas should make this clear to participants when training them to recruit others, and they 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](#). As project areas prepare for data collection, they should begin drafting sections of the checklist and send them to their CDC project officer for review. Sections of the checklist should be sent as soon as they are completed so that project areas have sufficient time to respond to any questions their CDC project officer may have, and thereby, avoid a delay to the start of data collection. Project areas should send their CDC project officer the final version of the checklist, along with any requested attachments, **no later than May 15, 2024**. The CDC project officer will then set up a conference call with the project area to review the checklist and ensure that all preparatory activities have been satisfactorily completed. Data collection **cannot** begin until the CDC project officer has reviewed the final version of the checklist and given approval by email. Over the course of data collection, project areas 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.

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2.1 Chapter 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, along with information on staff training and evaluation.

2.1a Chapter outline

- Project management ([Section 2.2a](#)) and data manager ([Section 2.2c](#)) positions:
 - Principal investigator is responsible for the project’s overall success and serves as the primary contact for CDC.
 - Project coordinator is responsible for day-to-day project management.
 - Data manager ensures data quality and adherence to the required data security and confidentiality standards, and communicates issues to the NHBS Data Coordinating Center (DCC) and CDC (**note:** the data manager’s duties can also be assumed by the project coordinator).
 - Field supervisor oversees field operations, including field staff and field sites.
- Field staff positions ([Section 2.2b](#)):
 - Field staff include coupon manager, interviewers, and HIV test counselors.
 - Cross-training to perform multiple field staff positions will maximize the flexibility of operations and staff coverage.
- The quality of NHBS data depends on the staff’s ability to ensure standardization of operations within their project area and across all the project areas ([Section 2.4](#)).
- Staff training is key to skill standardization and quality assurance ([Section 2.5](#)).
 - All project staff must complete required trainings for their positions.
 - Safety training should be conducted prior to the start of data collection and safety procedures should be reviewed with project staff at least once a month.
 - Cultural humility and health diversity courses are recommended for all project staff who interact with participants.
 - NHBS guidance and training materials developed by the CDC and the DCC are stored in the DCC’s online repository called the Training Asset Management System (TAMS).
 - [Table 2.3](#) provides a summary of required and recommended trainings.
- Staff evaluations are important to maintaining skill standardization and data quality throughout the project cycle ([Section 2.6](#)).

- Evaluations prior to start of data collection ensure that all project staff successfully meet the recommended performance standards.
- Ongoing evaluations are conducted on a regular basis throughout data collection to ensure performance standards are maintained; over time, even staff with extensive experience may drift from the NHBS performance recommendations.
- Retraining should occur whenever staff have not maintained a performance recommendation, and reevaluation should occur before they reenter the field.
- Guidance for project management staff on conducting evaluations is provided in [Sections 2.6c](#) and [2.6e](#).
- [Table 2.4](#) provides a summary of evaluation and retraining recommendations.

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 areas 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 conducting project operations in accordance with all NHBS guidance (e.g., *Model Surveillance Protocol*, *Formative Assessment Manual*, *Operations Manual*, and *Interviewer Guide*), as well as in compliance with any local 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 together 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 <i>Model Surveillance Protocol</i> per project area-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. • <i>For health department only:</i> Ensure that all IRBs providing approval have an active Federalwide Assurance (FWA) number. • <i>For health department only:</i> 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. • <i>For health department only:</i> Oversee the preparation and submission of annual cooperative agreement reports, such as annual progress reports and financial status reports, to the CDC Office of Financial Resources (OFR). • Oversee the development of local 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, regular conference calls, and national calls.	• If applicable, manage contracts related to the project. • 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, regular conference calls, and national 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 questions.	• Participate in CDC site visits, trainings, regular conference calls, and as available, national calls.
Project management	• Serve as the backup for the project coordinator in the event of their 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 project 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 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. • <i>For health department only:</i> Oversee development of policies pertaining to analyses and dissemination of data. • Oversee data analyses. • <i>For health department only:</i> Ensure data is released in accordance with local policy and data use agreements. • Produce reports and disseminate data analysis findings. • Use data analysis findings for the development, modification, and evaluation of local prevention programs.	• Coordinate and ensure staff access to CDC's Secure Access Management Services (SAMS). • Ensure that coupon manager information, data errors, HIV testing data, DBS information, and if applicable, other testing data are submitted into the DCC data portal daily. • If participant data, such as local questions, are collected on the interview computers, ensure that the data are transferred from the computers to a secure drive daily. • Review the Process Monitoring Reports, and ensure that problems are resolved and improvement is seen. • Make sure issues listed in the Daily Data Management Report are addressed within a week. • Coordinate and implement policies pertaining to data analysis and dissemination. • Participate in data analysis and dissemination. • Evaluate the need for ongoing formative assessment and make changes based upon findings.	• Schedule field site hours of operation. • Review, tabulate, and reconcile forms and logs used in the field. • Review data errors with the coupon manager, interviewers, and HIV test counselors. • Oversee the documentation of data errors. • Supervise the submission of coupon manager information, data errors, HIV testing data, DBS information, and if applicable, other testing data into the DCC data portal. • Review the Process Monitoring Reports and the Daily Data Management Report at least weekly, identify issues of concern, and implement changes for improvement.
HIV testing operations	• Develop a local HIV testing protocol and oversee HIV testing activities. • Ensure procedures are developed for making linkages to care and other services.	• Oversee the maintenance of HIV testing supplies. • If applicable, obtain CLIA waiver. • If applicable, ship or transport HIV test specimens to the lab. • If applicable, receive and log HIV test results from the lab. • Develop procedures for making linkages 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 linkages to care and other services.
Safety, security, and confidentiality	• Assume responsibility for the 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 2 business days of occurrence and to the IRB(s) per local policy.	• Coordinate the development of local procedures for field incident reporting, safety, and the handling of participants who are under the influence, unruly, or behaving inappropriately. • Report field incidents and adverse events to CDC within 2 business days of occurrence and to the IRB(s) per local policy.	• Ensure adherence to all local procedures for field incident reporting, safety, and the handling of participants who are under the influence, unruly, or behaving inappropriately. • Report field incidents and adverse events to CDC within 2 business days 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 the interviewers provide 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). • Sync 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. • If applicable, accurately document participant information on the consent form and Participant Tracking Form. • Conduct the eligibility screener, consent, and core questionnaire according to the instructions in the <i>NHBS Interviewer Guide</i>. • Maintain data integrity (i.e., all data collected accurately represent the information provided by participants during the interview). • If applicable, provide recruiter training. • 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 NHBS and local guidelines. • If applicable, is knowledgeable of the information in the rapid test package insert. • Document HIV test results. • If applicable, accurately record information on lab slips, HIV Testing Logs, and Specimen Transport or Shipping Logs. • <i>For project areas with separate interviewers and HIV test counselors:</i> 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 the daily receipt of forms and logs, and review errors or concerns with the field supervisor or project coordinator. • Enter data errors, HIV testing data, DBS information, and if applicable, other testing data into the DCC data portal daily. • If applicable, transfer participant data, such as local questions, from the interview computers to a secure drive daily. • Maintain data integrity (i.e., each participant's record in the database accurately reflects the data collected from that participant). • Review the Daily Data Management Report from the DCC at least weekly, 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 and surveillance activities, strong leadership and supervisory skills, and a high attention to detail. In addition, the project coordinator should have excellent word processing, spreadsheet, and file management skills, along with a willingness to learn additional computer programs, such as 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 field sites. Field supervisors will spend up to 100% of their time on the project. As mentioned above, the project coordinator and field supervisor positions together comprise 1.5-2.0 FTEs.

A successful field supervisor has considerable knowledge of HIV and surveillance activities and a deep understanding of the communities in which NHBS is conducted. 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 the CMP.

2.2b Field staff

Project areas 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*), as well as in compliance with any local policies.

The field staff are the face of the project and should be outgoing and welcoming. Furthermore, it is important that they feel 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 computers, and if applicable, making appropriate linkages to care and social services after the survey is completed.

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 area and are responsible for adhering to local HIV counseling and testing standards and following NHBS HIV testing guidelines. HIV test counselors are also responsible for providing tailored prevention messages to each participant based upon risk behaviors identified during the interview or counseling session. If needed, HIV test counselors must make a linkage to care and case management services for any participant living with HIV.

An HIV test counselor should have strong counseling skills and a thorough understanding of the informed consent process, along with 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 ensuring data quality; entering data in the DCC data portal; communicating issues to the DCC, CDC, and other project staff; and if applicable, managing local data, such as local questions. Data managers must ensure that data are handled and stored in a manner that meets the required security and confidentiality standards for HIV surveillance data. Data managers will spend approximately 15-20% of their time on the project. Because of this limited time commitment, the data manager's duties could be assumed by the project coordinator if it conforms to a project area's staffing structure.

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 the CMP and the Voxco Command Center.

2.3 Spanish-speaking Staff

Project areas that utilize Spanish language materials would need to have Spanish-speaking staff available for interviewing and HIV counseling. Ideally, the coupon manager would also have some understanding of Spanish, but if they did not, another staff member could translate for them. Since project areas with few monolingual Spanish-speaking participants may not need Spanish-speaking staff during all hours of operation, they 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 area and across all the project areas. 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 7 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.

Training Asset Management System (TAMS)

All NHBS guidance documents and training materials developed by the CDC and the DCC are stored in the DCC's online repository called TAMS. TAMS facilitates project staff training by grouping documents and materials in a single location that is readily accessible and easily navigated. Access to the documents and materials in TAMS is obtained through links called Learning Trees, which cover specific training areas. For example, the NHBS-PWID2024 Data Management Learning Tree includes links to all documents and materials needed for training project staff to conduct NHBS data management activities.

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 will be conducted via an in-person training and a series of live webinars and recorded presentations. The project coordinator and field supervisor must attend or view these trainings, and they are responsible for incorporating the information from the CDC Field Operations Training

Table 2.3 – Pre-implementation guidance and trainings

	Guidance Documents							Required Trainings						Recommended Trainings	
	Model Surveillance Protocol	Formative Assessment Manual	Operations Manual	Interviewer Guide	Questionnaire	Data Management Training Materials	Project area-specific HIV testing documents	Field Operations Training	Security and confidentiality of HIV surveillance data	Field safety, occupational health, emergency procedures, adverse events, and field incidents	Project area- and job-specific trainings	Coupon Manager Program	DCC Data Management	Human subjects and scientific ethics training	Cultural and health diversity course
Project Coordinator	X	X	X	X	X	X	X	Attend CDC training and view presentations	X	X	X		X*	X	X
Field Supervisor	X	X	X	X	X	X	X		X	X	X	X		X	X
Coupon Manager	X	X*	X			X		Attend local training and view applicable CDC presentations	X	X	X	X		X	X
Interviewers	X	X*	X	X	X				X	X	X			X	X
HIV Test Counselors	X	X*	X				X		X	X	X			X	X
Data Manager	X	X*	X	X	X	X			X	X	X		X	X	

*If applicable.

into their local field operations training. All materials and recorded presentations used in the CDC Field Operations Training will be provided to project areas via TAMS for use in their local trainings.

Required participants: *Project coordinator and field supervisor to attend in-person CDC training and view CDC live webinars and recorded presentations. All relevant field staff to attend local training and view any applicable CDC live webinars or recorded presentations.*

Field safety, occupational health, emergency procedures, adverse events, and field incidents

Project staff should be trained in general field safety and occupational health. They should be taught how to handle emergency situations and 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 interview or their HIV test result). Project staff should also receive instruction on responding to and reporting field incidents and adverse events, and they should be taught how to alert one another and communicate during an emergency. Throughout the project cycle, the field supervisor should review safety procedures with the project staff at least once a month to ensure that they can successfully handle difficult situations.

Required participants: *All project staff*

HIV counseling and testing

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

Required participants: *All HIV test counselors*

Coupon manager program training

During the FOT, CDC will provide instruction on operating the CMP and using the program to manage coupons, conduct participant check-in and check-out, and pay recruiter rewards. After the FOT, training materials on these topics will be available through TAMS.

Required participants: *Field supervisor and the coupon manager*

DCC data management training

The DCC will conduct a webinar to train data managers or other designated project staff on the best practices for organizing and editing NHBS data, reviewing the Daily Data Management Report, and responding to data management problems.

Required participants: *Data manager, project coordinator, field supervisor, 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 online training covers the historical background of behavioral and biomedical research, the ethical principles for human subject research, and the role of the IRB. Online completion time is approximately 30-90 minutes depending upon an individual's familiarity with the material. Courses can be found at either the National Institutes of Health (NIH) Protecting Human Research Participants (PHRP) website ([Protecting Human Research Participants | PHRP Training](#)) or the Collaborative Institutional Training Initiative (CITI) website ([Research, Ethics, and Compliance Training | CITI Program](#)). Once registered, project staff can complete the course in multiple sittings.

Recommended participants: *All field staff*

Cultural humility and health diversity courses

Cultural humility and health diversity courses are recommended for all project staff who interact with participants. The goals of these trainings are to increase awareness and 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 are also available, like those offered by the National Center for Cultural Competence ([NCCC | Distance Learning \(georgetown.edu\)](#)).

Recommended participants: *All field staff*

2.6 Project Staff Evaluations

To help project areas 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 areas 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 the implementation of data collection, each staff member should meet all the

Table 2.4 – Evaluation and retraining recommendations

Staff Member	Evaluator	Pre-implementation Evaluation and Performance Recommendations	Recommended Ongoing Evaluation Schedule	Retraining Recommendations	Recommended Retraining Evaluation Schedule*
Field Supervisor	PI or PC	Successfully meets NHBS performance recommendations.	Project Management: For the first 3 weeks, 1 evaluation per week, and then 1 per month.	Retrained on any skills that are below standard.	Successfully meets NHBS performance recommendations.
			HIV Testing Operations: 1 evaluation per month.	Retrained on any skills that are below standard.	Successfully meets NHBS performance recommendations.
Coupon Manager	PI, PC, or FS	Successfully completes 3 consecutive mock check-in/check-out activities using the CMP and, if applicable, 3 consecutive recruiter trainings.	3 consecutive check-in/check-out activities using the CMP and, if applicable, 3 consecutive recruiter trainings during the first 2 weeks, and then 1 evaluation every 2 weeks.	Minor errors: Retrained on any skills that are below standard prior to resuming coupon manager duties.	Successfully completes the next 2 check-in/check-out activities using the CMP and, if applicable, the next 2 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 3 consecutive mock check-in/check-out activities and, if applicable, 3 consecutive recruiter trainings.
Interviewers	PI, PC, or FS	Successfully completes 3 consecutive full mock interviews (screening, consent, and interview) and, if applicable, 3 consecutive recruiter trainings.	3 consecutive interviews and, if applicable, 3 consecutive recruiter trainings during the first 2 weeks, and then 1 evaluation every 10 interviews. (If evaluating every 10 th 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 2 weeks.)	Minor errors: Retrained on any skills that are below standard prior to resuming interviewing and, if applicable, recruiter training.	Successfully completes the next 2 full interviews (screening, consent, and interview) and, if applicable, the next 2 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 and, if applicable, recruiter training.	Successfully completes 3 consecutive full mock interviews (screening, consent, interview) and, if applicable, 3 consecutive recruiter trainings.

Table 2.4 – Evaluation and retraining recommendations (continued)

Staff Member	Evaluator	Pre-implementation Evaluation and Performance Recommendations	Recommended Ongoing Evaluation Schedule	Retraining Recommendations	Recommended Retraining Evaluation Schedule*
HIV Test Counselors	PI, PC, or FS	Successfully completes 2 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).	2 consecutive testing sessions during the first 2 weeks, and then 1 evaluation every 2 weeks or, if a part-time counselor, 1 per month.	Minor errors: Retrained on any skills that are below standard prior to resuming HIV testing.	Successfully completes the <i>next</i> 2 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 2 consecutive mock HIV testing sessions.
Data Manager	PI or PC	Successfully meets NHBS performance recommendations and can proficiently enter data errors, HIV testing data, DBS information, and if applicable, other testing data into the DCC data portal.	1 evaluation during the first week of data collection and then 1 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.

performance recommendations for their position to ensure the standardization of skills within and across project areas from the onset of operations. 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 a lack of project 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 and interacting 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. 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 location and access to the forms should be limited to management staff.

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 included on the evaluation form. To accurately assess an interviewer, the best practice for the evaluator is to follow along with the interview either using their own computer or observing the interviewer's 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 interview being skipped), do not interrupt a staff member who is conducting an interview,

providing HIV counseling, or using the CMP with a participant. If an evaluator needs to interrupt, it should be done discreetly, with communication directed to the staff member and not the participant.

- Following each evaluation, review the evaluation form with the staff member, give constructive feedback, and provide recommendations for improvement.
- Maintain pre-implementation and ongoing evaluation schedules.
- Discuss staff evaluations and retraining needs with the field supervisor.

2.6d Project staff

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

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 areas assess the interviewers and provide feedback for improving their techniques, the DCC will produce an *Interviewer Report* containing the following four tables: Interview Length, Interviewer Confidence in Responses, Testing Consent, and Coding of "Other" Insurance. An explanation of each table is provided in [Section 10.3i](#) of this manual. Project areas should review the report weekly and discuss the findings with their interviewers to identify strengths and any deficiencies requiring improvement.

3.1 Chapter Overview

The purpose of this chapter is to describe the preparations that should be made prior to starting data collection. These preparatory tasks include: 1) developing a project logo and marketing materials, 2) obtaining project supplies, 3) requesting access to the CDC's Secure Access Management Services (SAMS), and 4) establishing local safety and field incident reporting procedures. Other preparatory tasks, such as training staff and planning HIV counseling, testing, and linkage to care are described in [Chapters 2](#) and [9](#) of this manual, respectively.

3.1a Chapter outline

- Project logos and marketing materials (e.g., flyers, palm cards) are ([Section 3.2](#)):
 - Used to garner community support and to promote project identity and name recognition.
 - Guided by formative assessment and input from members of the community.
 - Reviewed according to local health department policy and approved by the project area's CDC project officer.
- The Field Site Checklist ([Appendix H](#)) has a model list of supplies and materials which are described in more detail in [Section 3.3](#).
- SAMS provides authorized project staff with secure access to the NHBS Data Coordinating Center (DCC) data portal, the Voxco Command Center, and the following 4 survey applications ([Section 3.4](#)):
 - NHBS Interview (to conduct NHBS interviews)
 - NHBS Field Testing Form (to collect testing data in the field)
 - Mock NHBS Interview (to conduct practice interviews)
 - Mock NHBS Field Testing Form (to conduct practice testing sessions)
- Steps that project staff must follow to register for SAMS authorization are listed in [Section 3.4](#).
- Local safety procedures include ([Section 3.5](#)):
 - Emergency action and communication plan.
 - Plans for responding to dangerous or difficult situations, including implementing de-escalation techniques to manage aggressive individuals and stopping an interview in response to sexual harassment.
 - Guidance for occupational health, such as using appropriate personal protection equipment (PPE) and having a first aid kit.
 - Procedures for reporting field incidents locally (immediately to the field)

supervisor and within 24 hours to the PI) and to CDC (within 2 business days) ([Section 3.6](#)).

3.2 Project Logo and Marketing Materials

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

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 areas 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. Nevertheless, if enrollment is not progressing sufficiently during data collection, project areas may find it useful to distribute their marketing materials more widely within the community to try to further build name recognition and foster project acceptance.

3.3 Project Supplies and Materials

This section describes the supplies and materials that project areas should obtain before starting data collection. The Field Site Checklist ([Appendix H](#)) has a model list of supplies and materials that project areas can modify to meet their local needs.

3.3a Computers

NHBS interviews must be conducted using computers, such as tablets or laptops, with internet access. Therefore, before each day of operations, project areas should check that their computers and, if applicable, Wi-Fi hotspots are functioning properly, and they

should ensure that they have a sufficient number of each for the staff assigned to work that day (including at least one backup computer and, if applicable, one backup Wi-Fi hotspot). Please refer to the *NHBS Round 7 Interviewer Guide* for detailed instructions on the preparation and use of computers for conducting NHBS interviews.

When not in use, computers that contain participant data, such as local questionnaire data or personally identifiable information (PII), must be stored in a locked file cabinet or locked box in a secured room in the project office. That being said, it is not always feasible for staff to return computers to the project office at the end of each day of operations. In those circumstances, a senior staff member may take the computers home, but the computers must still be securely stored in either a locked file cabinet or a locked box.



To minimize the risk of data loss or theft, project areas should transfer and delete any participant data from computers as soon as possible after each day of operations.

3.3b Forms and logs for project management

To ensure successful project management and quality data collection, project areas 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 7 Model Surveillance Protocol*. Project areas can customize the documents for local use, and they can develop additional documents to help manage project operations as needed. For example, project areas that are providing HIV or other 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 project areas can use to develop a protocol, along with a form and log they can use to track the provision of results). [Table 3.1](#) summarizes some forms and logs that are recommended for project operations.



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) nor Office of Management and Budget (OMB) approval.

For easy access by staff, hard copies of forms and logs can be stored in an indexed binder and electronic copies can be stored on a shared network drive. In addition to the aforementioned forms and logs, other materials and information could be kept in the indexed binder for easy reference, such as memorandums of understanding (MOUs) with police representatives or with the owners or managers of field sites.

Personally identifiable and confidential information

Hard copies of forms and logs that contain personally identifiable or confidential

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

Form or Log	Purpose	Location in This Manual
<i>Project Staff Evaluation Forms</i>	Observe and evaluate project staff.	Appendices B-G
<i>Field Site Checklist</i>	Facilitate field site operational and closeout activities.	Appendix H
<i>Appointment Book or Log</i>	Schedule and track appointments.	Chapter 4
<i>CMP Log</i>	Maintain a backup copy of Coupon Manager Program information.	Appendix I
<i>Participant Tracking Forms</i>	Record participant information, completed project activities, and data errors.	Appendix J
<i>Rapid Testing Quality Control Log</i>	Record external rapid test control results.	Appendix K
<i>Rapid Testing Temperature Log</i>	Record temperatures at which rapid tests and quality controls are stored and run.	Appendix L
<i>Lab slips</i>	Identify test specimens.	Chapter 9
<i>Appointment and Phone Results Cards</i>	Make appointments for returning test results or provide contact information to do so.	Appendix M
<i>Return of Lab-based Test Results Form and Log</i>	Record information for returning test results.	Appendix N
<i>HIV Testing Log</i>	Record HIV testing data.	(Appendix J [†])

*Located in the *NHBS Round 7 Model Surveillance Protocol*.

information (e.g., Appointment Book or Log, Coupon Manager Program [CMP] Log, Return of Laboratory-based Test Results Form or Log, and HIV Testing Log) should be stored in a **locked** file cabinet and electronic copies should be stored on a **secure** network drive. When in use, hard copies of these forms and logs must remain in the possession of project staff at all times. Most importantly, forms and logs that contain personally identifiable or confidential information must be 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 [Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and](#)



Starting with NHBS-PWID2024, project areas can store survey IDs and laboratory IDs with contact information. This change will simplify the process of scheduling appointment reminders and returning test results by phone. While survey IDs and laboratory IDs can now be stored with contact information, ***no other NHBS data, such as test results, can be stored with contact information or any other PII.***

3.3c Materials on prevention and linkage to care and services

All participants who complete at least part of the survey should be provided with materials on HIV, STI, and hepatitis prevention and linkage to health care and social services. Project areas should develop or compile these materials and have them readily available at their field sites. Examples of materials on prevention and linkage to care and services 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.
 - Pre-exposure prophylaxis (PrEP) and other strategies for preventing HIV infection through sex and substance use.
 - HIV, STI, and hepatitis testing services.
 - Syringe services programs (also known as syringe or needle exchange programs).
 - Alcohol and substance use disorder treatment services.
- **List of care and service agencies** and contact persons to provide to participants who are HIV-positive so that they can receive health care and case management services. Furthermore, so that project areas can easily make any other necessary linkages, they should maintain a list of the names and contact information for a variety of health care 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 linkage to care and services is included in [Section 9.9](#) of this manual.
- **Harm reduction supplies**, such as injection equipment (like syringes or cookers), fentanyl test strips, naloxone, bleach kits, condoms, and lubricant. If permitted by local policy, project areas may distribute syringes, cookers, fentanyl test strips, and naloxone, but they cannot use NHBS funds to purchase these items. Instead, they must use local funds to purchase them, or

alternatively, they could distribute items donated from a collaborating agency or organization. In addition, areas must obtain approval from their CDC project officer before distributing syringes, cookers, fentanyl test strips, or naloxone. On the other hand, NHBS funds may be used to purchase other harm reduction supplies, such as bleach kits, cotton, alcohol wipes, band aids, sharps containers, condoms, and lubricant.



Some project areas have found that packing materials in creative ways, such as goody bags, increases their appeal to participants.

3.3d Other supplies and materials

Project areas should obtain any other supplies or materials needed to conduct operations in the field. For example, before each day of operations, project areas should ensure that they have an adequate number of Participant Tracking Forms, consent forms, flashcards, and incentives; and for HIV testing, they should have an adequate supply of test kits, specimen collection devices, PPE, biohazard waste containers, and if applicable, package inserts for the rapid test(s) being used. Project areas should refer to the Field Site Checklist for additional supplies and materials they may need in the field.

3.4 Secure Access Management Services (SAMS)

SAMS is a CDC system that provides secure access to NHBS applications via the internet. Project staff must use SAMS to access the DCC data portal; the Voxco Command Center, which is needed to download local questionnaire data; and the following 4 survey applications:

- NHBS Interview (to conduct NHBS interviews)
- NHBS Field Testing Form (to collect HIV and, if applicable, hepatitis testing data in the field)
- Mock NHBS Interview (to conduct practice interviews)
- Mock NHBS Field Testing Form (to conduct practice testing sessions)

Because project areas should only enter data from actual participants into the NHBS Interview and NHBS Field Testing Form applications, mock versions of these applications are available for conducting practice interviews and testing sessions during staff training. Project areas that plan on programming their own local questions will need additional survey software for collecting the local questionnaire data, and they must ensure that the local questionnaire data are collected and stored in a secure manner.

To receive authorization to use SAMS, project staff must register with the service by following these steps:

- 1) The project coordinator or field supervisor should request a new DCC user account for the staff member by completing the New User Account Request Form on the Help Desk tab of the DCC data portal. They should also send the staff member's name and email address to their CDC project officer, and they should indicate the NHBS application(s) to which the staff member requires access.
- 2) The staff member should wait for an email from the SAMS administrator inviting them to register. If the staff member does not receive their invitation email within 2 business days, they should notify their CDC project officer.
- 3) After the staff member receives their invitation email, they should login to SAMS with the temporary password contained in the email and complete the SAMS Registration Form. The staff member must complete the registration process within 30 days of receiving their SAMS invitation email. Otherwise, their SAMS invitation will expire, and the project coordinator or field supervisor will have to ask their CDC project officer to restart the process by sending the staff member a new SAMS invitation.
- 4) The staff member should then wait for an email from the SAMS administrator confirming their registration. If the staff member does not receive their confirmation email immediately upon submission of their SAMS Registration Form, they should contact the SAMS Help Desk (samshelp@cdc.gov).
- 5) After the staff member receives their confirmation email, they should verify their identity by using the Experian link contained in the email or by completing the Identity Verification Form contained in it. The staff member must complete the verification process within 60 days of submitting their SAMS Registration Form. Otherwise, their SAMS registration will expire, and the project coordinator or field supervisor will have to ask their CDC project officer to restart the process by sending the staff member a new SAMS invitation.
- 6) Once the staff member's identity has been verified, the registration process is complete and the staff member is authorized to use SAMS.



Since SAMS invitation or confirmation emails may be filtered to the staff member's spam or junk folder, the staff member should always look for the emails in this folder before requesting assistance from their CDC project officer or the SAMS Help Desk.



Identity verification for SAMS merely corroborates that the individual registering for the service is who they claim to be. It is **not** a credit check nor a criminal background check.

3.5 Local Safety Procedures

Before starting data collection, project areas 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 occupational health guidance, a communication plan for alerting project staff to a general threat, plans for responding to dangerous or difficult 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.

To ensure a safe working environment, project staff must be alert to their own safety and to that of their co-workers at all times. A basic awareness of one's surroundings is also critical when working in the field. The field supervisor is generally responsible for overall safety, crowd control, and adherence to occupational health guidelines. The field supervisor must have emergency contact information for each staff member and they must have this information readily available at all times. Project areas that use a van should have one staff member monitor the zone 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 when working in the field:

- 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.
- Adhere to all occupational health guidelines and, when applicable, use appropriate PPE.
- Have a first aid kit available.
- Always have at least 3 staff members at each field site.

3.5b Steps for field safety

Project areas should consider the following steps for safely conducting operations in the field:

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 an emergency.

- Always know the location of all exits at a field site.
- When interviewing or HIV testing, position yourself closest to the door. You always want a means of escape; 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 being alone with a participant 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 they are welcoming, but be cautious if you have concerns about them.

Use common sense

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

- Do not offer rides to participants or accept rides from them.

3.5c Techniques for handling dangerous or difficult situations

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

Aggressive or threatening individuals

If directly confronted by an individual, employ 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 their concerns; avoid becoming defensive; lower your voice, tone, and tempo; and respond to valid complaints. Local safety officials (police, fire, and rescue) may be able to provide de-escalation training.

Sexual harassment

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

Inebriated, high, or drowsy participants

Participants may not be able to complete the interview or give accurate responses for a variety of reasons. For example, they may be unable to give intelligible answers to the questions or they may nod off during an interview if they have had little sleep or have recently used alcohol or drugs. If participants are unable to provide coherent answers during eligibility screening, they should be made ineligible; and if they cannot provide coherent answers during the core interview, their interview should be stopped (see the *NHBS Round 7 Interviewer Guide* for further information).

3.5d Safeguarding computers

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

- Store your computer out of view in a secure place when you are not using it.
- Try to be inconspicuous when carrying and using your computer. ***Never*** leave it unattended in the field.
- At the end of each day of operations, computers that contain participant data, such as local questionnaire data or PII, must be stored in a locked file cabinet or locked box.

3.6 Field Incidents and Reporting Procedures

3.6a Field incidents

Field incidents are any occurrences in the field which disrupt operations. Examples of field incidents include threats to staff safety, sexual harassment, theft, property damage, and disclosures of PII or NHBS data, among others. Field incidents which also violate the human subjects protections of NHBS participants, such as disclosures of PII or NHBS data, are considered adverse events and must be reported to the project area's local Institutional Review Board(s) (IRB[s]).

3.6b Reporting procedures

Project areas should develop field incident reporting procedures and include them in the Operations Checklist. These procedures should adhere to all local IRB requirements. If an incident does occur, project staff should notify the field supervisor immediately and the PI within 24 hours. The field supervisor, project coordinator, or PI should then use a Field Incident Report to notify their CDC project officer of the incident within **2 business days**. A model Field Incident Report is provided in [Appendix O](#) that project areas can customize for local use. Incidents that are adverse events should also be reported to the local IRB(s) within **2 business days** or earlier if mandated by local IRB requirements (see Chapter 9 of the *NHBS Round 7 Model Surveillance Protocol*).

4

Field Sites and Appointments

4.1 Chapter 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 areas decide the optimal number and location(s) of their field sites. This chapter provides specific guidance on identifying and managing these field sites, as well as developing a system for scheduling interview appointments at them.

4.1a Chapter outline

- Field sites should be centrally located and easily accessible by foot or public transportation ([Section 4.2](#)).
 - A single field site may be used if it is located in an area where all subpopulations of PWID have equal access and would be equally willing to go.
 - Multiple field sites may be needed in project areas that have limited public transportation, cover large geographic areas, or are racially or ethnically segregated.
 - Multiple fields sites cannot operate simultaneously ([Section 4.3](#)).
- To maintain the integrity of the RDS method and avoid biasing the sample, field sites should **not** be located in ([Section 4.2a](#)):
 - Facilities that serve the homeless population nor near areas where **large** numbers of people experiencing homelessness congregate.
 - Substance use disorder treatment centers or methadone clinics.
 - Facilities that primarily or exclusively provide a specific type of service, like HIV care or syringe services.
- With approval from their CDC project officer, project areas can locate a field site in a facility that primarily or exclusively provides a specific type of service, like syringe services, if the field site is able to operate separately from the facility, such as on different days or at different times ([Section 4.2a](#)).
- Field sites can be located in facilities that provide multiple services that are not all aimed primarily or exclusively at people who use drugs, such as a community-based organization that provides a variety of services to the broader community ([Section 4.2b](#)).
- The field site should be welcoming and comfortable for participants while maintaining their safety and privacy ([Section 4.4](#)); and the hours of operation should not be too

restrictive, and they should be clearly communicated to participants ([Section 4.5](#)).

- Scheduling appointments allows project areas to better manage participant enrollment, minimize wait times, and potentially reduce crowding ([Section 4.6](#)).
 - Project areas may offer participants **the option** of scheduling their appointments with an online scheduling tool (**note:** because survey IDs cannot be stored in an online scheduling tool, proxy IDs must be used instead).
 - Project areas may offer participants **the option** of providing their contact information (e.g., phone number) to receive appointment reminders. If project areas do, they must develop a plan for managing and protecting the contact information collected ([Section 4.6a](#)).
 - Steps for scheduling appointments are outlined in [Section 4.6b](#) and for scheduling standby appointments, in [Section 4.6c](#).

4.2 Field Site Location

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

4.2a Restrictions on field sites

To maintain the integrity of the RDS method and avoid biasing the sample, project areas must adhere to the following restrictions when choosing field sites:

Homeless population

Field sites should not be located in facilities that serve the homeless population nor near areas where **large** numbers of people experiencing homelessness congregate. Economically disadvantaged populations, like those experiencing homelessness, may be more likely to participate in the project, which could bias the sample toward them. Another potential problem is that people experiencing homelessness who do not inject drugs could claim to inject drugs in order to participate in the project and collect the incentive.

Substance use disorder treatment

Field sites should not be located in substance use disorder treatment centers or methadone clinics. Locating a field site in one of these facilities could bias the sample toward people receiving substance use disorder treatment or harm reduction services, which are key outcomes measured in NHBS-PWID. In addition, people attending treatment centers or methadone clinics may not have injected drugs in the past 12 months.

Single-service facilities

Field sites should not be located in or near facilities that primarily or exclusively provide a specific type of service, like HIV care or syringe services. Locating a field site in such a facility could bias the sample toward people who receive that service, and it could lead to an overestimation of key NHBS-PWID outcomes, like HIV prevalence or the use of syringe services. This problem becomes compounded when there is stigma associated with the particular service offered. For example, people who do not have HIV infection may be reluctant to go to a field site in an HIV clinic because of a negative perception or fear of HIV.

However, there is an exception to the restriction on locating a field site in a facility that primarily or exclusively provides a specific type of service. With approval from their CDC project officer, project areas can locate a field site in a facility with a primary or exclusive service if the field site is able to operate separately from the facility, such as on different days or at different times. For example, a project area could operate a field site in a syringe services program (SSP) on weekends or in the evening if the SSP normally operates weekdays from 9 am to 5 pm. Ideally, when a project area operates a field site in a facility with a primary or exclusive service, they should also operate at least one other field site in a location that does not provide that service. This would further reduce the potential for bias in the sample.

4.2b Multi-service facilities

Field sites can be located in facilities that provide multiple services that are not all aimed primarily or exclusively at people who use drugs. An example of such a facility would be a community-based organization that provides HIV testing, general medical care, mental health counseling, and social services to the broader community. A multi-service facility can even provide some harm reduction services, like syringe services, as long as these services are only ancillary. When facilities provide a vast array of services that are not all aimed primarily or exclusively at people who use drugs, it is not likely that the sample will become biased toward people who receive any one particular service, such as HIV care, nor will it become biased toward people who use drugs and receive a set of services, such as hepatitis testing, substance use disorder counseling, and syringe services.

4.2c Additional considerations for vans

Project areas that plan to use a van must identify fixed locations where the van will be parked on each day of project operations. They should also create a set schedule of hours

of operation at each location. Fixed locations and schedules are essential for ensuring that people always know where to go to participate in the survey and at what times. Depending on parking regulations and availability, it may be necessary to obtain a parking permit for each location or to reserve the location in advance. In accordance with the restrictions on field sites discussed above, vans should not be parked near facilities nor in areas where large numbers of people experiencing homelessness congregate, near substance use disorder treatment centers or methadone clinics, near facilities that primarily or exclusively provide a specific type of service, nor near any other area that would not comply with the restrictions on field sites.

4.3 Multiple Field Sites

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

In addition, project areas should consider how operating multiple field site locations may bias the final composition of the sample. If a field site which focuses on a specific subpopulation of PWID operates for too many hours each week, that subpopulation may become overrepresented in the sample; whereas if the field site operates for too few hours, the subpopulation may become underrepresented. For this reason, field sites that focus on a specific subpopulation of PWID should have operating hours that are roughly proportional to the size of the subpopulation. For example, if a field site focuses on a subpopulation that comprises 20% of 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 that focus on a specific subpopulation of PWID; it does not apply to field sites that all subpopulations are equally willing and able to attend.

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

4.3a Cross-group recruitment

Cross-group recruitment means recruitment between two different groups of participants. In regard to field sites, cross-group recruitment occurs when a participant from one field site recruits a person who participates at a different field site, and vice-versa. Cross-group

recruitment is necessary to satisfy two of the RDS assumptions (see [Section 1.4b](#) of this manual):

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

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

4.4 Field Site Set-up

The field site should be welcoming and comfortable for participants while maintaining their safety and privacy. It should have adequate space for the coupon manager station, a waiting area for participants, interview spaces, and HIV counseling and testing spaces. If there is not sufficient space inside the field site for a waiting area, project areas could set up a makeshift waiting area outside the field site using a canopy tent and folding chairs. Whenever feasible, interviews and tests should be conducted in individual rooms to afford privacy. Alternatively, partitions or screens could be used to divide an open space and ensure that participants are not visible to others during interviewing or testing, and white noise machines could be used to mask voices and protect participant confidentiality.

4.4a Talk with local police and neighbors

Before setting up the field site, project areas 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, such as parking problems for project areas using vans. Project areas should also meet with the owners of neighboring businesses to inform them of the study. During data collection, it is possible that participants will loiter outside the field site, 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 areas 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 they should train them on how to respond to threatening situations and other field incidents (see [Section 3.5](#) of this manual). To prevent theft, project areas 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 forms and logs with personally identifiable or confidential information must be in limited-access areas and they must remain locked when not in use. Protecting participant confidentiality should always be a primary objective. Project areas that use a van should have one staff member monitor the zone immediately surrounding the van, as well as control who is allowed to enter it. Similarly, outdoor waiting areas should be monitored to prevent loitering or disturbances.

4.4c Crowd control

As the project becomes established in the community and recruitment increases, more and more PWID will be interested in participating. These individuals may crowd the field site or gather outside it. To help control the crowds, project areas should develop plans for managing large numbers of participants. For example, they could employ an appointment system, whereby a participant would be interviewed at a scheduled time (see [Section 4.6](#)). If project areas 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. Participants should be told how long they will have to wait to be interviewed, and if the wait will be too long, they could be told to return at a later time that day.



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

In previous RDS cycles, participants were sometimes accompanied by their family or friends who would crowd the field site. If this becomes problematic for a project area, they could ask these individuals to wait outside or ask 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. Thus, project areas should institute a clear policy regarding children at the field site. Since banning children could create a participation barrier for parents, project areas should ask 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.

4.5 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 participants show up when the field site is closed. Field sites should operate during a broad range of hours, including evening and weekend hours to accommodate participants who work during standard business hours. If hours of operation are too restrictive, certain subpopulations of PWID may be less likely to participate, which could bias the sample. Project areas should also ensure that field staff are allotted time each day for lunch or to take a break, which may require closing the field site. Once data collection has begun, project areas should not change their hours of operation unless absolutely necessary. Nonetheless, if project areas must adjust their hours of operation, they should update all their materials immediately and post the new hours so that participants do not become confused by the change.

4.5a Additional considerations for vans

Project areas 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 participants and tell them when the van will be available again. If an appointment system is used, the project staff should also reschedule the appointments that had to be cancelled. For safety reasons, project areas must send at least two staff members to notify participants; project staff should never work alone in the field.

4.6 Appointment System

Scheduling appointments for interviews allows project areas to better manage enrollment, minimizes wait times for participants, and may reduce crowding and loitering at the field site. Project areas should develop their appointment system based on the number of interviewers and test counselors they have available and the time required for a participant to complete project activities. Checking in and out, interviewing, recruiter training, and HIV testing should take approximately 1 hour, but additional time may be required to conduct other tests. More time may also be needed at the beginning of data collection when project staff are less accustomed to operations.

Project areas should offer participants the option of scheduling their appointments in person or by phone (preferably toll-free). Voice mail on the project phone should be turned off to prevent any participants from leaving confidential information, like their names or phone numbers. 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. If project areas wish, they may also offer participants the option of scheduling their appointments with an online scheduling tool, but they cannot require participants to do so and they cannot require participants to provide their contact information. Since survey IDs **cannot** be used to schedule appointments online, areas using an online scheduling tool must create proxy IDs that participants can use for online scheduling. Proxy IDs should be sufficiently different from survey IDs so that the two

types of IDs are not mixed up, and they should be included on the project areas' referral cards and coupons instead of survey IDs. Areas that would like to use an online scheduling tool should obtain approval from their CDC project officer, and they should consult their CDC project officer on methods of creating proxy IDs and linking proxy IDs and survey IDs.



To maximize participant enrollment, project areas 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.

4.6a Appointment reminders

Project areas can choose to offer participants the option of providing their contact information to receive appointment reminders. Areas may provide each participant with up to 2 reminders by text, email, or phone call prior to the participant's scheduled appointment. Likewise, if a participant does not keep their appointment, project areas may send up to 2 messages by text, email, or phone call letting them know that they can reschedule their missed appointment. Project areas choosing to provide appointment reminders must make them optional for participants, and they should outline their reminder procedures in the Operations Checklist ([Appendix A](#)). Areas must also develop a plan for managing and protecting the contact information they collect. This plan should be described in the Operations Checklist as well. Most importantly, project areas should never collect a participant's name and they should limit the number of staff who have access to participant contact information. Whenever possible, just the field supervisor or coupon manager should have access to any contact information. However, other staff members, apart from interviewers, may have access to contact information when necessary. Interviewers are the only staff members who should never have access to contact information under any circumstances. That being said, if another staff member, such as the field supervisor, must temporarily fill in as an interviewer, they may still have access to contact information, but they should not have access to the contact information of any individuals they have interviewed or might interview.

4.6b Scheduling appointments

Guidance to help project areas schedule appointments is outlined in the steps below (areas using an online scheduling tool should base their appointment system on these steps as well):

- 1) Greet the participant and ask them for their 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 participant does not have their coupon with them, instruct them to return with their coupon or call the field site to schedule an appointment over the phone. To ensure that a photo coupon has not been used previously, look up the coupon number in the Coupon Manager Program (CMP) or the project area's coupon tracking

system. If the coupon number has been used previously, explain to the individual that they will not be able to participate in the project because their coupon number has already been used and coupon numbers can only be used once. When scheduling over the phone, ask the participant for their coupon information (the coupon number, the activation date [if applicable], and the expiration date).



A coupon that is not valid should not be returned to the participant. It should be marked “Void” or “Expired,” as applicable, and then filed.

- 2) If the participant’s coupon is valid and has not been used previously, proceed with scheduling the appointment.
- 3) Tell the participant the approximate time required to complete the interview, the HIV test, and if applicable, any other tests.
- 4) Make sure the participant is 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) Schedule an appointment date and time with the participant and record it in a single hardcopy Appointment Book or electronic Appointment Log. To record the appointment, enter the participant’s coupon number next to their appointment date and time. **Never** collect or record the participant’s name in the appointment book or log.
- 6) If the project area is offering appointment reminders by text, email, or phone call, describe the reminder system and offer to send the participant one. Make it clear that reminders are optional and that the participant’s contact information will **never** be linked to their interview or testing data. Also describe how their contact information will be protected and destroyed. If the participant agrees to an appointment reminder, record the participant’s phone number or email address next to their coupon number and appointment date and time.



A hardcopy Appointment Book that contains contact information for appointment reminders must remain in the possession of project staff whenever it is in use, and it must be stored in a locked file cabinet whenever it is not in use. Similarly, an electronic Appointment Log that contains contact information for appointment reminders must be stored on a secure network drive. For further information on handling personally identifiable information (PII), see [Section 3.3b](#) of this manual.

- 7) Emphasize that the participant should be on time for their appointment. If they need to reschedule their appointment, they should call before the scheduled appointment time.

- 8) Notify the participant 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.
- 9) Tell the participant that they must bring their coupon to the appointment, or they cannot be interviewed. If the participant's coupon was collected to check its validity, return the coupon.
- 10) Conclude by reminding the participant of their appointment date and time. A participant who agrees to an appointment reminder can also be sent a confirmation message with their appointment date and time, along with any other relevant information (this confirmation message does not count toward the limit of 2 appointment reminders).



Project areas should not reserve appointment spots for members of any specific subpopulation of PWID. Denying available appointment spots to individuals who are not members of the specific subpopulation would undermine the RDS sampling method and bias the sample. Nevertheless, project areas that are having difficulty enrolling an important subpopulation should discuss scheduling options with their CDC Project Officer.

4.6c Standby appointments

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

Guidance to help project areas 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, record the participant's coupon number in the standby column next to their standby appointment time. If the participant agrees to an appointment reminder, their phone number or email address should be recorded as well. Explain to the participant that they are being scheduled for a standby appointment in the event that someone does not show up for a regularly scheduled appointment.

- 4) Ask the participant to call or return to the field site to see whether their standby appointment time has become available and they can be interviewed. If the participant agreed to an appointment reminder, they could be notified by text, email, or phone call instead.
- 5) If the standby appointment time did not become available, ask the participant if they would like to schedule a different standby appointment time or schedule a guaranteed appointment time.

5.1 Chapter Overview

Seeds are purposefully (not 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, they are asked to recruit 5 people they know who inject drugs and live in the project area. While a successful recruitment chain may grow from each seed, project areas should not expect or depend on all seeds to be productive. Analyses from prior NHBS cycles have found that less than half of seeds produced substantive recruitment chains.

5.1a Chapter outline

- A seed **must** be (Section 5.2):
 - A person who currently injects drugs.
 - Between the ages of 18 and 39 years old, with at least half of initial seeds being younger than 30 (for the age and other demographic characteristics of subsequent seeds, consult with the project area's CDC project officer).
 - A resident of the project area.
- Strategies to recruit seeds (Section 5.2):
 - Key informant referrals during formative assessment.
 - Community key informants interviewed during formative assessment.
 - Recruitment by project staff during outreach.
 - Potential seeds can be offered the option of providing their phone numbers so that they can be contacted at the start of data collection to schedule an interview.
 - Seeds should be recruited from multiple sources, and ideally, they should not know one another.
- Number of seeds (Section 5.2):
 - Start with 10-15 initial seeds.
 - Add more seeds if initial seeds are not productive (i.e., recruits are not coming in for the survey within one week of the initial seeds being interviewed).
- Ideal seed characteristics (Section 5.3):
 - Motivated to recruit others.
 - Connected to many other PWID in the community.
 - Respected and well liked.
 - Communicate well orally.
 - Represent diversity in race/ethnicity, drug preference, geography, and any other

- factors that may create more insular peer networks.
- Reflect subpopulations of greatest importance to the HIV epidemic among PWID.
- Potential seeds may be screened for eligibility, interviewed, and offered HIV testing at the project field site or in the field at the time of recruitment ([Section 5.4](#)).
- Referral cards ([Section 5.5](#)):
 - Given to recruited seeds to schedule interview appointments.
 - Referral card numbers serve as survey IDs for seeds.
 - Referral card numbers should be sequential and range from **0001** to **0888**.
 - Seed and non-seed practice interviews should use survey IDs between **9000** and **9999**.

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 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 areas 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 injects drugs,
- between the ages of 18 and 39 years old, with at least half of initial seeds being younger than 30, **and**
- a resident of the project area.

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

Project areas are not required to recruit seeds just through key informants. Seeds may also be recruited directly by project staff during outreach activities, or alternatively, key informants who 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 Talking Points ([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 areas may collect the phone number of that seed so they can be contacted at the start of data collection to schedule an interview. Contact information must be collected directly from the potential seed and only with the seed's permission; project areas cannot obtain contact information from a key informant or any other third party, and they cannot require potential seeds to provide contact information. Project areas should manage contact information collected from potential seeds the same as they manage contact information collected to provide appointment reminders (see [Sections 3.3b](#) and [4.6a](#) of this manual). In brief, contact information must be stored in a locked file cabinet or on a secure network drive, and it must be destroyed as soon as it is no longer needed. Project areas collecting contact information should describe their plans for managing and protecting this information in the Operations Checklist ([Appendix A](#)).

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 race/ethnicity, drug preference, geography, and any other factors that may create more insular peer networks. For example, if methamphetamine users in a city do not interact with heroin users in that city, cross-recruitment between these two groups would be very limited or non-existent. Accordingly, the project area should select some seeds who are methamphetamine users and some who are heroin users to ensure that both subpopulations are represented. Similarly, if white PWID do not interact with black PWID, the project area should select some seeds who are white and some who 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, they may produce a recruitment chain that is racially similar to a chain produced by a black seed. Therefore, whenever project areas are selecting seeds to target a specific demographic group, they should always ask the potential seeds about the demographic characteristics of their peer networks to ensure that the networks represent the targeted group.

Seeds should also reflect those subpopulations which are of greatest importance to the local HIV epidemic among PWID. During formative assessment, project areas should identify those subpopulations from which seeds should be chosen to yield a representative sample of at-risk PWID. During previous NHBS-PWID cycles, nearly all project areas experienced difficulty enrolling young PWID. Comparisons of NHBS-

PWID data to other sources of data among PWID suggest that young persons have been consistently underrepresented among NHBS-PWID participants. Accordingly, to improve enrollment among young PWID, **all** initial seeds must be less than 40 years old, and at least half of them must also be less than 30 years old. Because older PWID have demonstrated a greater willingness and ability to participate in NHBS-PWID in the past, choosing the youngest seeds possible will decrease the likelihood that recruitment chains become locked in networks of primarily older PWID.

When selecting young PWID as seeds, project areas should try to choose those young PWID who have been injecting the longest. An analysis of data from NHBS-IDU4 showed that seeds who were less than 30 years old and who had been injecting drugs for more than 5 years were the most successful at recruiting other young PWID. Young PWID who have been injecting for a longer period may have larger peer networks with stronger bonds and they may feel less internal stigma from injection drug use, thereby making them more effective recruiters.

5.2b Number of seeds

There is no specific number of initial seeds that will guarantee project areas reach the sample goal of 500 eligible PWID. However, based on prior RDS cycles, areas should select 10-15 seeds to initiate the recruitment process. To determine the most appropriate number of seeds, areas should consider how closely subpopulations of PWID are networked in their local community. If two or more subpopulations are **not** closely networked, areas will need to select a small number of seeds (2-3) from each of the subpopulations (see [Chapter 4](#) of this manual for a description of ways to focus on specific subpopulations using field sites). On the other hand, if two or more subpopulations of PWID are closely networked, a small number of seeds from any of the closely-networked subpopulations will be sufficient to start recruitment.

Project areas should not select seeds from every possible network of PWID in the community. Instead, they should focus on those networks that include the subpopulations of PWID at greatest risk of HIV infection. In most cases, fewer than 15 seeds will be needed. It is important that areas do not choose too many seeds because the sample size could be reached before equilibrium is achieved and the RDS method would be undermined. Project areas 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 a sufficient number of participants within a week (seeds usually do not recruit other participants more than a week after the seeds have been interviewed) or if enrollment later stalls because all the recruitment chains have “dried up” (i.e., stopped recruiting), then additional seeds will have to be selected. Project areas should not hesitate to select additional seeds when necessary. They should consult with their CDC project officer as soon as possible and together decide how many seeds are needed, as well as determine what the ages and other demographic characteristics of

those seeds should be. To minimize delays if more seeds are needed, it is often useful to have a plan for quickly selecting additional seeds via key informants, collaborators, or community outreach. With RDS, seeds do not all have to be chosen at the same time or at the beginning of data collection. Groups of seeds could be chosen in weekly waves until recruitment chains begin to grow and become self-sustaining. Furthermore, whenever recruitment is not progressing, project areas should 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.

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 who has numerous lines radiating out; that is to say, someone who is a focal point of a large 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 areas can ask are:

- *Do you know many people who inject drugs and live in [the project area]?*
 - *Of the people you know who inject drugs and live in [the project area], what proportion are [targeted demographic group]?*

- *Of the people you know who inject drugs and live in [the project area], what proportion inject [targeted drug]?*
- *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]?*
- *Have you been involved in any other health studies before?*

5.4 Screening and Interviewing Seeds

If a potential seed satisfies the assessment criteria, they should be referred for eligibility screening using a referral card (see [Section 5.5](#) below). Project areas should use the referral card to make an appointment to screen the potential seed at one of their field sites. Project areas can also screen a potential seed in the field where they were recruited. If a potential seed is screened and found to be eligible, they will be offered the opportunity to participate in the survey and receive an HIV test. Seeds who satisfactorily complete the survey will be able to recruit other participants.

5.4a Screening and interviewing by appointment

If a project area 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 they are approached, the project area 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 the appointment. They may also use an online scheduling tool. 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., Saturday, June 1, 2024 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 referral card number (survey ID). Seeds who are referred by a key informant can have their appointments scheduled by the key informant or they can be given a referral card and instructed to contact the project to schedule their appointments.

When scheduling an appointment with a potential seed, project staff should review the appointment information on the referral card and the directions to the field site. Staff should also tell the potential seed that they should call the project phone number on the card if they need to reschedule their appointment. If a project area wishes, they may offer

seeds the option of providing their contact information to receive an appointment reminder by text, email, or phone. Areas may provide each seed with up to 2 appointment reminders by following the guidance outlined in [Section 4.6a](#) of this manual.



Seeds **cannot** be required to provide contact information; providing contact information must always be optional.

Project areas 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 beginning of data collection when they are needed to initiate recruitment chains.

5.4b Screening and interviewing in the field

If potential seeds are available to be screened when they are approached, project areas may interview them in the field. To do this, project areas 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, computers, HIV test kits, incentives, recruitment coupons, and a computer with the Coupon Manager Program (CMP) or a remote link to the coupon manager and CMP. To operate in the field, project staff must adhere to local safety guidelines, and they must protect the confidentiality of the potential seeds 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 appointments to screen and interview the potential seeds 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 **unique** number, which will serve as the participant's survey ID. Referral card numbers should be sequential and 4-digits long, ranging from 0001 to 0888. Project areas should not use numbers greater than or equal to 1000 for referral cards because some of these numbers are reserved for recruitment coupons (see [Section 6.2](#) of this manual) and others are reserved for practice interviews (see note below). Since referral card numbers function as survey IDs for seeds, project areas must strictly adhere to these referral card numbering conventions.



When practicing both seed and non-seed interviews, project staff should just use survey IDs between 9000 and 9999 to enable the NHBS Data Coordinating Center (DCC) to readily identify practice interviews within the data. Only survey IDs in this range can be entered in the Mock NHBS Interview in CDC's Secure Access Management Services (SAMS).

5.5a Making referral cards

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

Figure 5.1 – Example of the front of a referral card

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

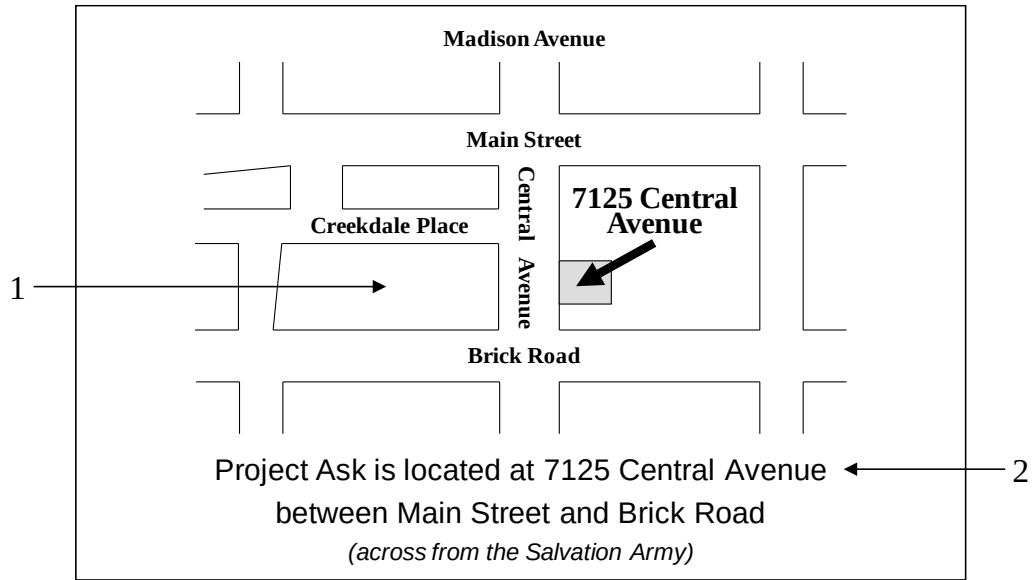
- 1 → **0001** **Project ASK** **0001** ← 2
- You have an appointment on
- 3 → Day: _____ Date: ____ / ____ / ____ Time: ____ : ____
- at 7125 Central Avenue, 2nd Floor. ← 4
- (Directions are on back.)
- 5 → Please call 1-888-865-4327 if you have any questions or if you need to reschedule.
- Coupon expires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

1. Referral card number ranging from 0001 to 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. It is best to have a toll-free number because of the likely disadvantaged economic status of many participants.
6. **Optional:** Space to record an expiration date.



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

Figure 5.2 – Example of the back of a referral card



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



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

6.1 Chapter 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, they 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 their recruiter. This recruiter-recruit linkage is an essential component of RDS analysis.

6.1a Chapter outline

- Coupon numbers ([Section 6.2](#)):
 - Serve as the survey IDs for non-seed recruits.
 - Coupon numbers should be sequential and 4-digits long, ranging from **1000** to **8888**.
 - Seed and non-seed practice interviews should use survey IDs between **9000** and **9999**.
- Number of coupons distributed ([Section 6.3a](#)).
 - **At the start of data collection:** To increase the likelihood that recruitment chains will be generated quickly and grow steadily, project areas should initially give 5 coupons to both seed and non-seed recruiters.
 - **When sample size reaches 100:** To address underrepresentation of young PWID (<40 years old) in NHBS, project areas should continue giving **5 coupons** to recruiters who are 18 to 39 years old, and start giving **3 coupons** to those who are 40 to 49 years old and just **1** or **2 coupons** to those who are 50 years old or greater.
 - **Throughout data collection:** In consultation with their CDC project officer, project areas may adjust the number of coupons to address potential recruitment problems (e.g., recruitment is too slow or fast, participation by a specific subpopulation is less or more than expected based on formative assessment).
 - **At the end of data collection:** project areas can 1) continue to give the same number of coupons and emphasize the project end date during recruiter training and when describing the project to potential participants, or 2) give fewer or no coupons close to the end of data collection to slow recruitment.
- Coupon activation dates (i.e., when coupons become valid) may allow better control of participant flow and decrease the likelihood of recruiting strangers (i.e., people the recruiter does not know personally) ([Section 6.3b](#)).
- Coupon expiration dates (i.e., when coupons are no longer valid) could motivate

recruits to enroll promptly, but do not need to be enforced so that recruitment is not hindered ([Section 6.3c](#)).

- Photos of coupons can be used in addition to paper coupons ([Section 6.3d](#)).
 - Project areas must accept all photo coupons on a first come, first served basis.
- Project areas should use a CMP Log (see model log in [Appendix I](#)) as a back to the CMP to keep track of the numbers on the coupons given out to participants.

6.2 Coupon Number

Each coupon should have a **unique** number, which will serve as the participant's survey ID. Coupon numbers should be sequential and 4-digits long, ranging from 1000 to 8888. Project areas should not use numbers less than 1000 for coupons because some of these numbers are reserved for seed referral cards (see [Section 5.5](#) of this manual). Since coupon numbers function as survey IDs for participants, project areas must strictly adhere to these coupon numbering conventions.



When practicing both seed and non-seed interviews, project staff should just use survey IDs between 9000 and 9999 to enable the NHBS Data Coordinating Center (DCC) to readily identify practice interviews within the data. Only survey IDs in this range can be entered in the Mock NHBS Interview in CDC's Secure Access Management Services (SAMS).

6.3 Coupon Options

Based on their experience from prior RDS cycles and their findings from formative assessment, project areas should determine how many coupons to distribute to recruiters. They should also decide 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, project areas are not limited to just using paper coupons. If they wish, project areas may also allow participants to photograph their coupons and send them to their recruits electronically.

6.3a Number of coupons distributed

Project areas may give up to 5 coupons to each participant who completes the survey and agrees to recruit others. The number of coupons that should be given to each recruiter depends, in part, on the pace of participant enrollment. When enrollment is progressing too slowly, more coupons should be given to recruiters to boost enrollment, and when enrollment is progressing too rapidly, fewer coupons should be given to temper enrollment. Thus, to increase the likelihood that recruitment chains will be generated quickly and grow steadily at the start of data collection, project areas should initially give the maximum of 5 coupons to both seed and non-seed recruiters. The number of coupons

given to each recruiter can then be reduced once enrollment has attained an optimal level and is self-sustaining, which should occur by the time the cumulative number of participants reaches 100. Throughout the initial phase of data collection, project areas should review their weekly and cumulative enrollment data with their CDC project officer, and together decide when enrollment has progressed sufficiently enough to decrease the number of coupons distributed.

Nevertheless, because young PWID, who are a priority subpopulation for enrollment in NHBS-PWID, have shown less willingness to participate in the past, project areas should not reduce the number of coupons distributed to them even when overall enrollment is progressing well. Instead, project areas should employ differential coupon distribution, whereby different numbers of coupons are given to various subpopulations in order to adjust their enrollment (see **Differential coupon distribution** below). When project areas, in consultation with their CDC project officer, determine that the number of coupons given to recruiters should be reduced, they should continue giving 5 coupons to recruiters who are 18 to 39 years old, and start giving 3 coupons to those who are 40 to 49 years old and just 1 or 2 coupons to those who are 50 years old or greater. By giving more coupons to younger PWID, project areas will greatly improve their chances of enrolling young PWID and obtaining a representative sample of participants.



If a project area believes that the recommended plan for differential coupon distribution by age would undermine their operations or enrollment, they should discuss alternative coupon distribution strategies with their CDC project officer and obtain approval to implement one of those alternatives.

To avoid negative impacts on project operations, data quality, and RDS analysis, project areas should reduce the number of coupons given to older recruiters as soon as overall enrollment is progressing sufficiently. If too many coupons are given to older recruiters, the number of recruits could greatly exceed the project staff's capacity to interview them. If the project staff were to become overwhelmed with recruits, many recruits would be denied the opportunity to participate in the project. Not only would this undermine the project's credibility in the community, but it would also increase the non-response bias in the sample. A large pool of recruits waiting to enroll could also diminish the effectiveness of differential coupon distribution. Lastly, distributing too many coupons to older recruiters could 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).

Differential coupon distribution

If participation by a specific subpopulation is less than what is expected based on formative assessment, project areas can increase the number of coupons given to recruiters from the underrepresented subpopulation to improve their enrollment. Likewise, to help prevent the sample from becoming biased if a specific subpopulation starts to dominate enrollment, project areas can decrease the number of coupons given to recruiters from that subpopulation or stop giving coupons to them altogether. As

mentioned above, this is referred to as differential coupon distribution. Differential coupon distribution is a drastic action, however, and should only be used when the sample would not represent those subpopulations of greatest importance to the local HIV epidemic without intervention. With the exception of implementing the recommended plan for differential coupon distribution by age, project areas should do the following before increasing the number of coupons given to an underrepresented subpopulation: 1) conduct ongoing formative assessment to determine why participation by that subpopulation is low, and 2) address any recruitment or participation barriers identified (see [Section 10.4](#) of this manual). If these actions do not improve enrollment by the underrepresented subpopulation, project areas may then distribute more coupons to them. The under- or overrepresentation of a subpopulation often requires immediate intervention. Accordingly, project areas should discuss any potential recruitment problems with their CDC project officer as soon as possible to prevent them from escalating into irreversible recruitment problems.

Ending coupon distribution

In previous RDS cycles, some project areas gave fewer or no coupons as the data collection period neared 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 project areas, but most others found it unnecessary. As the end of data collection neared, project areas 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. Project areas can continue to give out coupons toward the end of data collection as long as they have the capacity to interview participants. If project areas no longer have this capacity, they must stop giving out coupons.

Consulting CDC project officer

When deciding how many coupons to distribute, project areas need to balance the ability to enroll participants, which may require giving more coupons, with adherence to the best methodological practices, which necessitate giving fewer coupons. As discussed above, project areas 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 project manager(s) and their CDC project officer. In addition, whenever project areas 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 their

coupon to one of the field sites to begin the check-in process. Project areas 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 project areas set an activation date that was one day after the coupon was distributed.

Some project areas 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 areas have found that activation dates hinder recruitment. This was especially true for project areas 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 areas 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 areas may change the interval for their coupons to become valid if they think it will improve recruitment or operations. Similarly, project areas that do not initially include an activation date on their coupons may later add one, and project areas that do initially include an activation date may later eliminate it. Before making any changes to coupon activation dates, however, project areas should discuss the changes with their CDC project officer and obtain approval.

6.3c Coupon expiration dates

A coupon expiration date is the date when coupons are no longer valid for participation in the project. That being said, expiration dates are not hard-and-fast; project areas can choose to allow recruits with expired coupons to still participate. This practice of not enforcing expiration dates could motivate recruits to enroll in the project promptly, but without the negative consequences of denying anyone the opportunity to participate. Regardless of how project areas choose to treat expiration dates, they should be consistent, either allowing participation to all recruits with expired coupons or denying participation to all recruits with expired coupons.

Project areas must include an expiration date on their coupons. At the very least, this date

must be the last day planned for project operations. Project areas may also choose an earlier expiration date if they wish. For example, in previous RDS cycles, some project areas had coupon expiration dates that were 4 to 6 weeks after the coupons were distributed. These project areas felt that an earlier expiration date resulted in faster recruitment. Yet, many project areas 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, even if a project area allows recruits with expired coupons to participate, some recruits may not try to enroll in the project because they assume that their expired coupons will not be honored. Less busy project areas felt that early expiration dates would therefore be harmful to enrollment. Another possible problem is that early 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 a field site. For these reasons, early expiration dates should be used with caution. Project areas 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 areas may change the interval before their coupons expire if they think it will improve recruitment or operations. Expiration dates may be made earlier or later, but they may not be eliminated. As noted above, at the very least, coupons must expire on the last day planned for project operations. Project areas 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 areas have the option of allowing participants to use photo coupons in addition to paper coupons. Project areas choosing to permit photo coupons should explain this option to participants after they have been given their paper coupons. Participants could then distribute their coupons either by handing out the paper copies or by sending photos of them. Instructions for using the photo coupons can be incorporated into the recruiter training talking points ([Appendix Q](#)).

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, 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 areas 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 areas 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. Coupon numbers cannot be used again even if a recruit does not pass the eligibility screener, does not consent to participate in the project, or does not complete the interview.

Figure 6.1 – Example of a photo coupon



6.4 Making Coupons

Coupons can be professionally printed, or project areas can make the coupons themselves by following the instructions in [Appendix R](#). Coupons may be designed however a project area 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, project areas may choose to include the phrase “Not for Sale” on their coupons. In prior RDS cycles, some project areas added a sticker with a hologram, barcode, or quick response (QR) code to prevent counterfeit coupons. A QR code could also provide a link to project information or a project website. In addition, project areas 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 area become introduced locally.

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.

Figure 6.2 – Example of the front of a coupon

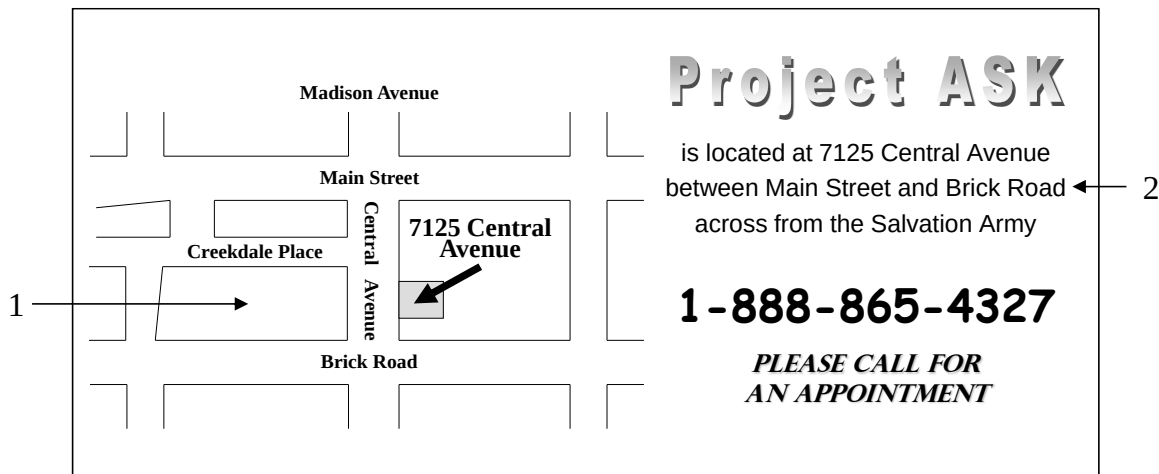


1. Coupon number ranging from 1000 to 8888.
2. Name of the local NHBS project.
3. Incentive amount for participants completing the survey.
4. Phone number to call for project information and to schedule appointments. It is best to have a toll-free number because of the likely disadvantaged economic status of many participants.
5. Days and hours of field site operations.
6. **If applicable:** Project logo.
7. **Optional:** Security feature, like a sticker with a hologram, barcode, or QR code.
8. Address of the field site.
9. **Optional:** Space to record an activation date.
10. 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 the location of the field site.
2. Directions to the field site.



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

6.5 Coupon Tracking System

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

6.5a Tracking coupons distributed

Project areas should use a log to keep track of the numbers on the coupons given out to participants. The CMP Log (**Appendix I**), 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 areas should keep track of the coupons returned by recruits, including coupons from ineligible recruits and if applicable, expired coupons. An easy way to manage returned coupons is to have a set of file folders or envelopes labeled with the dates for each week that data are collected (e.g., Week 1: 6/3 – 6/9, Week 2: 6/10 – 6/16, and so on). When a recruit returns a coupon, the coupon manager should validate the coupon in the CMP and update its status in the program by selecting “Submitted,” “Void,” or if a project area denies participation to recruits with expired coupons, “Expired.” The coupon manager should also write the same term (“Submitted,” “Void,” or “Expired”) on the

coupon to indicate that it 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.

7.1 Chapter 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](#) on page 7-3). Information on identifying and managing field sites is presented in [Chapter 4](#) of this manual.

7.1a Chapter outline

- The Coupon Manager Program (CMP) and the Participant Tracking Form ([Appendix J](#)) are used to track participants throughout the check-in, interview, and check-out process ([Section 7.2](#)).
- Three main functions of the CMP ([Section 7.2a](#)):
 - Link recruiters with their recruits.
 - Manage recruiter rewards.
 - Collect responses to the *Recruiter Questions*.
- To prevent data loss, project areas should keep a hard copy CMP log (see [Appendix I](#) for a model CMP log) ([Section 7.2a](#)).
- The Participant Tracking Form should be used to document and track the operational activities completed by each participant ([Section 7.2b](#)).
 - Add additional fields, if needed, to tailor the form to local operations.
 - Could use either paper copies or electronic copies stored on a secure network.
- Participant check-in is conducted by the coupon manager and includes the following steps ([Section 7.3](#)):
 - 1) *Validate the coupon or referral card.* [Section 7.3a](#) describes different check-in issues and how to address them, such as when the person does not have a coupon, appears too intoxicated, or is recognized as a previous participant.
 - 2) *Create a record in the CMP* for the potential participant if they have a valid coupon or referral card ([Section 7.3b](#)). It is important to **always** create a record in the CMP before the potential participant is screened by an interviewer.
 - 3) *Fill out the Participant Tracking Form.*
 - 4) *Introduce the participant to their interviewer.*
- The NHBS interview is conducted using a computer and includes the eligibility screener, consent, core questionnaire, and an optional local questionnaire ([Section 7.4](#) and the *NHBS Round 7 Interviewer Guide*).

- Recruiter training is key to the success of RDS and can be provided by the interviewers, the coupon manager, or both ([Section 7.7](#)).
 - [Appendix Q](#) contains model recruiter training talking points.
- Participant check-out is conducted by the coupon manager and may include:
 - Updating the participant’s CMP record.
 - Creating the recruiter ID, recording physical marks, and distributing coupons.
 - Reinforcing (or providing) recruiter training.
 - Giving out incentives.
 - Providing prevention materials and offering linkages to care and services.

7.2 Participant Information and Tracking

Project areas should use the Coupon Manager Program (CMP) and the Participant Tracking Form ([Appendix J](#)) to record participant information and to track participants throughout the check-in, interview, and check-out process.

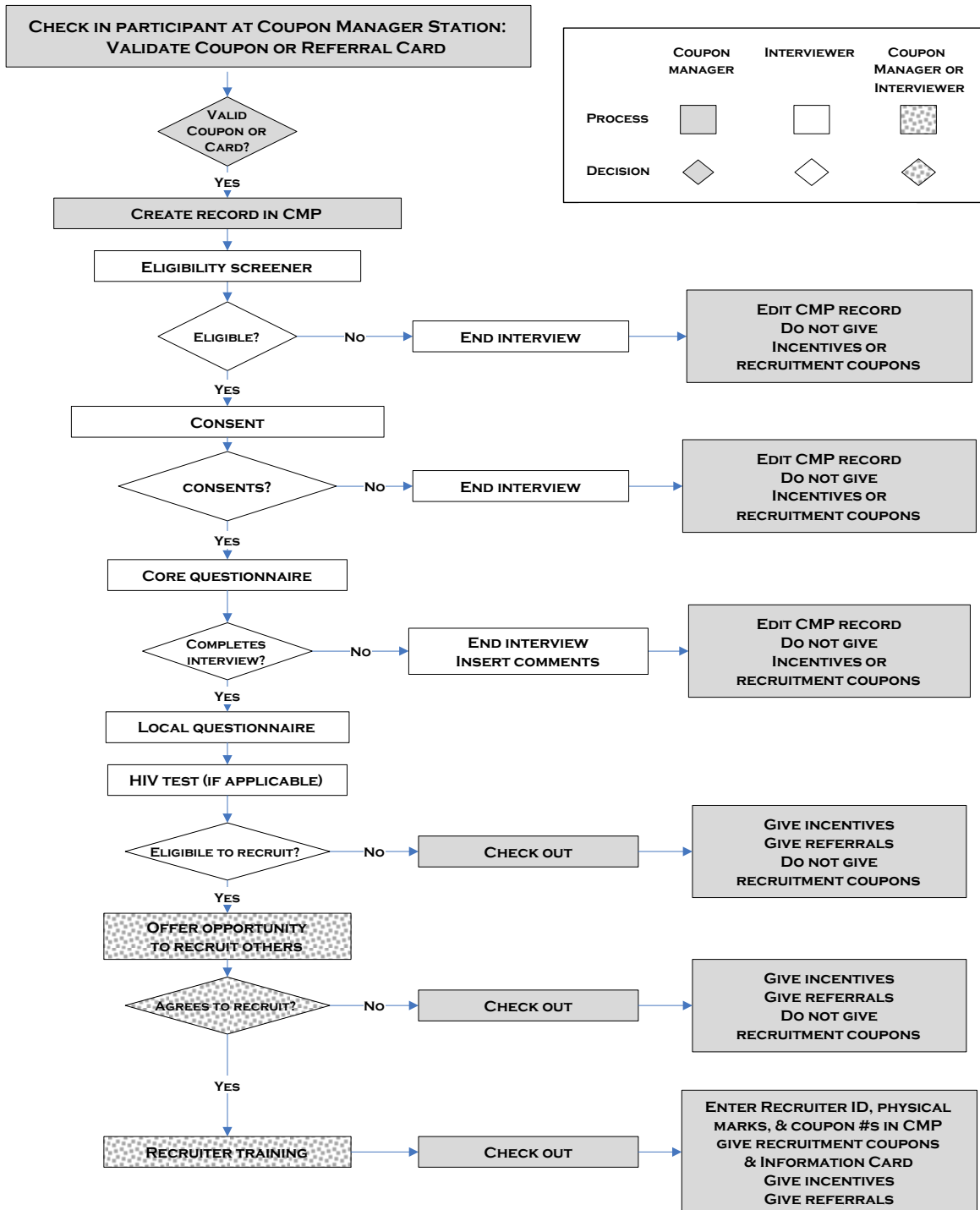
7.2a Coupon Manager Program

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

- 1) **Link recruiters with their recruits:** Each participant’s data is linked to that of their 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 their rewards for recruiting others. The *Recruiter Questions* will be discussed further in [Section 8.3](#) of this manual.

Instructions on using the CMP can be found in the NHBS-PWID2024 Coupon Manager Learning Tree on the NHBS Data Coordinating Center (DCC) data portal. The CMP should be installed on a laptop or desktop computer and kept at the “coupon manager

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



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

Project areas 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 areas 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, and the numbers on the recruitment coupons given to the participant. Some project areas also include the participant’s physical marks and recruiter ID in the log. Please see [Appendix I](#) for a model CMP Log. Furthermore, at the end of each day of operations, project areas should back-up their CMP database to a secure location, like an external drive or network. Important participant information, like recruiter IDs and physical marks, are stored only in the CMP and would be lost if there was a software malfunction and the CMP was not backed up.

Also at the end of each day of operations, project areas should check the **submitted** coupons on the *Recruiter TBD [to be determined] Coupons Report* under the Search tab in the CMP to look for any coupons that were submitted that day but are not linked to a recruiter. A coupon could be unlinked in the CMP if its number was incorrectly entered in the Processing Incoming Coupon field, if its number was not assigned to a recruiter on the Recruiter Detail page, or if its number was assigned to a recruiter on the Recruiter Detail page but was not saved. Whenever project areas identify an unlinked coupon in the *Recruiter TBD Coupons Report*, they should review their CMP Log and Participant Tracking Forms to see if they contain any information that could be used to link the coupon to a recruiter. If project areas are unable to rectify the problem of an unlinked coupon or are unsure how to do so, they should contact their DCC technical assistance coordinator (TAC) for help. It is important for project areas to check the *Recruiter TBD Coupons Report* daily to ensure that unlinked coupons do not accumulate in the CMP.

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 record 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 areas may add any additional fields they consider necessary.

Project areas with a secure network can store electronic copies of the Participant Tracking Form on the network and share them among staff. Otherwise, project areas should use paper copies of the form.



Electronic copies of the Participant Tracking Form **cannot** be exchanged among project staff by any unsecure means, such as email or text.

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 them for their coupon (or referral card). Paper coupons and referral cards should be collected from potential participants so that they cannot be used again. If the potential participant has an appointment scheduled, the coupon manager should verify the 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 them to return after the activation date or on a scheduled appointment date.
- ***If the coupon has expired and local policy does NOT allow people with expired coupons to be interviewed***, 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. They should explain to the person that their coupon has expired:

“I’m sorry, but your coupon has expired. We can’t interview anyone with an expired coupon.”

- ***If the coupon has expired but local policy allows people with expired***

coupons to be interviewed, the coupon manager should create a CMP record for the person as described in [Section 7.3b](#) below. Even if the CMP has automatically changed the status of the coupon to “Expired,” the CMP will still allow the coupon manager to change the status to “Submitted” and create a CMP record.

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

- ***If the person does not have their coupon with them***, they 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 them, and their appointment should be re-scheduled for another day. The coupon manager should use their own judgment as to how to best handle the situation and avoid confrontation. They could politely reply:

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

- ***If the person is recognized as a previous participant***, the coupon manager should confiscate the coupon and tell the person that they 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.” They 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 interview.

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. If the coupon has expired but local policy allows people with expired coupons to be interviewed, the coupon manager should change the status from “Expired” to “Submitted.” For all potential participants with valid coupons (or referral cards), the coupon manager should 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 areas 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). Project areas 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 interview record.

7.3c Fill out Participant Tracking Form

The coupon manager should begin to fill out the Participant Tracking Form by recording the following information:

- Date
- Interviewer ID
- Survey ID (same as the coupon or referral card number)
- Whether the participant is a seed
- Field Site ID

7.3d Introduce participant to their interviewer

After the coupon manager has checked in the participant, they should introduce the participant to their assigned interviewer, and they should give the Participant Tracking Form to the interviewer. If the participant and the interviewer know one another, 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 these and the needed interviewing skills are provided in the *NHBS Round 7 Interviewer Guide*. Before conducting any interviews with participants, 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 questionnaire. The interview is conducted using a computer and the entire process takes approximately 45 minutes to complete. All interviews must be conducted at the field site in a space that affords privacy and protects the participant's confidentiality. Other individuals should not be able to view the interview nor 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 PWID cycle-specific eligibility criteria. The 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.

PWID cycle-specific eligibility:

- Has injected drugs that were not prescribed for them in the past 12 months.

Individuals who do not meet one or more of the eligibility criteria will be told, “the computer has not selected you to participate in the health survey.” When this occurs, the interviewer should end the interview and thank the ineligible person for their time. The interviewer should follow the prompts in the computer to ensure that the interview is ended correctly and the data are saved. The interviewer should then escort the ineligible person from the interview space, and they should return the Participant Tracking Form to the coupon manager and tell them that the person was not selected for the survey. The coupon manager should indicate in the ineligible person's CMP record that their recruiter

is not owed a reward. If applicable, the ineligible person should be provided with a token “thank you” incentive.



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 they recognize 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 they are a “known previous participant.” The computer will then automatically make the person ineligible.



Only the field supervisor can make the final determination that a person should be screened out as a previous participant under these circumstances; project staff should not decide this on their own.

Intoxicated participants

During screening, if an interviewer determines that a potential participant is too intoxicated with alcohol or drugs to competently consent to participate in NHBS or to understand the survey, the interviewer should indicate during eligibility screening that the person is not alert and capable of completing the survey because they are “not able to understand or consent.” As with previous participants, the 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 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 the person’s interviewer to indicate during eligibility screening that the person cannot complete the survey because their “reported age is not plausible (< 18 years old).” The 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 areas that identify a pattern of underage individuals 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

To be eligible, NHBS-PWID participants must report that they have injected drugs that were not prescribed for them in the past 12 months. Unlike participants in prior NHBS-PWID cycles, NHBS-PWID2024 participants do **not** have to show physical signs of injection drug use, like track marks, **nor** do they have to demonstrate knowledge of drug preparation, injection, and syringes.

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 areas may choose to have the interviewer paraphrase the information in the consent form instead of reading it verbatim. If the local IRB requires informed consent to be obtained before a potential participant is screened for eligibility, project areas may do so. Consent to participate in NHBS should be obtained verbally and recorded in the computer (some local IRBs may also require project areas to maintain written documentation of consent). Since all NHBS data **must** remain anonymous, project areas cannot require participants to provide their names or other personally identifiable information (PII) as part of the consent process. Participants can consent to either: 1) the NHBS interview, or 2) the NHBS interview and an HIV test. If applicable, participants can also consent to hepatitis testing or having their HIV or hepatitis test specimen stored for future testing. Further details on the consent process are provided in the *NHBS Round 7 Interviewer Guide*.



It is critical for interviewers to accurately record consent in the computer. If consent is not recorded in the 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 follow the prompts in the computer to ensure that the interview is ended correctly and the data are saved. The interviewer should then escort the person from the interview space, and they should return the Participant Tracking Form to the coupon manager and tell them that the person has not provided consent. The coupon manager should indicate in the person's CMP record that their recruiter is not owed a reward.

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 they initially declined testing but then changed their mind during the interview.

7.4c NHBS questionnaire

The interviewer should use a computer to administer the NHBS questionnaire to eligible individuals who consent to participate. The questionnaire consists of the *Network Questions*, the core questionnaire, and if applicable, a local questionnaire developed by the project area. To minimize the burden on participants, the local questionnaire 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 7 Interviewer Guide* for important information on using the interview software, instructions for the interviewers, guidance on standardized interviewing, and explanations of the core questions.

Network questions

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

- 1) **Participants know one another as members of the target population:** The first *Network Question* asks the participant to classify their relationship to the person who gave them their recruitment coupon to determine whether the participant and their recruiter know one another or are “strangers.” Recruitment by a stranger violates the RDS assumption that “participants know one another.”
- 2) **Participants randomly recruit other participants from their personal networks:** The second *Network Question* asks the participant to estimate both the number of males and the number of females they know who inject drugs and have seen in the past 30 days. The gender composition of the participants’ personal networks can be compared to the gender composition of the sample to help determine whether participants recruit randomly or preferentially from their personal networks.
- 3) **Participants can accurately report their personal network size:** The third *Network Question* automatically sums the number of males and females who inject drugs that the participant knows and asks them to confirm that number. This is their 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 prevention activities. Participants are asked all sections.

At the end of the core questionnaire (and before the start of the local questionnaire), the

interviewer will be instructed to record their 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. Whenever an interviewer records that they are "not confident at all" in a participant's responses, that participant will not be eligible to recruit others and their interview data will not be included in the national NHBS dataset, albeit their interview will still count toward the process goal of 500 interviews completed by persons who injected drugs in the past 12 months.

Ending an interview early

If a participant does not want to continue the interview, 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 person from the interview space, and they should return the Participant Tracking Form to the coupon manager and tell them that the interview was ended early. The coupon manager should indicate in the person's CMP record that their recruiter is not owed a reward. However, some IRBs may require project areas to provide recruiter rewards if the participant was eligible and started the interview, but did not complete it. In those cases, the coupon manager should indicate in the participant's CMP record that their recruiter is owed a reward.

The participant should not be given an HIV test, they should not be paid any incentives, and they should not be given coupons to recruit others. Project areas 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 a means of making any needed corrections to the data, such as fixing a misentered survey ID (please see the NHBS-PWID2024 Data Management Learning Tree). 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 of operations, the field supervisor should review the Participant Tracking Forms from that day to make sure the information on the forms is complete, and they should discuss any data edits with the interviewers. 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. By promptly addressing data errors, the data manager will be more likely to be able to resolve any problems that require interviewer

recall and clarification.

7.6 HIV Counseling, Testing, and Linkage to Care and Services

This section briefly summarizes the process of providing HIV counseling, testing, and linkage to care and services as part of NHBS. More detailed guidance on this process is included 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 areas must conduct all HIV counseling and testing in accordance with the *NHBS Round 7 Model Surveillance Protocol* and their local testing policies. Most importantly, a participant **cannot** receive HIV counseling or their test result before they finish the core questionnaire. Some project areas are not required to provide pre-test counseling before they collect a specimen for HIV testing. These project areas may collect a specimen for rapid HIV testing prior to starting the interview if the test is not run in 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 project areas to run a participant's rapid HIV test while the participant is being interviewed. When the participant completes their interview, they would then receive HIV counseling and their rapid test result.



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

7.6b Linkage to care and services

All participants with positive HIV test results, including preliminary positive rapid test results, should be linked to appropriate medical care and HIV case management services when they receive their test results (see [Section 9.9](#) 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 linkages to care or services.

7.7 Recruiter Training

Recruiter training can be provided by the interviewers or the coupon manager. In previous RDS cycles, some project areas had the interviewers provide the recruiter training and then the coupon manager reviewed the instructions with the participant to reinforce them. If project areas 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 computer will automatically display a message indicating whether the participant was selected to 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 their confidence in the participant's responses as "not confident at all"). The interviewer should use the Participant Tracking Form to indicate whether a participant can recruit others and, if applicable, the number of coupons they should receive.

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 and the benefits it can provide to the PWID community depend on participants recruiting others to accrue a large sample of PWID from throughout the city.
- They have a chance to **earn \$**<recruiter reward amount> per PWID recruited, up to a maximum number of PWID 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 area, they 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 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 areas 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, project areas 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. [Appendix Q](#) contains model recruiter training talking points, which project areas may tailor to match their local operations. Project areas planning to conduct interviews in Spanish should also translate the recruiter training talking points into Spanish.

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



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 areas should also tell recruiters when they will stop giving coupons out and when they plan on ending enrollment.

7.8 Check-out

With RDS, survey participation 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 the HIV test counselor should escort them to the coupon manager station, and the Participant Tracking Form should be returned to the coupon manager with the following information:

- Whether the participant passed the screener (i.e., was eligible for the interview)
- Whether the participant consented to the interview
- Whether the participant consented to HIV testing
- *If applicable*, whether the participant consented to hepatitis testing
- *If applicable*, whether the participant consented to other testing

- *If applicable*, whether the participant consented to specimen storage
- Whether the participant completed the interview
- Whether the participant was selected to recruit others and agreed to do so
- *If applicable*, the number of coupons the participant should receive
- *If applicable*, whether the participant completed HIV testing
- *If applicable*, whether the participant completed hepatitis testing
- *If applicable*, whether the participant completed other testing
- *If applicable*, whether DBS were collected for storage and future testing
- *If applicable*, whether necessary care referrals were made

7.8b Coupon manager duties

During check-out, the coupon manager's responsibilities may include updating the participant's CMP record, distributing coupons, reinforcing (or providing) recruiter training, giving out incentives, providing prevention materials, and offering linkages to care and services.

Updating the CMP record

Once the coupon manager has received the needed participant information, they should use the participant's survey ID to search for the participant's record in the CMP. The coupon manager should then update the participant's CMP record:

- ***If the participant was not eligible, did not consent to the interview, or did not complete the interview***, the coupon manager should indicate in the participant's CMP record that their recruiter is not owed a reward. A project area'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 their recruiter is owed a reward. Participants who are not eligible, do not consent to the interview, or do not complete the interview **cannot** recruit others and should not be given coupons.
- ***If the participant completed the interview but did not agree to recruit others***, the coupon manager should indicate in the participant's CMP record that their recruiter is owed a reward.
- ***If the participant completed the interview and agreed to recruit others***, the

coupon manager should indicate in the participant's CMP record that their recruiter is owed a reward. Since the participant agreed to recruit others, the coupon manager should enter the participant's recruiter information into their CMP record:

- Step 1) The coupon manager should explain to the participant that they need to collect some additional information that will be used to identify the participant to pay their 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 they 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 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 them 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). To encourage candor, the coupon manager should remind the participant that the purpose of collecting physical marks is to ensure that only they can claim their rewards. The coupon manager should also examine the participant's face, neck, and arms for any other obvious physical marks, such as scars. 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 areas 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 project areas use this information to

help verify that the potential participant is not a previous participant.

Table 7.1 – Recruiter ID questions

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

Distributing coupons

If the participant agrees to recruit others, the coupon manager should give them coupons and reiterate that they will only receive rewards for the people they recruit who are selected and complete the interview. The coupon manager should also give the participant an information card with the project phone number and the hours and location(s) of the field site(s). Participants can call the project phone to see if they are owed any recruiter rewards. Please see [Appendix P](#) for a model information card and [Appendix R](#) for instructions on how to create the cards. Project areas should also keep track of the coupons given out using the CMP Log ([Appendix I](#)).



Some participants may know and have recently seen fewer PWID than the number of coupons being distributed. For example, a participant may report that in the past 30 days they have only seen 2 PWID they know, but the project area is giving 3 coupons to recruiters in their age group. 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 reiterate that the participant will only receive rewards for the PWID they recruit who are selected and complete the interview. The coupon manager should also verify that the participant understands how to use their coupons to recruit other PWID for the project. For example, the coupon manager could 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 they know and **not** to strangers. Lastly, the coupon manager should remind the participant of any coupon activation or expiration dates.

Table 7.2 – Collecting and recording physical marks

The coupon manager should explain to the participant why it is important to collect their 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 birthmarks. Like the ID we just created, this information will prevent someone else from claiming your money.”

Project areas 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 their body that are not readily visible. However, the coupon manager should only examine and note physical marks that are in areas of the body that are not considered “private.” For example, it would be appropriate to view a tattoo on a female participant’s ankle, but not on her breast. A simple rule of thumb is that if an area is not visible when the participant is wearing a bathing suit, it should **not** be viewed.

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

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

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

Giving out incentives

The coupon manager (or field supervisor) should then pay the participant the incentive for completing the interview and if applicable, the incentives for receiving the HIV and other tests.



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

Participants do not have to agree to recruit others to obtain their incentives. Those who recruit will be paid separately for that (see [Section 8.4](#) of this manual). To reduce the likelihood that participants provide a kickback to the person who recruited them, project areas could tell participants that the incentives are all theirs and that participants are not responsible for paying their recruiters. Project areas should emphasize that the project is responsible for paying a participant's recruiter. For example, project areas 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. Project areas should also develop their own accounting system for tracking incentive payments, and they should describe this system in the Operations Checklist ([Appendix A](#)).

The *NHBS Round 7 Model Surveillance Protocol* recommends an incentive of \$25 for participants who just complete the interview and \$50 for those who complete the interview and take an HIV test. Nevertheless, project areas are free to adjust these amounts based on the local standards in their communities. These local standards, along with findings from formative assessment, should also be used to determine the type of incentive provided, such as cash, bank cards, or electronic payments. Project areas must ensure that the type of incentive provided has an intrinsic value to PWID in their locality (e.g., if store gift cards are used as incentives, they should only be from stores that are locally accessible and well regarded by PWID).

When a potential participant is found to be ineligible, project areas may wish to provide a small thank you gift, such as a transportation pass or a gift card for coffee or gas. Furthermore, project areas that are conducting laboratory-based testing and have local funds available (i.e., funds that do not come from the NHBS cooperative agreement) may compensate participants who obtain their final test results. Project areas should specify the amount of this compensation in their consent form, and they must obtain approval from their CDC project officer.



Any contact information collected to provide electronic payments should be

managed the same as that collected to provide appointment reminders (see [Sections 3.3b](#) and [4.6a](#) of this manual). In brief, contact information must be stored in a locked file cabinet or on a secure network drive, and it must be destroyed as soon as it is no longer needed. Moreover, since participants cannot be required to provide their contact information to receive incentives, project areas using an electronic payment system must also offer a form of remuneration that does not require a participant's contact information.

Providing materials on prevention and offering linkages to care and services

Providing participants with prevention materials and offering them linkages to care and services are important components of NHBS; they facilitate rapport with participants and engender trust with the local community. Project areas should provide participants with prevention materials, such as informational pamphlets on safe drug injection practices, pre-exposure prophylaxis (PrEP), and HIV, hepatitis, and STI prevention; as well as provide them with harm reduction supplies, hygiene kits, condoms, and lubricants.

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

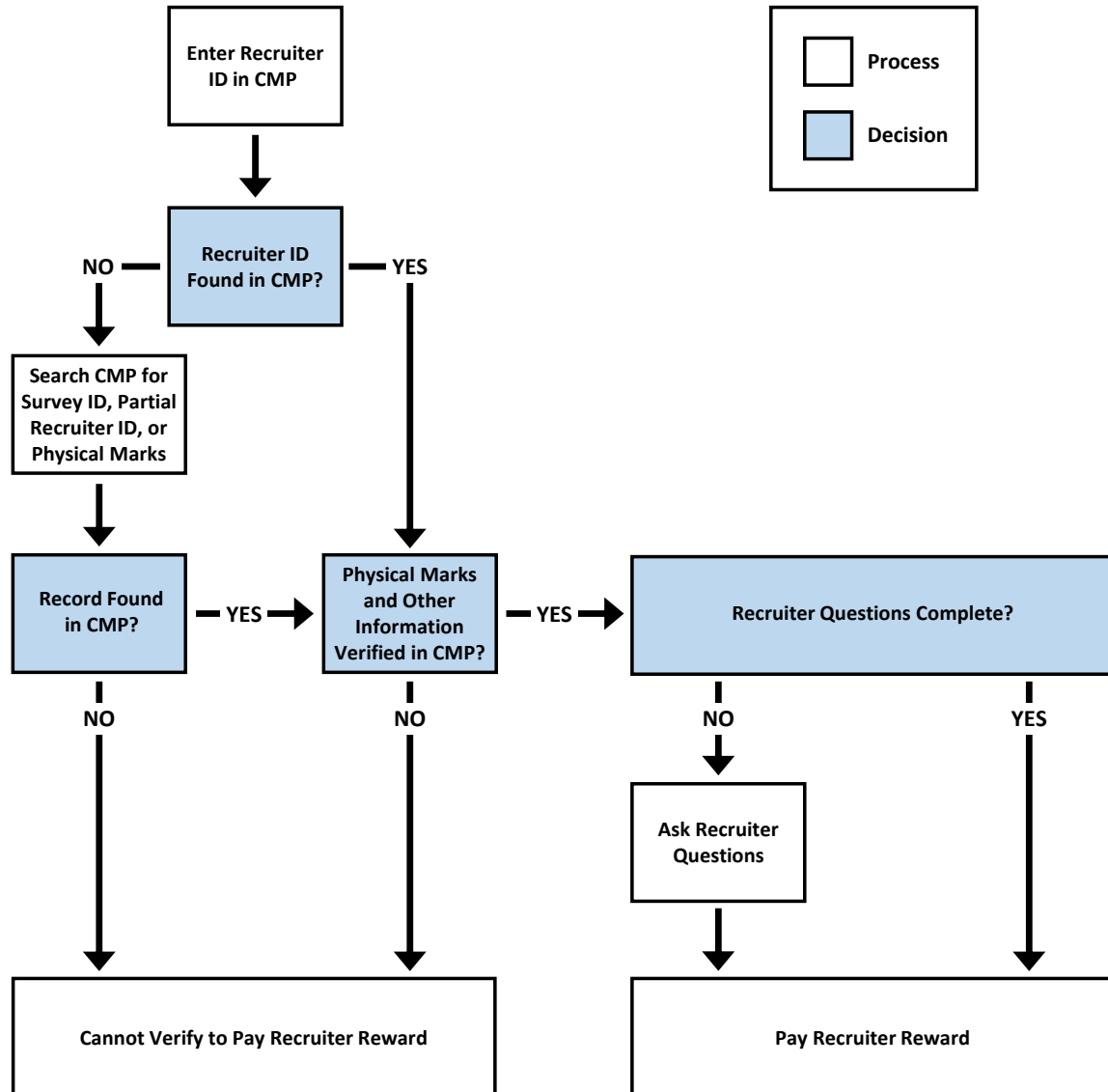
8.1 Chapter Overview

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 each unique participant, records their responses to the *Recruiter Questions*, and determines if they are owed recruiter rewards.

8.1a Chapter outline

- NHBS participants receive recruiter rewards for the people they recruit who complete the interview.
- The process for asking the *Recruiter Questions* and paying recruiter rewards is shown in **Figure 8.1** and includes the following steps (**Sections 8.2, 8.3, and 8.4**):
 - The coupon manager asks a series of questions to re-create the Recruiter ID documented during the participant's initial visit.
 - The Recruiter ID is entered into the CMP.
 - The CMP automatically locates the participant's record.
 - The coupon manager verifies the participant's identity by reviewing the physical marks listed in their record.
 - The coupon manager also checks whether the participant's appearance is consistent with the year of birth, gender, and race/ethnicity indicated by their recruiter ID.
 - The coupon manager asks the *Recruiter Questions* to measure non-response bias and records responses in the CMP.
 - If the CMP indicates that recruiter rewards are owed to the participant, the rewards can be paid.
 - The coupon manager updates the CMP record when rewards are paid.
- If the coupon manager is unable to locate the recruiter ID in the CMP, they should follow these steps (**Section 8.2a**):
 - First try to re-create the recruiter ID by asking the questions again.
 - If the recruiter ID is still not located, search for the participant's coupon number (survey ID) or a partial recruiter ID that contains information the participant is most likely to remember, such as their month and year of birth, gender, and race/ethnicity.
 - Search the CMP for the participant's physical marks.
 - If a recruiter ID or coupon number cannot be located or the person's physical marks or demographic characteristics do not match those listed in the record, the coupon manager should tell the person that there is not enough information to verify their identity, and as a result, they cannot be paid.

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 their record. The coupon manager should also check whether the participant's appearance is consistent with the year of birth, gender, and race/ethnicity indicated by their 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 they provided when their 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 often helps with recall. If the record still cannot be located, the coupon manager should search the CMP for the participant's coupon number (survey ID) or a partial recruiter ID that contains information the participant is most likely to remember, such as their month and 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 coupon number, 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 their 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 ID or coupon number 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 their identity, and as a result, they 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 they have.

Table 8.1 – Recruiter Questions

How many of the coupons did you give out?
Has anyone refused the coupons?
If anyone refused the coupons they were offered, the following questions are asked:
Of those who refused coupons, how many were male?
Of those who refused coupons, how many were female?
What is the race or ethnic background of those who refused coupons? That is, how many were American Indian or Alaska Native, Asian, Black or African-American, Hispanic or Latino, Native Hawaiian or Pacific Islander, or White?
Which of the following are reasons that people who refused gave you about why they did not take a coupon? (<i>Read each one, check all that apply</i>) • 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 someone who injects drugs • 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 contacts the project to collect their recruiter rewards or see if they are owed any rewards. When asking the *Recruiter Questions* a subsequent time, the coupon manager should explain that they may be repeating questions they asked before. The coupon manager can help the participant remember their previous responses by telling them what has already been recorded in the CMP. For example, the first time a participant answers the *Recruiter Questions*, they state that they gave out 2 coupons and 1 person refused a coupon. When they return 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 participants have given out all their 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.



Project areas may use reloadable gift cards to pay rewards to participants when their recruits complete the survey. However, rather than paying the rewards automatically, areas should ask participants to first contact the project to find out whether they are owed any rewards. This will give the coupon manager the opportunity to ask the *Recruiter Questions*.

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 their CMP record.

Project areas should consider the following when paying recruiter rewards:

- When participants contact the project to find out whether they are owed rewards, they can identify themselves by their recruiter ID or their coupon number.
- Reward payments can only be made directly to participants; they cannot be made to third parties, like friends or relatives.
- Rewards should be stored in a locked file cabinet or drawer for safety.
- Participants cannot receive replacement coupons for ineligible recruits or for lost or stolen coupons.
- Some local IRBs may require that participants still receive rewards when their recruits are unable to complete the survey or choose to end the interview early.

9.1 Chapter Overview

This chapter provides guidance on conducting HIV and other tests as part of NHBS. The purpose of this testing is to determine the prevalence of HIV and other related infections among NHBS participants and to describe behavioral risk factors associated with these infections. Before data collection can begin, project areas must use the Operations Checklist ([Appendix A](#)) to document procedures for testing, returning results, and making linkages to care. Any locally-developed testing forms or logs (e.g., lab slips and risk assessment forms) should be included in the Operations Checklist as well. Project areas are also responsible for following local laws, requirements, and guidelines for testing and counseling.

Project areas 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, processing, storage, transport, and shipping to ensure good specimen quality and the timely return of test results. Project areas 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. Project areas will need this information for entering HIV test results into the HIV Test Results Log on the NHBS Data Coordinating Center (DCC) data portal. Guidance on processing dried blood spots (DBS) specimens and shipping them to the CDC laboratory is included in [Sections 9.6a](#) and [9.7a](#) below.

9.1a Chapter outline

- Anonymity and Consent ([Section 9.2](#))
 - All rapid and laboratory-based testing specimens must be tested and stored anonymously.
 - Participants cannot be required to provide contact information or any personally identifiable information (PII) to perform testing, receive test results, or provide linkage to care.
 - Consent for HIV and other testing must be recorded in the NHBS Interview in CDC's Secure Access Management Services (SAMS) before specimens can be collected.
 - Participants who initially decline HIV testing at the beginning of the core questionnaire will have another opportunity to consent at the end of it.
- Testing ([Sections 9.3](#) and [9.3a](#))
 - Project areas are required to offer NHBS participants blood-based rapid HIV testing and any additional testing supported by CDC funds.
 - Project areas should obtain a CLIA waiver to perform the selected rapid HIV tests

in the field.

- Staff should not ask participants about HIV status prior to the interview. If participants disclose HIV status, it must be recorded in the NHBS Interview in SAMS, and HIV testing should still be offered to verify their reported status.
- Follow-up confirmatory testing must be conducted for 1) participants who did not self-report being HIV-positive during the interview but have an initial reactive rapid HIV test, and 2) participants who did self-report being HIV-positive during the interview but have an initial non-reactive rapid HIV test.
- Staffing and Training ([Section 9.4](#))
 - Project areas are responsible for hiring, training, and certifying project staff in testing and counseling for HIV and any other testing offered.
 - Project areas conducting venipuncture are required to have a certified phlebotomist.
- Specimen Collection ([Section 9.5](#))
 - Specimens must be collected during the same encounter as the NHBS interview.
 - Blood specimens should be collected via fingerstick or venipuncture according to rapid test instructions and local policy.
 - Project areas collecting blood specimens via venipuncture must use the appropriate blood collection tubes indicated by their local laboratory.
 - DBS must be collected from all HIV-positive participants; this includes participants who self-reported being HIV-positive in the interview or those who have at least 1 reactive rapid HIV test.
 - DBS should be collected at the time of the first rapid HIV test for participants who self-reported being HIV-positive and at the time of the follow-up HIV test for those who did not self-report being HIV-positive.
- Specimen Processing and Storage ([Sections 9.6a](#) and [9.6b](#))
 - DBS cards should be dry or close to dry before packaging, and they should be packaged within 24 hours of collection.
 - If applicable, blood specimens should be transported to the local laboratory and processed within 24 to 48 hours of specimen collection.
- Specimen Transport ([Sections 9.7a](#) and [9.7b](#))
 - Unless otherwise requested, only DBS cards from HIV-positive participants who consented to storage should be shipped to the CDC laboratory.
 - DBS cards should be shipped to the CDC laboratory on a weekly basis, and no more than 10 days after they are collected.
- Returning HIV Test Results ([Section 9.8](#))
 - HIV counseling, the return of rapid HIV test results, and linkage to care should occur after the interview is completed.
 - Project areas conducting laboratory-based testing to confirm infection can give

participants their results in person or, if permitted locally, over the phone (refer to [Appendix N](#) for guidance on returning laboratory-based test results).

- Linkage to Care and Services ([Section 9.9](#))
 - Project areas must make an effort to enroll participants in needed care or services.
 - NHBS staff can assist participants with scheduling medical appointments or completing paperwork or making calls for referrals.
 - All linkage to care must be made anonymously and must be voluntary.
- Data Management ([Section 9.10](#))
 - While in the field, project areas must enter HIV test results and other testing and specimen collection information into the NHBS Field Testing Form in SAMS.
 - Data collected in the NHBS Field Testing Form in SAMS will populate into the DCC data portal each night.
 - Project areas must enter DBS packaging and shipping information into the HIV Test Log on the DCC data portal.
 - Project areas conducting laboratory-based, follow-up testing should enter test results into the HIV Test Log on the DCC data portal daily, once results are available.
 - Project areas conducting hepatitis testing using supplemental NHBS funds must submit their test results to CDC and follow CDC data management procedures. Project areas using local funds for other testing are not required to submit those test results to CDC.

9.2 Anonymity and Consent

In NHBS, all rapid and laboratory-based testing specimens must be tested and stored anonymously. Therefore, 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. Project areas may obtain local approval to offer an option for participants to provide contact information to set up an appointment to participate, to receive results from local laboratory testing performed after their visit, or to facilitate linkage to HIV care and other services. Nevertheless, project areas **cannot** require participants to provide contact information or any other PII to participate in NHBS, undergo testing, receive their test results, or be linked to care. Prior to the start of data collection, project areas must develop procedures for making linkages to care for participants who are newly diagnosed with HIV or any other conditions for which they received testing. Lastly, because test results data in NHBS are anonymous, NHBS test results cannot be used for HIV or other infectious disease case reporting or for any other surveillance system.

Information about NHBS methods, including the interview and testing, is provided to individuals during the consent process (see [Section 7.4b](#) of this manual). Consent for each test must be obtained separately, and unless the test is conducted for local use only,

consent must be recorded in the NHBS Interview in SAMS. If consent is not recorded in the NHBS Interview in SAMS for a test that was conducted, the test result will not be included in any NHBS analyses of that infection.

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 7 Interviewer Guide* for further information). This will give the participant a second chance to consent to HIV testing if they changed their mind during the interview. 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 they want an HIV test after the core questionnaire has been completed, project areas may still perform the test, but it will not be considered an NHBS test. Thus, the HIV test result will not be used in national analyses or reports, and the participant should not receive an incentive for the test.



Project staff are not able to change the consent variable in the Data Error Log on the DCC data portal. Consent for HIV and other testing can only be recorded in the NHBS Interview in SAMS.

9.3 Testing

In all project areas, individuals who agree to participate in NHBS must be offered HIV testing. If funds are available, project areas may also offer other testing, such as viral hepatitis or STI testing. Agreeing to testing is voluntary; those who choose to participate in NHBS are not required to provide a specimen for testing.

The following requirements must be performed as part of NHBS HIV testing activities:

- Offer blood-based rapid HIV testing to all participants at the time of visit.
- Conduct a rapid-rapid algorithm (preferred) or perform one rapid test with laboratory-based follow-up testing to confirm infection.
- Offer any other testing funded by CDC.
- Collect DBS for the CDC laboratory from all NHBS participants who self-report previously testing positive for HIV or who have at least one rapid test that is reactive, and consent to storage for future testing.
- Provide linkages to additional follow-up testing, prevention services, and HIV care, as needed.

9.3a HIV testing

Because NHBS participants must be offered HIV testing, all NHBS data collection **must**

be suspended if HIV test kits or specimen collection devices are not available. CDC guidance for conducting HIV testing in nonclinical settings recommends HIV testing with blood specimens. HIV testing with blood specimens is more sensitive to early infection than testing with oral fluids. In addition, this guidance also recommends conducting follow-up testing of all initial rapid test results that are reactive to confirm infection. Guidance for conducting HIV testing in nonclinical settings is provided on the CDC website: [HIV Testing in Nonclinical Settings | HIV Testing | HIV/AIDS | CDC](#).

Based on this guidance and experience from prior NHBS cycles, CDC established standards for HIV testing for NHBS that require project areas to:

- Conduct HIV testing with blood-based specimens (e.g., via fingerstick, DBS). HIV testing using oral fluid specimens should only be used in rare circumstances when a blood specimen cannot be obtained from a participant.
- Use a rapid HIV test to screen for HIV infection to facilitate returning the test result to the participant. Laboratory-based tests take up to two weeks to receive the result, and project areas have to manage returning results to the participant. Some participants are not available to receive their laboratory result at this later date.
- Conduct follow-up testing to supplement an initial screening with a single rapid test that is reactive. Project areas may use a second rapid HIV test in accordance with a rapid-rapid HIV testing algorithm or they may opt to use laboratory-based tests to confirm infection. Project areas may conduct a laboratory-based test as the initial HIV screening test in rare circumstances when rapid HIV tests cannot be conducted.
- Collect DBS from participants who self-report previously testing positive for HIV or who have at least one rapid test that is reactive during NHBS HIV testing. Results of CDC testing on DBS cannot be returned to participants, but they can be used to update the variable indicating HIV infection used in NHBS analyses.



Staff should not ask participants about their HIV status prior to the interview. If participants disclose that they have previously been diagnosed with HIV, they should still be offered an HIV test to verify their reported status. ***Moreover, regardless of a participant's self-reported HIV status or when their HIV test specimen was collected, the return of HIV test results and HIV counseling must be conducted after the core questionnaire is completed so that it does not bias the participant's interview responses.***

Before data collection begins, all project areas must plan and practice their testing processes. Project areas must also review their testing methods with their CDC project officer and obtain their CDC project officer's approval.

Rapid HIV testing

Project areas must 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 single reactive rapid test result is considered preliminary, participants with preliminary positive test results should be immediately linked to care (see [Section 9.9](#) below).

To perform rapid testing, a project area must first obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver: [How to obtain a CLIA Certificate of Waiver \(cms.gov\)](#). Alternatively, project areas may operate under an existing waiver already held by their organization. While operating under a CLIA certificate of waiver, the project areas must follow the instructions in the package insert of the CLIA-waived rapid tests to avoid losing this waiver. Any deviation is off-label use. Currently, all CLIA-waived rapid HIV tests approved for use on blood specimens require that specimens be collected and tests performed by a trained staff member.

Table 9.1 lists the 7 rapid tests that are currently CLIA-waived for use in field settings by non-laboratory staff. The package insert for each of these rapid tests contains specific instructions for conducting that test, as well as instructions for running test controls. The insert outlines 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 an adequate workspace. Project areas conducting rapid testing on whole blood specimens collected by fingerstick can find some helpful hints for fingerstick blood collection in [Section 9.5a](#) (below).



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

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. Ideally, project areas should run rapid tests in an area that is separate from the participant's interview space. Nevertheless, if project areas must run the test in the same space as the interview, they **cannot** collect a specimen and run the test until after 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**.



HIV counseling and testing should be conducted in a private area to maintain the participant's confidentiality and to avoid identifying those who are receiving

follow-up testing to confirm infection.

Table 9.1 – Read times for CLIA-waived rapid tests

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

Project areas should consider the timing of the specimen collection with the interview and other field site logistics to minimize how long the participant has to wait for their test results after completing the NHBS interview ([Table 9.1](#) lists the read times for the current CLIA-waived rapid tests). Project areas should discuss logistical considerations with their CDC project officer before choosing rapid tests to use in the algorithm.

Although follow-up testing is required to confirm infection among participants who were not previously diagnosed, all participants with at least one rapid test that is reactive should be linked to a clinical provider for care. [Sections 9.8](#) and [9.9](#) provide more information about returning test results and linking participants to care.

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 that are CLIA-waived allow 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 areas should conduct quality assurance monitoring, including the running of controls, to identify any potential problems with rapid HIV testing. Project areas should maintain logs to monitor the following activities:

- 1) Testing records for individual test results, follow-up testing, and if applicable, follow-up appointments. The NHBS HIV Testing Log (Appendix J of the *NHBS Round 7 Model Surveillance Protocol*) can be used for this purpose.

- 2) Scheduled supervisor observed counseling and testing sessions to ensure that the HIV test counselor conducts the entire testing process correctly according to protocol instructions. The HIV Counseling and Testing Evaluation Form ([Appendix F](#)) can be used to document staff performance.
- 3) External test control results recorded with each new test kit lot or other additional intervals determined by local protocols and the test package insert. It is important for project staff to run external rapid test controls 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 project area 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 areas 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 J](#)). Guidance on rapid testing and rapid testing quality assurance can be found at [Waived Tests | CDC](#), and as mentioned above, guidance on HIV testing in non-clinical settings can be found at [HIV Testing in Nonclinical Settings | HIV Testing | HIV/AIDS | CDC](#).

Follow-up HIV testing

CDC requires project areas to conduct follow-up testing to confirm an initial **reactive** rapid test result (i.e., confirmatory testing), which may include using:

- a second rapid test that employs a sufficiently different infection detection method (i.e., rapid-rapid algorithm using two orthogonal tests), or
- a local public health or commercial laboratory to conduct testing with a blood-based specimen (e.g., DBS or whole blood). These laboratories must be CLIA-certified or CLIA-exempt.

If a participant reports during the NHBS interview that they previously had an HIV-positive test result (i.e., were previously diagnosed with HIV infection), they only need the first rapid test to be **reactive** to confirm their infection. However, if their first rapid test is **non-reactive**, one of the above options should be used to confirm infection. For example, a second rapid test, which uses a different type of detection method than the first rapid test, should be used to confirm infection. Collecting a specimen for follow-up testing is important since only the confirmed HIV test result will be used in key NHBS analyses and reports.

Project areas should verify whether their planned methods to follow-up on reactive HIV screening tests meet any local policies that require confirming infections detected using rapid screening tests.

Refusal to provide a specimen for follow-up testing

As noted above, it is very important for project areas to collect a specimen for follow-up testing when necessary. Accordingly, if a participant refuses to provide a specimen for follow-up testing, project staff should probe to determine why the participant has refused. They should then attempt to address the participant's concerns and encourage the participant to provide a specimen for follow-up testing, and if the participant consented to storage, to provide DBS as well. If allowed by their local Institutional Review Boards (IRBs), project areas could also try to motivate participants to provide specimens for follow-up testing by informing them that the testing incentive will only be given for completing the NHBS testing process, which includes follow-up testing when necessary. Participants who refuse to provide a specimen for follow-up testing but consented to storage might be willing to provide DBS instead. This approach could be especially helpful for those project areas collecting specimens for follow-up testing with phlebotomy, which some participants may be reluctant to undergo. The DBS collected would then be tested for HIV at the CDC laboratory to be included in the NHBS dataset, but the results would not be returned to the participant. Lastly, participants should be reminded that they can provide a specimen for follow-up testing without having to receive the result (see refusal to receive a rapid test result in [Section 9.8](#) below).

Rapid-rapid algorithm

The preferred method for follow-up testing after an initial reactive rapid test is the “rapid-rapid algorithm.” The rapid-rapid algorithm refers to an algorithm that uses results from two different HIV rapid tests to screen and confirm HIV infection. Project areas using the rapid-rapid algorithm may use any two rapid tests that employ different methods of detection (i.e., orthogonal tests). At present, the only two tests that are not sufficiently different to be used together in the algorithm are the Chembio SURE CHECK and the Chembio STAT-PAK.

With the rapid-rapid algorithm, project areas screen participants with one rapid test and then follow up any reactive test results with a second rapid test. A reactive second test confirms the first reactive result and therefore would not require further testing. A non-reactive second test would require referral to an agency for follow-up testing. If a participant reports during the NHBS interview that they previously had an HIV-positive test result (i.e., were previously diagnosed with HIV infection), they only need the first rapid test to be **reactive** to confirm their infection. However, if their first rapid test is **non-reactive**, a second orthogonal rapid test should be used to confirm infection. If a rapid test result is invalid, project areas should follow the procedures described in the rapid test package insert, which is usually to rerun the test.

Ideally, the first rapid test used in the algorithm would be the most sensitive one,

meaning the test that detects HIV earliest in infection (please refer to the rapid test's package insert for the time from HIV infection to test detection [the window period]). That being said, project areas can also consider how the methods of the various tests would impact field operations. It may be most efficient to choose a rapid test with a shorter read time for the second test to minimize how long the participant has to wait for their test results ([Table 9.1](#) lists the read times for the current CLIA-waived HIV rapid tests). When deciding which rapid tests to use, project areas should discuss these logistical considerations with their CDC project officer before choosing which rapid tests to use in the algorithm.

9.3b Hepatitis testing

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

If project areas wish to conduct hepatitis testing, they may use local funds or unobligated NHBS funds for the collection, processing, and testing of specimens. Project areas using local or unobligated NHBS funds must send their CDC project officer a written description of their proposed plans for testing, returning test results, and making linkages to care, and they must obtain CDC approval before specimen collection can begin. If a project area receives supplemental NHBS funds to conduct viral hepatitis testing, they can only use these funds to conduct the viral hepatitis testing specified by CDC, and they must also follow the guidance on viral hepatitis testing methods provided by CDC in the *NHBS-PWID2024 Operations Manual—Hepatitis Testing Supplement*. [Appendix S](#) provides further guidance on testing for HBV and HCV, as well as information on interpreting test results.

9.3c STI testing

Project areas may offer testing for STIs, such as gonorrhea and chlamydia, to determine the prevalence of these infections among NHBS participants and to describe behavioral risk factors associated with them. Specimens collected for gonorrhea and chlamydia testing can be obtained from 1 or more anatomic sites (e.g., oropharynx, urethra, vagina, or rectum).

If project areas wish to conduct STI testing, they may use local funds or unobligated NHBS funds for the collection, processing, and testing of STI specimens. Project areas using local or unobligated NHBS funds must send their CDC project officer a written description of their proposed plans for testing, returning test results, and making linkages to care, and they must obtain CDC approval before specimen collection can begin. Justifications for STI testing plans in NHBS must take into account disease prevalence in

the population, testing acceptability by participants, and the feasibility of testing as part of NHBS operations.



During NHBS-PWID cycles, consent for STI testing cannot be recorded in the NHBS Interview in SAMS. As a result, project areas conducting STI testing should document consent on a hard copy of the consent form.

9.3d Future testing

Project areas should ask participants to store their HIV and, if applicable, hepatitis specimens at CDC for future testing. **Test results from any future CDC testing cannot be returned to participants.** Project areas may also store specimens locally for future testing. If they choose to do so, they should contact their local laboratory for instructions on processing and shipping the specimens. The NHBS Interview in SAMS will automatically ask participants to consent to storage of their “test sample(s)” if they consent to HIV or hepatitis testing.



Consent for specimen storage must be documented in the NHBS Interview in SAMS 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 areas can use the following talking points:

- *An example of a test that may be performed is [testing for recent HIV infection, testing for HIV viral load, testing for the presence of antiretroviral drugs for treatment or pre-exposure prophylaxis (PrEP), testing for antiretroviral drug resistance, or if applicable, any other tests planned locally].*
- *The tests that may be performed on your stored test sample are for project purposes only and the results will not be returned to you.*
- *Your stored test sample will not be used for cloning.*
- *No information that identifies you will be linked to your test sample; the laboratory staff performing the tests will not know that the sample is from you.*

9.4 Staffing and Training

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

Project areas that choose to collect blood by venipuncture are required to have a

phlebotomist on staff since any person who collects blood via venipuncture must be certified in phlebotomy. Project areas should check their local policies to determine how many hours of phlebotomy training are required for certification. Most states do not have specific phlebotomy regulations. Instead, regulations are developed by the organization overseeing the blood collection (e.g., health department, clinic, or hospital). Project areas 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 areas 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: [Bloodborne Pathogens - Overview | Occupational Safety and Health Administration \(osha.gov\)](https://www.osha-slc.gov/bloodborne-pathogens-overview-occupational-safety-and-health-administration). Project areas are responsible for training their staff on these standards, and may be able to get training support from health departments, hospitals, and community-based organizations that perform HIV testing.

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

The project coordinator should provide overall management of NHBS testing activities and serve as the primary point of contact for CDC. The project coordinator should work with the field supervisor to determine the most feasible means of testing. Project areas 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, project areas should identify a point person in the laboratory to oversee the processing, testing, and storage of NHBS specimens.

9.5 Specimen Collection

Specimens for HIV tests can be collected with a fingerstick or venipuncture in accordance with the test package inserts and local policies.



All testing specimens must be collected from participants during the same

encounter as their interviews; specimens **cannot** be collected at a later date.

DBS from **all** HIV-positive participants who consent to specimen storage should be collected by trained project staff and sent to the CDC laboratory. For the purposes of DBS collection, HIV-positive participants are defined as those who self-report previously testing positive for HIV or who have at least one NHBS rapid HIV test that is reactive. 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 follow-up HIV test (e.g., the second rapid test or a laboratory-based confirmatory test).

9.5a Fingerstick specimens

Manufacturers of rapid tests, as well as health departments, hospitals, and community-based organizations that conduct 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 that will 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") their hand or squeeze and release a stress ball several times to increase blood circulation. Having the participant hold their hand below the level of their heart before performing the stick increases blood circulation as well.
- 3) Prior to the stick, clean the fingertip with a 70% isopropanol swab and allow it to air dry completely for a few seconds.
- 4) Using a sterile, disposable lancet, make the puncture just off the center of the finger pad at right angles to the ridges of the fingerprint so that the blood does not run down the ridges. Avoid the tip and center of the finger, as well as the edge of the nail bed and the side of the finger where there is less soft tissue. The participant's hand should be laid flat against a hard surface to ensure a deeper stick.
- 5) With a sterile gauze or cotton ball, wipe away the first drop of blood, which tends to contain excess tissue fluid. Allow a new drop of blood to form before collecting the blood specimen.

Dried blood spots from fingersticks

A reference guide for fingerstick blood collection for DBS can be found in [Appendix T](#). 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 U](#) for examples). Following the fingerstick blood collection process described in steps 1 through 5 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 near (but not directly on top of) where the first drop was in order to more completely fill the circle before moving to the next circle. Note that it is okay for the blood drop to absorb outside of the circle’s dotted line. Then, moving from 1 circle to the next, fill the remaining circles in the same way. Project areas should try to fill all the circles on the cards that will be sent to the CDC laboratory. Those project areas 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 or another type of rack for drying. If necessary, the racks can be placed in a cardboard box for transport from the field to the project office, but they should not be kept in a closed box because the cards may not dry. 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 U](#). Project areas using DBS for laboratory-based HIV testing should have trained project staff prepare 2 DBS cards: 1 for the local laboratory and 1 for the CDC laboratory. Project staff should begin the DBS collection process by recording the collection date and the participant’s DBS specimen ID number on the DBS card. If the local laboratory uses a separate laboratory ID, that ID should also be included on the card for the local laboratory. 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 areas, a 2-letter code indicating the project area must be added to the beginning of the survey ID to create the DBS specimen ID. The 2-letter codes that have been assigned to each project area are shown in [Table 9.2](#). For example, survey ID “2475” from Chicago would be labeled as “CH2475” on the DBS card.

Table 9.2 – 2-letter project area codes

Atlanta	AT	Los Angeles	LA	San Francisco	SF
Baltimore	MD	Newark	NJ	San Juan	PR
Chicago	CH	New Orleans	NO	Seattle	SE
Denver	CO	New York City	NY	Virginia Beach	VA
Detroit	MI	Philadelphia	PH	Washington, DC	DC
Houston	HO	Portland	PO		
Indianapolis	ID	San Diego	SD		

9.5b Venipuncture specimens

If project areas are collecting blood specimens via venipuncture, blood collection tubes appropriate for the type of testing that will be performed should be used. Project areas 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 an ID number should be recorded on the collection tubes before blood collection begins. If needed, staff should also document the linkage between the ID number used on the tube and the survey ID. 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.

Local policies and the specific rapid HIV tests used will dictate whether a project area can perform rapid HIV testing from venipuncture whole blood specimens in the field. Project areas should work with their local collaborators, such as the party holding their CLIA waiver, their laboratory partners, and the representatives of the test manufacturer, to confirm that their methods are acceptable for use in their local setting.

Dried blood spots from blood tubes

If local policy permits, project areas 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 near (but not directly on top of) where the first drop was in order to more completely fill the circle before moving to the next circle. Note that it is okay for the blood drop to absorb outside of the circle's dotted line. After the needed circles on the card have been filled, the card should be dried as described above in the "Dried blood spots from fingersticks" section. Project staff should try to fill all circles on the cards that will be sent to the CDC laboratory. Those project areas 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.

9.6 Specimen Processing and Storage

9.6a Fingerstick specimens

If project areas are collecting a fingerstick specimen for rapid testing, they should follow the instructions for specimen processing provided by the rapid test manufacturer.

Dried blood spots from fingersticks

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 project

area 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 areas 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 card in each bag on a **daily** basis and to replace the desiccant packs in a bag if the indicator card has changed 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.

9.6b 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.

Dried blood spots from blood tubes

Project areas making DBS from venipuncture specimens should follow the guidance described above in [Section 9.6a](#) for processing and storing DBS made from fingerstick specimens.

9.7 Specimen Shipping and Transport

9.7a Shipping DBS

Unlike liquid or frozen blood samples, DBS do not require special labeling or shipping. 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 areas. The DBS should not be frozen before shipping. It is important to check the humidity indicator cards in the bags immediately before shipping 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 shipping. 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

Unless otherwise requested, the only DBS cards that should be shipped to the CDC laboratory for future testing are those from participants who consented to storage and who are HIV-positive (i.e., self-reported previously testing positive for HIV or had at least one NHBS rapid HIV test that was reactive). DBS should not be transported to the local laboratory or frozen for storage before shipment to CDC.

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 Test Log on the DCC data portal and included in the envelope sent to the CDC. On the day project areas ship DBS to the CDC, they should use the Send Shipment Information function on the HIV Test Log on the DCC data portal to select the package(s) being sent and to enter the Date Shipped, the UPS or FedEx tracking number, and any other shipping-related information. By clicking “Save and Send Shipment Notification,” the data entered will be saved and an email will be autogenerated and sent to the NHBS lab email address (nhbslab@cdc.gov) notifying them of the shipment. Overnight shipping should be used, and the packages should be timed to arrive at CDC Monday through Thursday. Shipments should be sent to the attention of Wei Luo:

ATTN: Wei Luo
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Building 17, Room 3017
Atlanta, GA 30329
Phone: 404-639-0778

Project staff should develop a shipping schedule and record scheduled shipments on a monthly calendar. After arrival at the CDC, the DBS specimens will be stored in temperature-controlled CDC freezers until all testing is completed.

9.7b 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 areas 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.

9.8 Returning HIV Test Results

Project areas should provide HIV test results to all NHBS participants tested. Because only about 30% of participants obtained their laboratory-based test results during previous NHBS cycles, CDC prefers all project areas use the rapid-rapid algorithm so that participants with HIV can receive their final test result and can be linked to care at the time of their visit. Project areas should keep track of the provision of results to participants. After the NHBS interview is completed, project areas should provide counseling and return negative and preliminary positive test results to participants ([Table 9.3](#) provides possible counseling messages for some rapid testing scenarios common in NHBS). Participants should also be given one of the “subject information” pamphlets that come in each box of rapid tests. These pamphlets provide an explanation of the rapid test and test results.

As discussed in the *NHBS Round 7 Model Surveillance Protocol*, test counselors should target prevention messages to specific risks identified during the interview and counseling session. Project areas 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 use the Participant Tracking Form to 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 Surveillance Data (see the *NHBS Round 7 Model Surveillance Protocol*).

Refusal to receive a rapid test result

Although participants have the right to refuse receipt of their rapid test result, follow-up testing may be needed to confirm a rapid test result and include the final test result in key NHBS analyses. Depending on whether project areas are using the rapid-rapid algorithm or laboratory-based follow-up testing to confirm rapid test results, they should follow the guidance outlined below when a participant refuses to receive the result of their first rapid test:

For project areas using the rapid-rapid algorithm: If a participant states that they do not want to receive their rapid test result before they provide a specimen for rapid testing, the

Table 9.3 – Counseling messages for common HIV rapid test result scenarios

Self-reported HIV-Positive?	Result of 1st Rapid Test	Result of 2nd Rapid Test	Counseling Message
No	Reactive	Reactive	<i>“The result of your second test was also positive, which means you have HIV infection. I’d like to refer you to a health care provider who can do some additional testing and get you enrolled in medical care.”</i>
No	Reactive	Non-reactive	<i>“The result of your first test was positive, but the result of your second test was negative. Since these 2 tests gave us different results, we can’t be sure whether you have HIV infection. I’d like to refer you to a health care provider who can do some additional testing to determine if you have HIV infection and can get you enrolled in medical care if you do.”</i>
No	Reactive	Not done*	<i>“The result of your rapid test is positive, which means the test detected HIV antibodies, and it is very likely that you have HIV. I’d like to refer you to a health care provider who can do some additional testing and get you enrolled in medical care.”</i>
Yes	Non-reactive	Not done*	<i>“The result of your first rapid test result was negative. This result does not correspond with your self-reported status. If you are not already in care, I’d like to refer you to a health care provider who can do some additional testing and get you enrolled in medical care.”</i>

*Whenever possible, a second rapid test should be performed.

project area 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 their rapid test result after a specimen for the first rapid test has been collected,

project areas should request that the participant provide a specimen for the second rapid test so that their final test result can be linked to their interview data. DBS should also be collected from those who consented to specimen storage. If a participant refuses to provide a specimen for the second rapid test, project areas should refer to the recommendations in [Section 9.3a](#) above for those who refuse to provide a specimen for follow-up testing.

For project areas using laboratory-based follow-up testing to confirm infection: If a participant states that they do not want to receive their rapid test result before they provide a specimen for rapid testing, the project area could collect specimens for rapid testing, laboratory-based follow-up testing, and if applicable, DBS for storage and future testing. Alternatively, the project area could choose not to conduct a rapid test. Instead, they could collect a specimen for full laboratory-based testing and, if applicable, DBS for storage and future testing. Full laboratory-based testing includes both a screening HIV test and if needed, a follow-up test to confirm HIV infection. In situations where the participant declines receipt of their rapid test result after a specimen for rapid testing has been collected, project areas should request that the participant provide a specimen for laboratory-based follow-up testing so that their final test result can be linked to their interview data. DBS should also be collected from those who consented to specimen storage. If a participant refuses to provide a specimen for laboratory-based follow-up testing, project areas should refer to the recommendations in [Section 9.3a](#) above for those who refuse to provide a specimen for follow-up testing.

9.8a Returning laboratory-based test results

Project areas conducting laboratory-based follow-up testing to confirm infection can give participants their results in-person or, if permitted by local policies, over the phone. Project areas planning to provide laboratory-based test results to participants **must** refer to [Appendix N](#) for guidance on returning laboratory-based test results. Project areas should check with their local laboratory to find out the test turnaround time to properly inform the participant of when they should expect to receive their results. Project areas could try to increase the number of participants who receive their local laboratory-based test results by 1) offering participants the option to provide their phone numbers so that project staff can contact them when their test results are available; 2) scheduling appointments for participants to obtain their results in-person, and 3) if **local** funds are available, providing incentives to participants who obtain their results. Appointment Cards and Phone Results Cards found in [Appendix M](#) can be used to facilitate plans and make appointments for participants to receive their test results.

Note that project areas collecting participant phone numbers to return laboratory-based test results can only offer this as an option to participants; they **cannot** require participants to provide their phone numbers or any other contact information to obtain their test results. Project areas offering this option must also abide by the guidance on collecting contact information in [Sections 3.3b](#) and [4.6](#) of this manual and [Appendix N](#). This includes having a staff member other than an interviewer (e.g., field supervisor or

project coordinator) be responsible for collecting and managing participant phone numbers and using the phone numbers only for the purposes for which they were collected. Although participant phone numbers can be stored with survey IDs and laboratory IDs, **they cannot be stored with test results or any other NHBS data**. Phone numbers and test results must be stored separately, and then linked to one another by survey ID, laboratory ID, or a proxy ID. Furthermore, hard copies of forms containing participant phone numbers should always be stored and kept in a locked location under the supervision of the field supervisor or project coordinator, and electronic forms containing participant phone numbers should always be kept on a secure network drive. Forms containing participant phone numbers should only be accessed by a limited number of staff who are responsible for managing this information and returning results. Project areas returning results over the phone must also have a plan for two-step verification (e.g., ID number and security question and answer) to confirm that the person on the phone is the corresponding NHBS participant before returning results. Participant phone numbers must be destroyed once they are no longer needed for the purpose for which they were collected; for the return of laboratory-based test results, this means once the results have been returned to the participant, once staff have attempted to return results to the participant 3 times, or by 6 weeks after the end of data collection, whichever comes first.



As a reminder, results of CDC laboratory testing with DBS **cannot** be returned to participants.

9.9 Linkages to Care and Services

All linkages to care, support services, case management, or partner notification services must be made anonymously. Project areas must establish relationships with agencies that accept anonymous linkages before data collection can begin. The policy on anonymous linkages 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).

Linkage to care or services should involve more than simply telling a participant where to go to receive care or services. Project areas should make an effort to actually enroll the participant in the needed care or services. This effort is especially warranted when linking participants to HIV or other infectious disease care. Agencies providing HIV or other infectious disease care to which participants are linked would have to conduct their own tests to confirm a participant's diagnosis. Furthermore, these care and service agencies should not have access to any NHBS code numbers, such as survey or laboratory IDs, which could link participants to their NHBS data. The NHBS test results may not be used in name-based reporting of a new diagnosis to the state or local health department for HIV or other infectious disease surveillance or included in medical records. NHBS test results can only be used for NHBS analysis purposes and to identify participants who may need to be linked to care.

Project staff may provide direct assistance to participants during linkage to care. While helping participants with linkage to care, project staff (apart from interviewers) may view participant contact information, but they should not record or save the information with NHBS data in order to share it with a care or service agency. NHBS data, including NHBS test results, may never be shared with staff at a care or service agency.

To be successful at linking participants to care and other services, project areas should collaborate with local community-based organizations (CBOs) and clinics that provide common services and HIV care. Through these partnerships, project areas should develop a method of transferring participants to the care or service agency in a manner that 1) does not require project staff to store or maintain PII and 2) facilitates and simplifies the linkage process for the participant as much as possible.

The following are some examples that may be used when linking an NHBS participant to HIV care:

- Project staff could offer to help a participant schedule a medical appointment by connecting the participant with a contact at a clinic or an HIV case manager who, in turn, could collect the necessary information from the participant and make an appointment for HIV care and any other services needed.
- Project staff could help the participant complete a referral form that is sealed in an envelope before the participant leaves, and then mailed or delivered to a clinic by project staff.
- Project staff could help the participant complete an online referral form or schedule an appointment online, provided the participant's information is submitted before they leave. If an online system requires setting up a login account with a password, project staff **cannot** view or assist in creating the participant's password.

Project areas must develop a plan for linking HIV-positive participants to care and services. This plan should be described in the Operations Checklist. If the plan includes potentially viewing or obtaining participant contact information, the checklist should also include the type of contact information, the purpose of viewing or obtaining it, and the steps taken to ensure that it will not be saved by project staff or be accessible to them after the participant completes the testing session.

Project staff can offer to make linkages to care or services during counseling or during other project activities, such as check-out. Project staff must maintain the anonymity of NHBS data at all times and they should make this clear to participants. For standardization, project areas should develop a script to explain the linkage process and other options the participant might have available to them. A copy of the script should be included in the Operations Checklist and should contain the following points:

- Acceptance of a linkage to care or services is completely voluntary.

- Declining a linkage will not adversely affect any incentives the participant is entitled to receive.
- The care or service agency is totally separate from the local NHBS project.
- The care or service agency may collect the participant's name, but it will not be linked to NHBS data or shared with project staff. The individual's NHBS data and test results will remain anonymous.
- The local NHBS project will not give any of the participant's information to the care or service agency, and the care or service agency will not give any of the participant's information to the local NHBS project.
- *If applicable:* Participants can choose to share contact information with project staff who are helping them link to care or services, but the local NHBS project will not record or store the participant's information.

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



All participants with a reactive rapid test should be immediately linked to care or services. Project areas using laboratory-based follow-up testing to confirm infection should not wait until they receive final test results from the local laboratory before making linkages because participants rarely return for their laboratory-based test results.

9.10 Data Management

Procedures for managing testing data must adhere to NHBS guidance for privacy, anonymity, data security, and the protection of human subjects as described in the *NHBS Round 7 Model Surveillance Protocol* and required by local policies for the security and confidentiality of HIV, viral hepatitis, and STI surveillance data.

If project areas that are conducting laboratory-based testing to confirm HIV infection or to detect other infections (e.g., hepatitis, STIs) collect any participant contact information to return test results, they must destroy the contact information once it is no longer needed for returning results. This means destroying it once the results have been returned to the participant, once staff have attempted to return results to the participant 3 times, or by 6 weeks after the end of data collection, whichever comes first. More information about data management with respect to returning laboratory-based test results can be found in [Section 9.8](#) above and [Appendix N](#).

9.10a HIV testing

While in the field, project areas should enter HIV test results and other testing and specimen collection information into the NHBS Field Testing Form in SAMS. Information collected with the NHBS Interview in SAMS that is relevant to testing and specimen collection will auto-populate in real-time into the NHBS Field Testing Form in SAMS, including testing consents and whether the participant reported a previous HIV-positive test during the interview.

Project areas can still choose to record HIV test results and related information in a hard or electronic copy of the HIV Testing Log (see Appendix J of the *NHBS Round 7 Model Surveillance Protocol*) or the Participant Tracking Form. When in use, hard copies of the HIV Testing Log or other forms must be secured and in the possession of project staff at all times; otherwise, the forms and logs should be kept locked in a file cabinet or file box. Electronic copies of testing forms and logs should be stored on a secure network drive.

Each night, data collected with the NHBS applications in SAMS will upload into the DCC data portal. Subsequent to this, project areas should enter DBS packaging and shipping information in the HIV Test Log on the DCC data portal to prepare DBS for shipping. Project areas that are conducting follow-up laboratory-based HIV testing should enter those test results into the HIV Test Log on the DCC data portal on a **daily basis**. Once laboratory-based test results become available, it is important for project areas to enter them into the DCC data portal daily so that the process monitoring reports generated by the DCC are up-to-date and reflect each project area's latest data. Project areas should refer to the NHBS data management training materials for specific instructions on data entry and a listing of required variables. Up to four different types of laboratory-based HIV tests can be entered in the DCC data portal using the fields for Test 1, Test 2, Test 3, and Test 4. Project areas can use [Table 9.4](#) to ensure that the type of laboratory test performed is entered correctly according to the possible response options for these fields.

At the end of data collection, all HIV-positive and indeterminate test results should be validated against the hard or electronic copy of the HIV Testing Log and any laboratory reports. This can be accomplished by downloading the HIV Test Log on the DCC data portal to an Excel spreadsheet, sorting by "HIV Result Interpretation" to group the different results together, and then checking all the positive and indeterminate test results against the hard or electronic copy HIV Testing Log, as well as against any laboratory reports. Staff can also sort by "Results Fields Pending" to check that all laboratory results were entered. 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. Any necessary edits to rapid HIV test results should be made in the NHBS Field Testing Form in SAMS and will update nightly. Any necessary edits to laboratory results should be made in the HIV Test Log on the DCC data portal.

Table 9.4 – Trade names of laboratory-based HIV tests and the corresponding response options in the HIV Test Log on the DCC portal

Trade Name of Laboratory-based HIV Test	DCC Portal HIV Test Log Response Option
Abbott Architect HIV Ag/Ab Combo Assay ADVIA Centaur HIV Ag/Ab Combo (CHIV) BioPlex 2200 HIV Ag-Ab Bio-Rad GS HIV Combo Ag/Ab EIA Ortho VITROS HIV Combo Test Roche Elecsys HIV combi PT	Ag/Ab Combo Immunoassay
ADVIA Centaur HIV 1/O/2 Enhanced (EHIV) Bio-Rad GS HIV-1/2 Plus O Ortho VITROS ECi/ECiQ Anti-HIV 1 + 2 Reagent pack Avioq HIV-1 Microelisa System	Antibody Immunoassay
Chembio DPP HIV-1/2 Chembio SURE CHECK HIV 1/2 Assay 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 <i>Any viral load assay (e.g., Abbott m2000, Roche COBAS v2.0, Hologic HIV-1 RNA quant)</i>	Nucleic Acid Test
Bio-Rad Genetic Systems HIV-1 Western Blot Cambridge Biotech HIV-1 Serum Western Blot	Western Blot

9.10b Hepatitis testing

For project areas conducting hepatitis testing, data management requirements are similar to those for HIV testing. While in the field, project areas should enter any rapid HCV test results and other testing and specimen collection information in the NHBS Field Testing Form in SAMS. Project areas can choose to also record hepatitis specimen collection and testing information in a hard or electronic copy of the Hepatitis Testing Log (see Appendix K of the *NHBS Round 7 Model Surveillance Protocol*) or the Participant Tracking Form. When in use, hard copies of hepatitis testing forms and logs must be secured and in the possession of project staff at all times; otherwise, the forms and logs should be kept locked in a file cabinet or file box. Electronic copies of testing forms and logs should be stored on a secure network drive. Each night, data collected with the NHBS applications in SAMS will upload into the DCC data portal. Subsequent to this, project areas conducting laboratory-based hepatitis testing should enter their laboratory-based test results into the online Hepatitis Test Log on the DCC data portal on a **daily basis**. Once laboratory-based test results become available, it is important for project areas to enter them into the DCC data portal daily so that the process monitoring reports generated by the DCC are up-to-date and reflect each project area's latest data.

Project areas conducting hepatitis testing using local funds or unobligated NHBS funds are **not** required to submit test results to CDC. However, if these project areas wish, they may share hepatitis test results with CDC by recording rapid HCV test results and other specimen collection information in the NHBS Field Testing Form in SAMS while in the field and by entering laboratory-based test results into the online Hepatitis Test Log on the DCC data portal on a **daily basis**. At data closeout, the DCC will include the project area's hepatitis test results in their final NHBS dataset.

9.10c STI testing

During NHBS-PWID cycles, the NHBS Field Testing Form in SAMS and the online STI Test Log on the DCC data portal are not operational. As a result, project areas conducting STI testing in NHBS-PWID2024 cannot enter STI specimen collection or testing information into these online databases. Instead, project areas should record STI specimen collection and testing information in a hard or electronic copy of the STD Testing Log (Appendix L of the *NHBS Round 7 Model Protocol*), the Participant Tracking Form, or a locally-developed form or log. When in use, hard copies of STI testing forms and logs must be secured and in the possession of project staff at all times; otherwise, the forms and logs should be kept locked in a file cabinet or file box. Electronic copies of testing forms and logs should be stored on a secure network drive.



Because STI specimen collection and testing information is not sent to the DCC during NHBS-PWID cycles, the DCC cannot include a project area's STI test results in their final NHBS-PWID dataset.

10.1 Chapter Overview

Process monitoring and ongoing formative assessment enable project areas 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 past 12 months. The information project areas obtain through these monitoring and assessment methods will complement the information they gathered during their formative work at the start of the project cycle.

10.1a Chapter outline

- CDC has established the NHBS process goals to monitor and evaluate recruitment and enrollment. Because failure to meet these goals could jeopardize the external validity of NHBS data, achieving the goals is critical to the success of the project ([Section 10.2](#)).
- The NHBS Data Coordinating Center (DCC) produces process monitoring reports for project areas to assess recruitment and enrollment, coupon distribution, eligibility, sample characteristics, HIV and hepatitis testing, seeds, RDS methods, previous participants, and interviewer skills ([Section 10.3](#)).
 - [Sections 10.3a to 10.3i](#) describe the different process monitoring reports and the reasons for examining them.
 - The reports should be reviewed by project areas **weekly** and discussed with their CDC project officer at least **every two weeks**.
 - Project areas may create their own reports to monitor any issues of local interest.
- To address a problem identified in the process monitoring reports, CDC project officers may recommend ([Section 10.3](#)):
 - Adjusting operations.
 - Providing additional staff training.
 - Conducting ongoing formative assessment.
- Ongoing formative assessment is the collection and assessment of additional quantitative and qualitative data to evaluate and address operational problems that have been identified through process monitoring or reported by field staff ([Section 10.4](#)).
 - Project areas should begin ongoing formative assessment with the least labor-intensive and time-consuming methods (e.g., the review of existing data, observations, and informal conversations) and then, if these methods do not yield results, they should proceed to more labor-intensive and time-consuming methods (e.g., brief intercept surveys, key informant interviews, and focus groups).

- Formative assessment methods are described in detail in the *NHBS-PWID2024 Formative Assessment Manual*.
- **Table 10.1** provides some examples of operational problems and the methods that could be used to evaluate them.

10.2 NHBS Process Goals

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

- 90% 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.

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 areas should continuously monitor their recruitment and enrollment data. If their data do not meet the target goals, they 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 DCC will produce the process monitoring reports for project areas 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 areas weekly. They 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 CDC project officer may recommend that they address the problem by adjusting operations or by providing additional staff training. The CDC project officer may also recommend that they further evaluate the problem by conducting ongoing formative assessment. In addition, if project areas 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 V**.

10.3a Recruitment Monitoring Report

The *Recruitment Monitoring Report* (**Section V.1** of this manual) contains data from non-

seed participants and provides information on eligibility, enrollment, testing, and recruitment:

- The number of participants screened for NHBS-PWID eligibility.
- The number and proportion of participants screened who were eligible for NHBS-PWID.
- The number and proportion of eligible participants who completed an interview.
- The number and proportion of participants who completed an interview who consented to HIV testing.
- *If applicable*, the number and proportion of participants who completed an interview who consented to hepatitis testing.
- The number and proportion of participants who completed an interview who consented to specimen storage for future testing.
- The number and proportion of participants who completed an interview who were eligible to recruit others.

This report should be reviewed to identify problems such as low or declining enrollment; a low proportion of eligible participants; a low proportion of participants consenting to HIV testing, hepatitis testing, or specimen storage; and a low proportion of participants eligible to recruit others. Furthermore, project areas can use the report to track progress toward reaching the sample goal of 500 completed interviews among persons who injected drugs in the past 12 months.

10.3b Coupon Manager Program Report

The *Coupon Manager Program Report* ([Section V.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 areas 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 project areas 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 project area is using photo coupons, this table will allow them 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 areas track and manage coupon distribution, especially differential coupon distribution. It lists the number of coupons given to each type of recruiter (e.g., young PWID) and the date any changes were made to this number.

The four “coupon refusals” tables summarize the participants’ responses to the *Recruiter Questions* (Section 8.3 of the manual). 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 project 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 would then be warranted.

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 areas can use this information to determine whether any particular demographic subpopulations are more likely to decline participation in NHBS. The specific reasons why people decline participation are listed in the Reasons for Coupon Refusals table. The information in the “coupon refusals” tables will enable project areas to more effectively identify and address any participation barriers they experience.

10.3c Sample Characteristics – Screened Report

The *Sample Characteristics – Screened Report* (Section V.3 of this manual) shows the questionnaire version used to screen participants for NHBS-PWID eligibility, along with the demographic characteristics of those who were screened, stratified by whether they were eligible. The characteristics examined are:

- Age
- Gender Identity/Sex at Birth
- Race/Ethnicity
- MSA Resident
- Known Previous Participant

- Able to Participate (i.e., able to complete the interview in English or Spanish)
- Too Young to Participate
- Injection in the Past 12 Months
- Type of Drug Injected Most Often

Project areas should review this report to monitor the proportion of participants screened who were not eligible based on key demographic variables (age, gender identity/sex at birth, and race/ethnicity) and who were not eligible based on each eligibility criterion (age, MSA resident, known previous participant, able to participate, too young to participate, and injection drug use). Particular attention should be paid to the drug injection table. If the proportion of participants who injected drugs in the past 12 months is low, project areas may need to improve their recruiter training so that participants only recruit people who currently inject drugs. Moreover, project areas should always remain vigilant for potential participants who do not currently inject drugs. People who formerly injected drugs or those who never injected may claim to currently inject so that they can participate in NHBS and collect the incentives.



Because RDS relies on peer recruitment, schemes to fraudulently enroll in the project 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 V.4](#) of this manual) shows the demographic characteristics of participants who completed the interview. The characteristics listed are:

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

Project areas should review the tables in this report to monitor the demographic characteristics of participants who successfully completed an interview. The characteristics of these participants should reflect those of the local PWID population, as

described in the project area's formative assessment reports. Project areas should also ensure that there is adequate representation of those subpopulations of greatest importance to the local HIV epidemic, like young PWID.

10.3e Test Results Report

The *Test Results Report* ([Section V.5](#) of this manual) consists of six tables:

- HIV Rapid Test Result
- Self-reported HIV Test Result
- Specimen Collected for CDC Lab
- Hepatitis C Test Result
- Returned Hepatitis C Lab Results
- Hepatitis B Test Result

Using this report, project areas 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 Self-reported HIV Test Result table shows whether the participant self-reported being HIV-positive compared to their 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 Self-reported HIV 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 self-report being HIV-positive, but had a final HIV test result that was positive), along with the proportion of possible false-negative HIV test results (i.e., did self-report being HIV-positive, but did not have an HIV-positive test result).

The Specimen Collected for CDC Lab table tracks the shipment of dried blood spot (DBS) specimens to the CDC lab. Project areas can use this table to determine whether they sent CDC the proper DBS specimens, such as DBS from participants who are self-reported HIV-positive and those with positive or discordant HIV test results.

If hepatitis C test results were entered into the Hepatitis Test Results Log on the DCC data portal, they will appear in the Hepatitis C Test Result and Returned Hepatitis C Lab Results tables; and if hepatitis B test results were entered, they will appear in the Hepatitis B Test Result table. The data in these tables can be used to monitor hepatitis prevalence in participants. The Hepatitis C Test Result table also compares hepatitis C rapid test results to hepatitis C RNA test results. This information allows project areas 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. In addition,

project areas conducting hepatitis C RNA tests can utilize the Returned Hepatitis C Lab Results table to track the return and explanation of test results to participants. The Hepatitis B Test Result table not only provides the interpretation of the final hepatitis B test result based on the individual HBsAg, anti-HBs, and anti-HBc values, but it also shows whether the results were provided to participants so that project areas can monitor their success at returning test results.

All pending test results will be coded as “Unknown” in the tables, and project areas that do not conduct rapid HIV tests, hepatitis C tests, or hepatitis B tests will have those test results coded as “Not Done” or “Specimen Not Collected.”

10.3f Seed Report

The *Seed Report* ([Section V.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 areas assess the success of seed enrollment. The Seed Characteristics table indicates the sex at birth, gender identity, race/ethnicity, age, drug of choice, and network size for each seed, as well as whether the seed was eligible to recruit. If the *Sample Characteristics – Interviewed Report* shows underrepresentation of any subpopulations, project areas should review the Seed Characteristics table to determine whether this lack of sample diversity could be due to a lack of seed diversity. That being said, even if seeds are diverse, some subpopulations could be less effective recruiters than others. Since seeds with smaller social networks may have a lower likelihood of recruiting others for NHBS than do seeds with larger networks, project areas should examine the network size of each seed to determine whether seeds from underrepresented subpopulations have smaller social networks, and thus, may be less effective recruiters.

10.3g Respondent-Driven Sampling Report

The *Respondent-Driven Sampling (RDS) Report* ([Section V.7](#) of this manual) includes seven tables:

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

- Network Size by Field Site
- Recruitment Chains

Project areas should review the Recruitment by Stranger table to determine whether recruitment is occurring outside of personal networks (i.e., participants are being recruited by strangers). If participants are being recruited by strangers, project areas 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 they were recruited by a stranger. Interviewers should be able to help participants differentiate between recruitment by a stranger and recruitment by an acquaintance. A high level of recruitment by strangers may also indicate that a “recruitment scheme,” like selling coupons or receiving kickbacks from recruits, is occurring in the community.

The Field Site Enrollment table will show enrollment by field site for each day of the week. This table will not only allow project areas to track the pace of enrollment by field site and day of operation, but it will also help them identify incorrect field site IDs, which can occur when an interviewer enters the wrong ID at the beginning of the interview. Correct field site IDs are essential for ensuring the accuracy of the Cross Recruitment table (see below).

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

Ideally, field site locations should be accessible to all major subpopulations 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 subpopulations are not accessing a particular field site. This information can help project areas determine if ongoing formative assessment is needed to assess the field site for potential barriers to accessibility. Alternatively, if a field site was selected to reach a specific subpopulation, project areas can use these tables to monitor how successful the field site is at reaching that subpopulation.

If enrollment is not progressing overall or just not progressing at a particular field site, project areas can use the Network Size by Field Site table to examine whether the size of

the participants' social networks may be contributing to this problem. Individuals with smaller social networks have a lower likelihood of being recruited for NHBS than do those with larger networks. Accordingly, enrollment among participants with smaller social networks may not progress as well as it does among those with larger networks.

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 areas 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 project areas how well enrollment is progressing and the density of the chains (i.e., the number of recruits per recruitment wave) will indicate how effectively potential participants are being recruited.

10.3h Possible Previous Participant Report

To help project areas identify participants who may have been interviewed more than once, the *Possible Previous Participant Report* ([Section V.8](#) of this manual) contains a table listing participants who have the same date of birth, sex at birth, and race/ethnicity. This table just includes those participants who were not identified as previous participants during eligibility screening.

To help determine whether participants with the same date of birth, sex at birth, and race/ethnicity are the same person, project areas 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, project areas should analyze their interview data and examine participant characteristics that should not change over time (e.g., country of birth, age of sexual debut, age when first injected drugs) or characteristics that are not likely to change during the data collection period (e.g., educational level, zip code). When project areas 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 NHBS dataset.

10.3i Interviewer Report

The *Interviewer Report* ([Section V.9](#) of this manual) consists of the following tables:

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

Project areas should review the tables in this report to identify possible interviewer deficiencies or areas for improvement. These reports are intended to supplement the project areas' ongoing evaluation of their interviewers (see [Section 2.6](#) and [Appendix E](#) of this manual). Whenever interviewers perform below acceptable standards, project areas should provide them with any additional training needed and closely monitor their progress. If the interviewers fail to show improvement, project areas 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 screening for eligibility, providing informed consent, and administering the core questionnaire. Project areas should compare each interviewer's screening, consent, and core questionnaire 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 interview 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 those who are eligible fully understand NHBS procedures and the options for participation in the project. This problem could result in lower rates of enrollment, HIV or hepatitis testing, or specimen storage.

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 areas 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 individuals who do not inject drugs are providing false information so that they can enroll in the project.

The Testing Consent table shows the number and proportion of participants who completed an interview who consented to HIV testing, hepatitis testing, and specimen storage. This information is stratified by interviewer so project areas 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 hepatitis testing even though it is not offered by the project area. Interviewers making this error would need 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 areas 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 project areas 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 7 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 areas 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 brief intercept surveys, or discussing operational issues with key informants or focus groups. Project areas should refer to the *NHBS-PWID2024 Formative Assessment Manual* for additional information on ongoing formative assessment and for instructions on formative assessment methods.

When conducting ongoing formative assessment, project areas 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., brief intercept surveys, key informant interviews, and focus groups). Project areas should also assess whether an operational problem is associated with a particular demographic subpopulation, field site, or staff member. **Table 10.1** provides examples of some operational problems and the methods that could be used to evaluate them. Project areas should only use ongoing formative assessment to investigate operational problems that have been identified in NHBS-PWID2024. They should not use it to conduct sub-studies or to evaluate new research questions. Before starting ongoing formative assessment, project areas 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 areas should review the Coupon Tracking table in the <i>Coupon Manager Program Report</i> to determine how many coupons have been distributed and the number and proportion of coupons returned. The number of coupons distributed less the number returned equals the number of coupons currently in circulation in the community. A small number of coupons in circulation means there are few potential participants who can enroll in NHBS. A low proportion of coupons returned indicates a barrier to recruitment or participation, which should be further assessed using the “coupon refusals” tables in the <i>Coupon Manager Program Report</i>. To help project areas monitor the progress of recruitment and enrollment, they could examine the Recruitment Chains table in the <i>Respondent-Driven Sampling Report</i> or they could produce network diagrams of their recruitment data using RDS Analyst (RDS-A), yEd, or a similar program. Qualitative: Project areas should use observations, informal conversations with participants, or brief 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 participants are not eligible	Quantitative Project areas should review the <i>Sample Characteristics – Screened Report</i> to determine if there are any particular eligibility criteria that potential participants are failing or if certain demographic subpopulations are less likely to be eligible. Qualitative If a large proportion of participants are not eligible because they have not injected drugs within the past 12 months, project areas should observe recruiter training to ensure that staff are providing the necessary instruction. Project areas

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

Operational Problem	Potential Evaluation Methods
A large proportion of participants are not eligible (continued)	should also conduct exit interviews with participants to see if the participants know that they should only recruit people who currently inject drugs, even if they only inject once in a while. In addition, project areas should have informal conversations with participants or conduct observations, brief intercept surveys, or key informant interviews to find out if people in the community are falsely claiming to inject drugs so that they can participate in the project.
The demographic characteristics of participants do not match those of the local PWID population	Quantitative Project areas should review the <i>Sample Characteristics – Interviewed Report</i> to determine if the demographic characteristics of the people interviewed reflect the demographic characteristics of the local PWID population as described in the formative assessment reports and secondary data tables. If they do not, project areas should examine the <i>Sample Characteristics – Screened Report</i> to assess whether individuals from the underrepresented subpopulations are less likely to be eligible to participate in the project. Project areas may also be able to use the <i>Sample Characteristics – Screened Report</i> to identify the reason(s) why these individuals are not eligible. Project areas should check the “coupon refusals” tables in the <i>Coupon Manager Program Report</i> to find out if members of the underrepresented subpopulation are more likely to refuse coupons. They should also review the Seed Characteristics table in the <i>Seed Report</i> to assess whether a lack of sample diversity could be due to a lack of seed diversity. Project areas should use the RDS Analysis Tool (RDSAT) to examine any variables relevant to the underrepresented subpopulation (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 subpopulation are substantially less likely to be recruited by members of other subpopulations and they should check the recruitment count in the output to see if members of the underrepresented subpopulation are less effective recruiters (i.e., are less likely to recruit other participants).

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

Operational Problem	Potential Evaluation Methods
The demographic characteristics of participants do not match those of the local PWID population (continued)	Qualitative If members of the underrepresented subpopulation are less likely to be eligible, project areas should observe the recruiter training provided by staff and they should conduct exit interviews with participants from the underrepresented subpopulation to see if the participants understand who should be recruited. Project areas should also use brief intercept or key informant surveys to determine whether there are misperceptions in the community regarding the eligibility criteria. If members of the underrepresented subpopulation are more likely to refuse coupons or less likely to recruit others, project areas should have informal conversations with participants or community members from the underrepresented subpopulation to determine whether recruitment and participation are being hindered by such factors as the field site location or hours of operation, the incentive amount or type, safety or confidentiality concerns, or a poor reputation for the project. If members of the underrepresented subpopulation are substantially less likely to be recruited by members of other subpopulations, project areas should have informal conversations with participants or conduct brief intercept surveys, key informant interviews, or focus groups to see if members of the underrepresented subpopulation are less likely to mix socially with members of other subpopulations.
Stranger recruitment	Quantitative Project areas should review the Recruitment by Stranger table in the <i>Respondent-Driven Sampling Report</i> to check whether a high proportion of participants were recruited by a stranger. They could also analyze their survey data to determine if certain demographic subpopulations are more likely to recruit people who are strangers. Qualitative Project areas should observe the recruiter training provided

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

Operational Problem	Potential Evaluation Methods
Stranger recruitment (continued)	by the 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 they were recruited by a stranger. Project areas 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 kickbacks from recruits.

11.1 Chapter Overview

The purpose of this chapter is to briefly describe NHBS data submission and management procedures. Project areas will submit their data through CDC's Secure Access Management Services (SAMS) using the following online applications: 1) the NHBS Interview, 2) the NHBS Field Testing Form, and 3) the NHBS Data Coordinating Center (DCC) data portal, which includes the Coupon Manager Program (CMP), the HIV Test Log, the Hepatitis Test Log, and the Data Error Log. Specific instructions on submitting and managing data can be found in the NHBS-PWID2024 Data Management Learning Tree. The data management staff from each project area are required to review all these materials prior to the start of data collection. If needed, the DCC can also provide project areas with additional one-on-one staff training.

11.1a Chapter outline

- **Table 11.1** lists the types of data that project areas are responsible for submitting to CDC ("Data"), how the data are submitted ("Action"), and the submission schedule ("Frequency").
- Project areas must develop a **data management plan** to ensure that data submission activities are implemented in a systematic, complete, and timely manner ([Section 11.3](#)).
 - The data manager is responsible for all data management activities outlined in the data management plan.
 - The data manager serves as the DCC's primary point-of-contact.
 - Each project area's staffing structure should include a back-up for the data manager.
 - The Participant Tracking Form ([Appendix J](#)) should be used to track key interview information (e.g., survey ID, interview date, eligibility status), as well as to record any needed data edits.
- The Daily Data Management Report is available on the DCC data portal and provides a cumulative listing of a project area's data issues.
 - The data manager should review the Daily Data Management Report at least weekly.
 - Data corrections should be addressed as soon as possible.
 - To ensure the timely processing of data, Daily Data Management Reports should never contain error messages with interview dates that are **more than 2 weeks old**.

11.2 Data Submission

The DCC, which is operated by ICF International, is responsible for managing NHBS data nationally and they will produce the process monitoring reports described in [Chapter 10](#) of this manual. For their part, project areas are responsible for providing the DCC with the following data:

- CMP data
- NHBS interviews
- HIV test information and results
- Dried blood spot (DBS) specimen information
- Hepatitis test information and results (required from project areas that received supplemental NHBS funds for hepatitis testing; optional from all other project areas)
- Data corrections

Project areas should observe the schedule in [Table 11.1](#) for submitting their data, and they should refer to the NHBS-PWID2024 Data Management Learning Tree for guidance on utilizing SAMS and the DCC data portal.

11.3 Data Management Plan

Project areas must develop a local data management plan that outlines the activities necessary for ensuring the systematic, complete, and timely submission of NHBS data. The data manager should ensure that this task is accomplished according to both the local plan and the schedule in [Table 11.1](#), and they should serve as the DCC's primary point-of-contact for data management communications. The local plan should also identify which staff member(s) will back up the data manager and, if applicable, which will assist with data management responsibilities. Another essential element of the local plan is a system for tracking interviews and data corrections. Project areas should use the Participant Tracking Form ([Appendix J](#)) to track key interview information (e.g., survey ID, interview date, eligibility status), as well as to record any needed data edits. Project areas should always review and process their data in accordance with their local plan and the *NHBS Round 7 Model Surveillance Protocol*.

11.4 Daily Data Management Report

Each evening, the DCC will process all interview, testing, and coupon manager data submitted that day, and evaluate the data for completeness and accuracy. Any problems

Table 11.1 – Data submission schedule

Data	Action	Frequency
- CMP data	Sync to the DCC data portal	Daily , at the end of each day of operations
- NHBS interviews	Enter in the NHBS Interview in SAMS	Daily , at the time of interview
- HIV test information - Rapid HIV test results - DBS specimen information - Hepatitis test information* - Rapid hepatitis test results*	Enter in the NHBS Field Testing Form in SAMS	Daily , at the time of testing
- Lab-based HIV test results	Enter in the HIV Test Log on the DCC data portal	Daily , after lab-based HIV test results are obtained
- DBS packaging and shipping information	Enter in the HIV Test Log on the DCC data portal	Daily , when packaging and shipping DBS
- Lab-based hepatitis test results*	Enter in the Hepatitis Test Log on the DCC data portal	Daily , after lab-based hepatitis test results are obtained
- Data corrections	Enter in the Data Error Log on the DCC data portal	Daily , as soon as errors are identified

*The submission of hepatitis test results is required from all project areas that received supplemental NHBS funds for hepatitis testing. The submission of hepatitis test results is optional from all other project areas, but if they enter their hepatitis test information and results in the NHBS Field Testing Form in SAMS and the Hepatitis Test Log on the DCC data portal, the test results will be included in their final NHBS dataset.

identified in a project area's data will then be included in that area's Daily Data Management Report on the DCC data portal. This report is a cumulative listing of data issues that a project area must address to complete the processing of their data. The data manager should review the Daily Data Management Report at least weekly, and they should make any needed data corrections as soon as possible. To ensure the timely processing of a project area's data, their Daily Data Management Report should never contain any error messages with interview dates that are **more than 2 weeks old**. Project

areas should also ***promptly*** respond to any other DCC communications with either the requested information or a timeline when the requested information will be sent. If a project area has any questions about data management procedures or their Daily Data Management Report, they should contact their DCC technical assistance coordinator (TAC) or the Help Desk on the DCC data portal.

Appendix A NHBS-PWID2024 Operations Checklist

A model Operations Checklist is shown below. The actual checklist can be completed using the Word file named [Appendix A – Updated NHBS-PWID2024 Operations Checklist](#).

Draft Date: _____
CDC-Approved Date: _____ Updated Version Date: _____
mm / dd / yyyy mm / dd / yyyy

Instructions to Project Areas:

The FINAL completed checklist should be sent to your CDC Project Officer **on May 15, 2024**. Please send drafts of the checklist to your CDC Project Officer before the final version is due to address questions and potential revisions earlier in the process.

The final checklist must have all applicable sections completed. Please submit all attachments as separate documents unless otherwise noted (i.e., do not copy or paste large documents into the checklist). Include a corresponding section number or label in the file name for each attachment (e.g., “1b_IRB Approval Letter”).

Once your CDC Project Officer has approved the checklist, you will receive an email stating that your project area can begin data collection. **You cannot begin data collection until you receive this email.** As a final step, please enter the CDC-approved date in the field above and send a clean version of the approved checklist to your Project Officer for CDC records.

If any information in the checklist changes after it has been approved (e.g., new staff added), you must **update the checklist and resubmit it to your CDC Project Officer**. Updated versions of the checklist should be tracked using the “Updated Version Date” (see field above).

Please contact your CDC Project Officer with any questions.

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NOTE: Press the Ctrl key and click the section name to skip directly to that section.

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1 – IRB Review

1a. Enter the name(s) of all local Institutional Review Board(s) (IRBs) that reviewed the NHBS-PWID2024 project locally and select the type of review each IRB completed:

	Name of IRB	Type of review
Funded Health Department IRB		☐ Full ☐ Expedited ☐ Exempt
Other Local IRB (if applicable)		☐ Full ☐ Expedited ☐ Exempt
Other Local IRB (if applicable)		☐ Full ☐ Expedited ☐ Exempt

1b. **Attach** the letter(s) of approval or other documentation from all IRB(s) listed in the table above.

1c. Did any of your local IRBs defer to another?

☐ Yes ☐ No

1c1. **If Yes:** Specify which IRBs were involved:

1c2. **If Yes:** **Attach** letter(s) or other documentation for each IRB deferral.

1d. **Attach** your local survey consent form(s), including the Spanish version(s) if applicable.

1e. How will interviewers read the survey consent form to participants? *(check all that apply)*

- ☐ Read consent form verbatim
- ☐ Read summary of consent form (**attach summary**)
- ☐ Read highlighted excerpts from the consent form (**attach highlighted form**)
- ☐ Read bulleted list of consent talking points (**attach talking points**)

1f. Will participants provide verbal consent or written consent?

☐ Verbal consent ☐ Written consent

1f1. **If written consent:** Describe how you will protect the confidentiality of participants

(e.g., the participant signs the consent form with their survey ID, the interviewer signs the consent form)

--

2 – Project Staff Training and Evaluation

2a. In the following table, list the project staff and the trainings they have completed. **See instructions at the bottom of the table**, and **Chapter 2** of the *NHBS-PWID2024 Operations Manual* for required and recommended project staff training.

NOTE: If a specific training does not apply to a staff member, record “N/A” for not applicable.

Name of Staff Member				
Position				
ID Code (if applicable)				
CDC-provided training and materials				
Attended the CDC in-person Field Operations Training				
Completed the NHBS-PWID2024 Project Overview and Management Learning Tree				
Completed the NHBS- PWID2024 Interviewing Learning Tree				
Completed the NHBS- PWID2024 HIV Testing Learning Tree				
Completed the NHBS- PWID2024 Coupon Manager Program Learning Tree				
Completed the NHBS- PWID2024 Data Management Learning Tree				
Other CDC Training (if applicable, specify type and dates):				
Locally-provided training and other job requirements				
Received Confidentiality Training				
Date Signed Confidentiality Agreement				
Received Local Job-specific Field Operations Training				
Date HIV Counseling and Testing Certification Expires				
Read package inserts for rapid test(s)				

Other Local Training (if applicable, specify type and dates):				
Final evaluation				
Evaluated and Met Performance Criteria for Position(s)				

Instructions for completing the table:

Name of Staff Member: List the name of each staff member. If you need to add more columns to add project staff, please submit the larger table as a separate attachment.

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

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

CDC-provided training and materials:

Attended the NHBS-PWID2024 Field Operations Training: Record Yes to indicate that the project coordinator, field supervisor or another senior staff member attended this training.

Completed the NHBS- PWID2024 Project Overview and Management Learning Tree: Record Yes to indicate that the project coordinator and field supervisor reviewed the materials and presentations in this learning tree.

Completed the NHBS- PWID2024 Interviewing Learning Tree: Record Yes to indicate that the interviewers, as well as anyone who manages, trains, or evaluates them, reviewed the materials and presentations in this learning tree.

Completed the NHBS- PWID2024 HIV Testing Learning Tree: Record Yes to indicate that HIV counselors and staff members who handle specimens, as well as anyone who manages, trains, or evaluates them, reviewed the materials and presentations in this learning tree.

Completed the NHBS- PWID2024 Data Management Learning Tree: Record Yes to indicate that the project coordinator, the data manager, and other staff members who manage NHBS data, as well as anyone who manages, trains, or evaluates them, reviewed the materials and presentations in this learning tree.

Completed the NHBS- PWID2024 Coupon Manager Program Learning Tree: Record Yes to indicate that staff members with coupon manager responsibilities, as well as anyone who manages, trains, or evaluates them, reviewed the materials and presentations in this learning tree.

Other CDC Training: Using a separate row, list any other 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.

Locally-provided training and other job requirements:

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.

Received Local Job-specific Field Operations Training: Each member of the field staff must be trained to successfully perform their job-specific duties and responsibilities. Record Yes to indicate that a staff member received this training.

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. If an HIV test counselor’s certification does not expire, record “N/A” for not applicable.

Read Package Insert for Rapid HIV Test(s): The field supervisor and all HIV test counselors conducting rapid HIV testing must read the information in the package insert(s) for the rapid HIV test(s) being used. Record *Yes* to indicate that a staff member read the package insert(s) for the test(s).

Other Local Training: Using a separate row, list any other local training that project staff have completed, such as any cultural and health diversity training. Include the name of the training and the date(s) that it was conducted. Add more rows to the table if necessary.

Final evaluation

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 **Table 2.4** and **Appendices B** thru **G** of the *NHBS-PWID2024 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.

2b. Based on the evaluation recommendations in **Table 2.4** of the *NHBS-PWID2024 Operations Manual*, describe your plans for evaluating project staff during data collection.

NOTE: *Specify who will conduct the evaluations and estimate their weekly time commitment for this task.*

2c. 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)*

NOTE: *If the field supervisor **will not** conduct staff evaluations, record “N/A” for not applicable.*

3 – Project Identification

3a. Record your NHBS-PWID2024 project name:

3b. **Insert or attach** your NHBS-PWID2024 project logo.

4 – Field Sites

4a. 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, note that a van will be used and list the address(es) where the van will be parked.

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

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

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

Population(s) Targeted: List any subpopulations of PWID who are expected to have greater access to the field site. If no subpopulations are expected to have greater access, record "N/A" for not applicable.

4b. **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).

4c. Describe the setup of your field site(s) (waiting area, coupon manager station, interview spaces, HIV testing spaces, etc.) and the planned flow of participants.

4d. Will you conduct interviews or HIV tests in a van?

☐ Yes ☐ No

4d1. If Yes: Describe your contingency plans if the van is not available due to mechanical problems; include the method of informing participants if operations have stopped:

5 – Seeds

5a. What is the total number of **initial** seeds you plan on recruiting: _____

5b. Use the following table to list the characteristics of each **initial** 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 injected most often	Geographic Area**
1					
2					
3					

**To improve the age distribution in NHBS samples, all initial seeds should be 18-39 years old, and at least half of these seeds should be 18-29 years old.*

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

5c. **Insert or attach** a copy of your referral card.

NOTE: *If you are also creating a referral card in Spanish, include a copy of that card as well.*

6 – Coupons

6a. To maximize recruitment at the start of data collection, project areas should give 5 coupons to both seed and non-seed recruiters. Do you plan on giving **fewer** than 5 coupons to either seed or non-seed recruiters at the start of data collection?

☐ Yes ☐ No

6a1. If Yes:

# of coupons distributed to seeds at the start of data collection:	
# of coupons distributed to non-seeds at the start of data collection:	

6b. Will you use coupon activation dates?

☐ Yes ☐ No

6b1. If Yes: What is the coupon activation period (e.g., 1 day): _____

6c. What is the coupon expiration period or date
(e.g., 4 weeks, November 30, 2022): _____

6d. Will you allow participants to use photo coupons?

☐ Yes ☐ No

6e. **Insert or attach** a copy of your coupon.

NOTE: If you are also creating a coupon in Spanish, include a copy of that coupon as well.

7 – Recruiter Training

7a. **Attach** a copy of your recruiter training talking points.

7b. **Insert or attach** a copy of your information card.

8 – Project Phone

8a. List your project phone number(s). Write *pending* if a phone number has not been obtained yet:

Phone #:	
Phone #:	

8b. Is voicemail activated on your project phone?

☐ Yes ☐ No

8b1. **If Yes:** Describe your procedures for protecting participant anonymity:

--

9 – Appointment System

9a. Will you use an appointment system to schedule interviews?

☐ Yes ☐ No

If No: Skip to section “10 – Participant Contact Information.”

9b. Step-by-step, describe how you will schedule appointments:

NOTE: Include whether “walk-ins” or standby appointments will be allowed, and whether an online scheduling tool will be used, including how proxy IDs will be created, if necessary.

--

9c. Will you provide appointment reminders?

☐ Yes ☐ No

9b1. **If Yes:** Describe your procedures for providing appointment reminders:

--

10 – Participant Contact Information

10a. Will you collect participant contact information to follow-up with seeds, for appointment reminders, or to provide laboratory test results?

☐ Yes ☐ No

If No: Skip to section “11 – Incentives.”

10b. Use the following table to describe the type(s) of contact information you plan on collecting:

Type of Contact Information	Project Staff	Use(s)

Instructions for completing the table:

Type of Contact Information: List each type of contact information you plan on collecting (e.g., phone numbers, email addresses). Only include one type of contact information in each row.

Project Staff: Indicate which project staff will have access to each type of contact information (e.g., field supervisor, test counselors).

Use(s): Briefly describe how each type of contact information will be used for NHBS-PWID2024 operations. One type of contact information may have multiple uses (e.g., a phone number could be used to both text an appointment reminder and call with lab-based test results).

10c. Describe your procedures for collecting, securely storing, and destroying participant contact information:

NOTE: Include when contact information will be destroyed.

--

10d. If collecting participant contact information to return test results, describe how you will link the participant’s contact information to their test results:

NOTE: If you are using a proxy ID to link the participant’s contact information to their test results, describe how you will create the proxy ID.

--

10e. If collecting participant contact information to return test results, describe how you will confirm that you have contacted the correct person and that the test results you are providing are that person’s results:

--

11 – Incentives

11a. What is the amount and type of compensation that each participant will receive?

Compensation for:	Amount	Type
Interviewing		
HIV testing		
Recruitment (per recruit)		

11b. 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.

Additional compensation provided for:	Amount	Type
Did not pass the eligibility screener		
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 or other test result (NOTE: only non-NHBS funds can be used)		
Hepatitis testing (if applicable)		
Other activity or test (specify):		

11c. In total, what is the maximum amount of compensation that each participant could potentially receive:

Max. Amount	
-------------	--

11d. Describe your system for tracking incentive payments:

NOTE: Include details on how incentives will be transported to the field, how incentives will be stored and accessed, how the distribution of incentives will be tracked, and the approximate dollar amount of incentives that will be kept in the field.

--

11d1. **Attach** a copy of your payment tracking log.

12 – HIV Testing

12a. Rapid HIV Testing

12a1. Do you have a CLIA certificate of waiver?

☐ Yes ☐ No

12a2. Trade name of the **screening** rapid HIV test (e.g., Abbott Determine, Insti, Uni-Gold):

12a3. Type of **screening** specimen collected:

- ☐ Blood from fingerstick
☐ Blood from venipuncture

12a4. How will you confirm a reactive rapid HIV test result?

- ☐ Rapid testing
☐ Laboratory-based testing

If Laboratory-based testing: Skip to question 12a7

12a5. Trade name of **confirmatory** rapid HIV test (e.g., Abbott Determine, Insti, Uni-Gold):

12a6. Type of **confirmatory** specimen collected:

- ☐ Blood from fingerstick
☐ Blood from venipuncture

12a7. Describe the procedures you will use to ensure that rapid test results are read during the time frame indicated in the test package insert:

12a8. 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

If No: When will you collect the test specimen for the first rapid test?

- ☐ Before the core questionnaire
NOTE: Collection can only take place before the core questionnaire if pre-test counseling is not required locally.
- ☐ Between the core and local questionnaires
- ☐ After both the core and local questionnaires

12b. Local Laboratory-based HIV Testing

NOTE: If using the rapid-rapid algorithm for HIV testing and no local laboratory-based HIV testing will be conducted, skip to section 12c. ***“HIV Counseling and Testing Procedures.”***

12b1. Type of specimen collected:

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

12b2. ***If collecting blood via venipuncture,*** will an alternative specimen collection method be offered if venipuncture is not possible (e.g., the phlebotomist is not available or venipuncture is not possible on the participant)?

- ☐ Yes ☐ No ☐ N/A

12b2a. If Yes: Describe your alternative testing plan:

--

12b3. Trade name of laboratory-based test(s), as applicable:

(e.g., Abbott 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.)

Laboratory-based test #1

Laboratory-based test #2

Laboratory-based test #3

Laboratory-based test #4

12b4. Name and contact information for the laboratory performing HIV testing:

Name	
Contact information	

12b5. **Attach** your laboratory specimen slip or form. Fill it out with example data.

12c. HIV Counseling and Testing Procedures

12c1. Step-by-step, describe your HIV counseling and testing procedures:

***NOTE:** Include the flow of participants and staff in the field during the counseling, testing, and DBS collection process.*

--

12c2. **Attach** any other HIV testing forms or logs that you plan on using (e.g., HIV Testing Log, specimen transport or shipping log for the local laboratory, risk assessment forms).

12d. HIV Test Results and Linkage to Care

12d1. Describe your procedures for returning rapid and, if applicable, laboratory-based HIV test results:

--

12d2. Describe your procedures for anonymously linking HIV-positive participants to care:

--

12d3. **Attach** a copy of the script you will use to explain the anonymous linkage process to participants (please refer to **Chapter 9** of the *NHBS-PWID2024 Operations Manual* for guidance).

12e. HIV Specimen Storage, Transport, and Processing

12e1. Please check this box to confirm that you have established processes for safe disposal of biohazard materials in the field

☐ Processes for safe disposal of biohazard materials in the field have been established

12e2. Describe how and where specimens (including DBS) will be stored before they are sent to CDC and, if applicable, to the local laboratory:

12e3. Describe procedures for sending DBS specimens to CDC:

NOTE: Include planned day/time of shipping, and frequency of shipments.

12e4. If applicable, describe procedures for transporting or shipping specimens to the local laboratory for HIV testing (e.g., courier, delivery by project staff, FedEx):

NOTE: Include planned day/time of shipping, and frequency of shipments.

12e5. If applicable, describe how project staff will communicate to the local laboratory which specimens are from participants who are self-reported HIV-positive:

NOTE: All specimens from self-reported HIV-positive participants must receive laboratory-based confirmatory testing even if the participants had non-reactive rapid tests, invalid rapid tests, or non-reactive laboratory-based screening tests.

12e6. Will you obtain consent to store specimens **locally** for **additional** testing?

☐ Yes ☐ No

If No: Skip to section 13. “STI, Hepatitis, and Other Testing.”

12e7. Type of specimen stored **locally** for additional testing:

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

12e8. 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:

13 – STI, Hepatitis, and Other Testing

13a. STI testing

13a1. Will you conduct pharyngeal and rectal gonorrhea and chlamydia testing?

☐ Yes ☐ No

13a2. Will you conduct any other STI testing?

☐ Yes ☐ No

If Yes: What other STI testing will you conduct?

If Yes to either 13a1 or 13a2: Complete the remainder of section **13a. “STI Testing”**; otherwise, skip to section **13b. “Hepatitis Testing.”**

13a3. What source of funding will you use to conduct STI testing? (*Check all that apply*)

☐ Local funds

☐ Unobligated NHBS funds

13a4. Step-by-step, describe your procedures for STI specimen collection:

NOTE: Include the flow of participants and staff in the field during the counseling and testing process. Specify how and when specimens will be labeled, including how you will create specimen IDs for each specimen type.

13a5. Describe how STI specimens will be stored in the field:

13a6. If applicable, describe how STI specimens will be transported to the project office and stored before they are sent to the local laboratory:

13a7. Describe procedures for transporting or shipping specimens to the local laboratory:

NOTE: Include time of day/time of shipping, and frequency of shipments.

13a8. Describe the type(s) of swabs that will be used to collect STI specimens:

13a9. Describe the specific assay and platform the local laboratory will use to perform the STI tests:

13a10. Will you obtain consent to store specimens **locally** for future testing after completion of the STI testing?

☐ Yes ☐ No

13a11. Name and contact information for the laboratory performing STI testing:

Name	
Contact information	

13a12. Attach any other STI testing forms or logs that you plan on using (e.g., STI Testing Log, Participant Tracking Form, specimen transport or shipping log for the local laboratory, risk assessment forms).

13a13. Attach your laboratory specimen slip or form. Fill it out with example data.

13a14. Attach any instructions or documentation from the local laboratory about their STI specimen collection, storage, transfer/shipment, and testing procedures.

13a15. Describe your procedures for anonymously returning STI test results to participants:

NOTE: *If applicable, include procedures for participants who call outside of scheduled hours and procedures for Spanish-speaking participants.*

--

13a16. Describe your procedures for anonymously referring participants to care:

--

13a17. Attach a copy of the script you will use to explain the anonymous linkage process to participants (please refer to **Chapter 9** of the *NHBS-PWID2024 Operations Manual* for guidance).

13b. Hepatitis Testing

13b1. 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 **13c. "Other Testing."**

13b2. What source of funding will you use to conduct hepatitis testing?

- ☐ Local funds
- ☐ Unobligated NHBS funds
- ☐ Supplemental NHBS funds (CDC DVH funds)

13b3. *If using local funds for hepatitis testing*, will you enter your hepatitis test results in the NHBS Field Testing Form and, if applicable, the DCC Data Portal Hepatitis Test Log?

- ☐ Yes ☐ No

If conducting HCV testing: Complete **13b4 – 13b7 (HCV Testing)**; otherwise, skip to **13b8 (HBV Testing)**.

13b4. Which test(s) will you use? *(Check all that apply)*

**Required for project areas that received supplemental NHBS funds (CDC DVH funds) for HCV testing*

- ☐ *OraQuick rapid HCV test
- ☐ *Laboratory-based HCV RNA test (NAT)
- ☐ Laboratory-based HCV EIA test

13b5. If applicable, trade name of laboratory-based HCV screening EIA:

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

13b6. If applicable, type of laboratory-based HCV RNA test:

- ☐ Qualitative NAT
- ☐ Quantitative NAT (HCV viral load)

13b7. If applicable, trade name of laboratory-based HCV RNA test:

(e.g., Abbott Realtime HCV Assay, Abbott Alinity mHCV, Roche COBAS HCV, Roche COBAS AmpliPrep/COBAS TaqMan HCV v2.0, Hologic Aptima HCV Quant Dx, Siemens Versant HCV 3.0, Bayer Versant HCV Qual)

If conducting HBV testing, Complete **13b8 (HBV Testing)**; otherwise, skip to **13b9 (Hepatitis Counseling and Testing Procedures)**.

13b8. Indicate the trade name(s) of the screening EIAs for the following HBV antigens and antibodies (e.g., VITROS system [from Ortho Clinical Diagnostics], Abbott AxSYM and Abbott Prism, Siemens Advia Centaur, ETI-MAK-2 assay by Diasorin):

**Required for project areas that received supplemental NHBS funds (CDC DVH funds) for HBV testing*

*Hepatitis B surface antigen (HBsAg):	
*Antibody to hepatitis B surface antigen (anti-HBs):	
*Total antibody to hepatitis B core antigen (anti-HBc):	
IgM antibody to hepatitis B core antigen (IgM anti-HBc) (optional):	

13b9. Step-by-step, describe your hepatitis counseling and testing procedures:

NOTE: Include the flow of participants and staff in the field during the counseling and testing process, methods of specimen collection, types of collection tubes, and counseling messages for rapid and laboratory-based test results.

13b10. *If collecting venipuncture specimens for lab-based hepatitis testing*, describe how specimens will be stored and, if applicable, processed **in the field** (e.g., refrigerated, centrifuged, timing between steps):

13b11. *If collecting venipuncture specimens for lab-based hepatitis testing*, describe procedures for transporting or shipping specimens to the local laboratory:

NOTE: Include planned day/time of shipping, frequency of shipments, and if applicable, how specimens will be transported to the project office and stored before they are sent to the local laboratory.

13b12. *If conducting lab-based hepatitis testing*, will you obtain consent to store specimens **locally** for future testing after completion of the hepatitis testing?

☐ Yes ☐ No

13b13. Name and contact information for the laboratory performing testing (if applicable):

Name	
Contact information	

13b14. **Attach** any other Hepatitis testing forms or logs that you plan on using (e.g., Hepatitis Testing Log, Participant Tracking Form, specimen transport or shipping log for the local laboratory, risk assessment forms).

13b15. **Attach** your laboratory specimen slip or form (if applicable). Fill it out with example data.

13b16. **Attach** any instructions or documentation from the local laboratory about their hepatitis specimen collection, tube types, specimen processing, storage, transfer/shipment, and testing procedures (if applicable).

13b17. Describe your procedures for anonymously linking HCV- or HBV-positive participants to care:

13b18. Describe your procedures for anonymously linking participants for hepatitis A and B vaccination:

13b19. **Attach** a copy of the script you will use to explain the anonymous linkage process to participants (please refer to **Chapter 9** of the *NHBS-PWID2024 Operations Manual* for guidance).

13c. Other Testing

13c1. Will you conduct any other testing?

☐ Yes ☐ No

If No: Skip to section “14 – Local Questions.”

13c2. List any other tests you plan on conducting:

Test:

Will you return test results to participants?

☐ Yes ☐ No

Test:

Will you return test results to participants?

☐ Yes ☐ No

13c3. Describe how any other tests will be incorporated into NHBS operations:

13c4. *If returning test results to participants*, describe your procedures for anonymously linking participants with positive test results to care:

14 – Local Questions

NOTE: Per the NHBS Round 7 Model Surveillance Protocol (see Section 3.1d Questionnaire):
“Project areas may include additional questions on topics of local interest. The local use questions shall not exceed 10 minutes maximum for administration.”

14a. Will you ask participants local questions after they have completed the NHBS core questionnaire?

☐ Yes ☐ No

If **No**, skip to section “15 – Data Management.”

14b. Will the DCC program your local questionnaire in the Voxco Survey Software?

☐ Yes ☐ No

14b1. *If No:* What questionnaire design platform (e.g., REDCap, QDS) are you using to program your local questions?

14b2. *If No:* **Attach** the interviewer version of your local questionnaire produced by the questionnaire design platform. For example, in QDS™ this is an **.rtf** file that you can create with the QDS™ Design Studio [under the “Build” tab, select “Questionnaire (Interviewer)”].

15 – Data Management

15a. List the name(s) and contact information for your data manager(s):

Name	Phone	E-mail

15b. List the name(s) and contact information for the staff member(s) responsible for submitting NHBS data to the DCC data portal. Indicate the type of data that each will submit (Coupon Manager Program [CMP] data, test results, or data edits):

Name	Phone	E-mail	Data Type

15c. **Attach** the following documents:

15c1. Data security and confidentiality policy

15c2. Data transfer protocol (i.e., how data are transferred from the point of collection to the point of upload to the DCC data portal). **NOTE:** *Include how forms and computers containing data are securely transported and stored.*

15d. ***If conducting any laboratory-based testing***, describe how laboratory-based test results will be securely transferred between the laboratory and the project staff:

--

16 – Local Safety and Field Incident Reporting Procedures

16a. **Attach** the following documents:

16a1. Local safety protocol

16a2. Field incident reporting procedures

17 – Prevention and Other Materials

17a. **Attach** any **written** prevention or informational materials that will be distributed to

participants.

17b. List any other prevention materials, that will be distributed to participants:

Item	Item Description
Naloxone	
Syringes	
Cookers	
Fentanyl test strips	
Safer sex materials, such as condoms and lubricants	
Hygiene materials and other essentials, such as soap, toothbrush and toothpaste, socks	
Nutritional supplements, including snacks (e.g., granola bars) and drinks (e.g., water, juice)	
Other (specify)	
Instructions for completing the table: Provide a brief description of each item that you plan to distribute to participants. If an item will not be distributed, record "N/A" for not applicable. As a reminder, Naloxone, syringes, cookers and fentanyl test trips CANNOT be purchased using NHBS funds; project areas must use local funds or donations for these items. NHBS funds may be used for safer injection items (<u>other than</u> syringes and cookers), safer sex materials, hygiene materials and other essentials, and nutritional supplements.	

Appendices B to G

Project Staff Evaluation Forms

Model evaluation forms for each staff position can be printed or modified using the Word files listed in the following table:

Appendix	Staff Position	File Name
B	Field Supervisor (Project Management)	Appendix B - Field Supervisor - Project Management Evaluation Form
C	Field Supervisor (HIV Testing Operations)	Appendix C - Field Supervisor - HIV Testing Operations Evaluation Form
D	Coupon Manager	Appendix D - Coupon Manager Evaluation Form
E	Interviewer	Appendix E - Interviewer Evaluation Form
F	HIV Test Counselor	Appendix F - HIV Counseling and Testing Evaluation Form
G	Data Manager	Appendix G - Data Manager Evaluation Form

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

Electronic equipment:

- ☐ Computers (1 for each interviewer or tester, plus backups)
- ☐ Computer for the coupon manager
- ☐ Wi-Fi hotspot(s) (plus 1 backup) (if applicable)
- ☐ AC adaptors for computers and, if applicable, Wi-Fi hotspots
- ☐ Communications equipment (e.g., 2-way radios or cell phones)
- ☐ White noise machines (if applicable)
- ☐ Other electronic equipment (e.g., telephone, printer): _____

Forms or logs:

- ☐ Appointment Book or Log
- ☐ CMP Log
- ☐ Participant Tracking Forms
- ☐ Consent forms (including copies for participants)
- ☐ HIV Testing Log (*Appendix J of the NHBS Round 7 Model Surveillance Protocol*)
- ☐ Hepatitis Testing Log (*Appendix K of the NHBS Round 7 Model Surveillance Protocol*) (if applicable)
- ☐ 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)
- ☐ Appointment Cards (if applicable)
- ☐ Phone Results Cards (if applicable)
- ☐ Return of Lab Results Log (if applicable)
- ☐ Return of Lab Results Forms (if applicable)
- ☐ Seed Referral Cards
- ☐ Coupons
- ☐ Information Cards
- ☐ Recruiter training talking points
- ☐ Incentive log or receipt book for tracking 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 7 Model Surveillance Protocol*
- ☐ *NHBS-PWID2024 Formative Assessment Manual*
- ☐ *NHBS-PWID2024 Operations Manual*
- ☐ *NHBS-PWID2024 Operations Manual - Hepatitis Testing Supplement* (if applicable)
- ☐ *NHBS Round 7 Interviewer Guide*
- ☐ Other documents: _____

Miscellaneous items:

- ☐ Flashcards for each interviewer
- ☐ Interview and HIV test incentives to cover the expected number of participants
- ☐ Incentives for hepatitis tests (if applicable)
- ☐ Incentives for ineligibles (if applicable)
- ☐ Recruiter rewards
- ☐ Electronic payment information (if applicable)
- ☐ Envelopes or file folders to store submitted coupons
- ☐ Signed memorandums of understanding (MOUs) (if applicable)
- ☐ Informational pamphlets on HIV, hepatitis, STIs, and other medical conditions
- ☐ Informational pamphlets on pre-exposure prophylaxis (PrEP) and HIV, hepatitis, and STI prevention
- ☐ Information to make linkages to HIV medical care and case management
- ☐ Information to make linkages to other health care and social services
- ☐ Harm reduction supplies (e.g., injection equipment, fentanyl test strips, naloxone, condoms, lubricant, hygiene kits)
- ☐ Other items: _____

2. Testing Supplies

Rapid testing supplies (if applicable):

- ☐ Rapid tests

- ☐ Rapid test controls
- ☐ Lancets
- ☐ Fingerstick blood collection devices (i.e., pipettes or loops)
- ☐ Test reagents (i.e., developer solution, wash solution, and running buffer)
- ☐ Fingerstick Quick Reference Guide(s)
- ☐ Package inserts for the specific rapid test(s) being used
- ☐ Subject information pamphlets for each participant who receives a rapid test
- ☐ Other rapid testing supplies: _____

Phlebotomy supplies (if applicable):

- ☐ Whole blood specimen collection tubes
- ☐ Phlebotomy equipment (e.g., tourniquet, vacutainer holders and needles, butterfly needles)
- ☐ Equipment to transport specimens (e.g., test tube racks, specimen transport box)
- ☐ Other phlebotomy supplies: _____

DBS supplies:

- ☐ DBS collection cards
- ☐ DBS collection devices (i.e., blade lancets if DBS from fingersticks or transfer pipettes if DBS from blood tubes)
- ☐ Equipment to dry DBS (e.g., drying or test tube racks, binder clips)
- ☐ Equipment to transfer DBS (e.g., specimen transport box) (if applicable)
- ☐ Materials to package DBS (e.g., low-gas permeable ziplock bags, desiccants, humidity indicator cards)
- ☐ Materials to ship DBS (e.g., anti-tear envelopes, shipping envelopes, labels)
- ☐ Other DBS supplies: _____

Miscellaneous testing supplies:

- ☐ Alcohol swabs
- ☐ Dry sterile gauze or cotton balls
- ☐ Band-aids
- ☐ Absorbent paper (e.g., Chux)
- ☐ Biohazard “sharps” container for lancets and needles
- ☐ Biohazard bags for non-sharp blood waste (e.g., gloves, Chux, band-aids)
- ☐ Personal protective equipment (e.g., disposable gloves, disposable gowns, face shields)
- ☐ Hand sanitizer
- ☐ 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 any paper coupons returned
- ☐ Collect and review the Participant Tracking Forms for completeness and accuracy
- ☐ Check the *Recruiter TBD Coupons Report* in the CMP to look for any unlinked coupons
- ☐ Back up the CMP data
- ☐ Sync the CMP to the DCC data portal
- ☐ Review the CMP Log for completeness and accuracy
- ☐ Lock up hard copies of completed forms and logs (if applicable)
- ☐ Review the Coupon Manager Evaluation Form or note if the scheduled evaluation did not occur and needs to be re-scheduled (if applicable)
- ☐ Other daily coupon manager activities: _____

Field supervisor with interviewers:

- ☐ Collect the interviewers' computers
- ☐ Determine if any problems occurred with the interviewers' computers or with internet access
- ☐ Review the Participant Tracking Forms (including data edits) for completeness and accuracy
- ☐ Determine if any unusual events occurred (e.g., participant ended the interview early, participant consented to an HIV test but then changed his mind)
- ☐ Lock up hard copies of completed forms and logs (if applicable)
- ☐ Review the Interviewer Evaluation Form(s) or note if the scheduled evaluation(s) did not occur and need to be re-scheduled (if applicable)
- ☐ Other daily interviewer activities: _____

Field supervisor with HIV test counselors*:

- ☐ Collect the HIV test counselors' computers
- ☐ Determine if any problems occurred with the HIV test counselors' computers or with internet access
- ☐ Collect the HIV Testing Log and any other HIV testing forms or logs (if applicable)
- ☐ Review the Participant Tracking Forms and, if applicable, the HIV Testing Log, and any other HIV testing forms or logs for completeness and accuracy
- ☐ Ensure that the survey IDs and, if applicable, laboratory IDs entered into the NHBS Field Testing Form in SAMS are accurate
- ☐ Review all HIV testing data collected in the field and ensure that they are entered correctly into the NHBS Field Testing Form in SAMS (cross-check the data against the HIV Testing Log, Participant Tracking Form, or other testing

- forms or logs)
- ☐ For each laboratory-based HIV testing entry in the NHBS Field Testing Form in SAMS, cross-check that there is a laboratory-based HIV test specimen, or a justification noted if a specimen is missing (if applicable)
 - ☐ Review the Return of Lab Results Log, the Return of Lab Results Form, or any other HIV testing logs or forms to ensure that each participant made plans to obtain their laboratory-based HIV test results by phone or scheduled an appointment to obtain their results in person (if applicable)
 - ☐ Review the lab slips and ensure that the laboratory IDs are accurate (if applicable)
 - ☐ Cross-check that there is a lab slip for each laboratory-based HIV test specimen (if applicable)
 - ☐ Ensure that laboratory-based HIV test specimen tubes are securely capped and properly labeled (if applicable)
 - ☐ Review the local specimen transport or shipping log for completeness and accuracy (if applicable)
 - ☐ While waiting to ship laboratory-based HIV test specimens, store them at the appropriate temperature indicated by the local laboratory (if applicable)
 - ☐ Transport or ship laboratory-based HIV test specimens to the local laboratory (if applicable)
 - ☐ Cross-check that there is a DBS specimen for each applicable entry in the NHBS Field Testing Form in SAMS or the HIV Testing Log
 - ☐ Keep DBS cards out of direct sunlight when drying and store them at the appropriate temperature
 - ☐ Package DBS cards in ziplock bags when drying is completed (**Note:** drying should not exceed 24 hours)
 - ☐ Ship DBS cards to CDC on a weekly basis
 - ☐ Lock up hard copies of completed forms and logs (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)
 - ☐ Other daily HIV test counselor activities: _____

*** Project areas conducting hepatitis testing can adapt these procedures to create a checklist for that testing.**

Data manager:

- ☐ Back up the CMP data (if applicable)
- ☐ Transfer and delete any participant data from the computers (e.g., local questionnaire data that were not collected with the NHBS Interview in SAMS) (if applicable)
- ☐ Enter data edits into the Data Error Log on the DCC data portal
- ☐ Enter edits to HIV testing information and rapid test results into the NHBS Field

Testing Form in SAMS

- ☐ Enter edits to hepatitis testing information and rapid test results into the NHBS Field Testing Form in SAMS (if applicable)
- ☐ Enter laboratory-based HIV test results into the HIV Test Log on the DCC data portal (if applicable)
- ☐ Enter laboratory-based hepatitis test results into the Hepatitis Test Log on the DCC data portal (if applicable)
- ☐ Lock up hard copies of completed forms and logs (if applicable)
- ☐ Charge and lock up the computers and, if applicable, Wi-Fi hotspots
- ☐ 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

CMP Log

A model CMP Log is shown below. The actual log can be printed or modified using the Excel file named [Appendix I - CMP Log](#).

CMP Log								
Date of Interview	Survey ID (Coupon #)	Physical Marks	Recruiter ID	Coupons Distributed to Participant				
				# on 1st Coupon	# on 2nd Coupon	# on 3rd Coupon	# on 4th Coupon	# on 5th Coupon

Page _____

Appendix J

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 J - Participant Tracking Form](#).

Participant Tracking Form																	
Interview Date	Interviewer ID																
Interviewer Computer #	Survey ID (Coupon #)																
<i>Data Manager Use Only:</i>		Seed? Y ☐ N ☐															
Interview Start Time	Field Site ID																
<table border="1" style="width: 100%; border-collapse: collapse;"><thead><tr><th style="width: 60%; text-align: center; padding: 5px;">INTERVIEWER</th><th style="width: 40%; text-align: center; padding: 5px;">NOTES</th></tr></thead><tbody><tr><td style="padding: 5px;">1. Passed the screener? Y ☐ N ☐</td><td rowspan="10"></td></tr><tr><td style="padding: 5px;">2. Consented to the interview? Y ☐ N ☐</td></tr><tr><td style="padding: 5px;">3. Consented to HIV testing? Y ☐ N ☐</td></tr><tr><td style="padding: 5px;">4. Consented to hepatitis testing? Y ☐ N ☐</td></tr><tr><td style="padding: 5px;">5. Consented to specimen storage? Y ☐ N ☐</td></tr><tr><td style="padding: 5px;">6. SRP during interview? Y ☐ N ☐</td></tr><tr><td style="padding: 5px;">7. Completed the interview? Y ☐ N ☐</td></tr><tr><td style="padding: 5px;">8. Selected to recruit? Y ☐ N ☐</td></tr><tr><td style="padding: 5px;">If yes, agreed to recruit? Y ☐ N ☐</td></tr><tr><td style="padding: 5px;">If yes, number of coupons due:</td></tr><tr><td style="padding: 5px;">9. Received recruiter training? Y ☐ N ☐</td><td></td></tr></tbody></table>			INTERVIEWER	NOTES	1. Passed the screener? Y ☐ N ☐		2. Consented to the interview? Y ☐ N ☐	3. Consented to HIV testing? Y ☐ N ☐	4. Consented to hepatitis testing? 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 ☐	
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DATA EDITS:																	
<table border="1" style="width: 100%; border-collapse: collapse;"><thead><tr><th style="width: 45%; text-align: center; padding: 5px;">Variable Name</th><th style="width: 25%; text-align: center; padding: 5px;">Old Value</th><th style="width: 30%; text-align: center; padding: 5px;">New Value</th></tr></thead><tbody><tr><td style="height: 20px;"></td><td></td><td></td></tr><tr><td style="height: 20px;"></td><td></td><td></td></tr><tr><td style="height: 20px;"></td><td></td><td></td></tr></tbody></table>			Variable Name	Old Value	New Value												
Variable Name	Old Value	New Value															

Appendix K

Rapid Testing Quality Control Log

A model Rapid Testing Quality Control Log is shown below. The actual log can be printed or modified using the Word file named [Appendix K – Rapid Testing Quality Control Log](#).

NHBS Rapid Testing Quality Control Log						
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: _____

Rapid Testing Temperature Log

NHBS Rapid Testing Temperature Log					
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: _____

[PROJECT NAME]

Please call us at ***[phone number to call for results]*** on or after:

_____ , _____
day date

[days of operation] from ***[opening time]*** to ***[closing time]***

ID Number: _____

Appendix N

Return of Laboratory-based Test Results

Project areas conducting laboratory-based testing to confirm HIV infection or to detect other infections (e.g., viral hepatitis, STIs) can give participants their test results **in person** or, if permitted by local policies, **over the phone**. Participants can obtain their laboratory-based test results **in person** by scheduling an appointment at the project office or another field site on a specific date and time. If allowed locally, participants can obtain their laboratory-based test results **over the phone** by calling the project or by providing their phone number for project staff to call them when their results are available. Note that if project areas offer to phone participants to return their test results, it must be optional; participants **cannot** be required to provide contact information like phone numbers. All approved options for returning test results must be offered to all participants, and the options must be offered in a neutral tone so that the staff do not influence the participant's decision. Nevertheless, staff may choose to not offer the option of receiving test results **over the phone** if a participant's mental state regarding their results (e.g., threat to harm self or others) indicates a need to return the results and conduct post-test counseling **in person**.



This appendix applies strictly to returning results from testing performed at local laboratories. Results from DBS testing performed at the CDC laboratory **cannot** be returned to participants under any circumstances.

N.1 Steps for Returning Test Results

Project areas planning to provide laboratory-based test results to participants should follow the guidance outlined in the steps below.

Step 1 – Explaining the Process

Participants should be told when their laboratory-based test results will be available and what the options are for receiving their results: in person, by phone - they call you, or by phone - you call them. This process should be explained prior to the return of results from rapid HIV tests or other rapid tests so that the participants can focus solely on understanding their rapid test results and, if applicable, receiving linkage to care. If contact information will be collected to return test results, that information **must** be collected before the return of any rapid test results as well.

If applicable, staff should remind participants that the project phone will not have voicemail activated to prevent them from leaving contact information or other personally identifiable information when they call for their test results. Furthermore, when presenting the option to collect contact information, staff should remind participants that the project will not leave any voicemail messages with test results.



For HIV tests, a participant who would like to obtain their test result by phone should be required to identify at least one friend or relative from whom they can seek support if their test result is positive or indeterminate.



Since participants will not receive laboratory-based test results at the time of specimen collection, post-test counseling should include information on locations where testing and treatment can be obtained. This is particularly important for participants who express concern about infection or describe symptoms that would warrant immediate linkage to additional testing and care.

Step 2 – Completing the Return of Lab Results Log or Form

To manage the return of laboratory-based test results, project areas that are **not** collecting phone numbers to provide results should use the Return of Lab Results Log ([Figure N.1](#) and [Appendix N - Model Return of Lab Results Log](#)) and areas that are collecting phone numbers to provide results should use the Return of Lab Results Form ([Figure N.2](#) and [Appendix N - Model Return of Lab Results Form](#)). These documents can be used to indicate how participants would like to receive their test results and to collect any information needed for that purpose. Information from the Return of Lab Results Form could also be entered into an electronic version, like an Excel spreadsheet, to help project staff organize and facilitate communications with participants.

Figure N.1 – Return of Lab Results Log

Return of Lab Results Log					
Test Date	ID	Security Question	Security Question Answer	Date Result Given	Notes

Page _____

If a participant chooses to receive test results **in person**, staff should try to schedule an appointment on a specific day and time for the participant to obtain their results. Participants will be more likely to return for their test results if they are given an appointment rather than just told to return at their convenience. An appointment also ensures that participants do not return before their test results are expected to be available.

Figure N.2 – Return of Lab Results Form

Return of Lab Results Form	
ID Number: _____	Test Date: _____
Your test results will be available about [# days/weeks] from today. Expected return date: _____	
1. How would you like to receive your test results?	
☐ In-person appointment ☐ Phone - you call us ☐ Phone - we call you	
2. If questionnaire was conducted in Spanish, would you prefer to receive your results in Spanish?	
☐ Yes ☐ No	
3. Add any additional instructions or notes: _____	

OPTION A: IN-PERSON APPOINTMENT	
4. On what day and time would you like to schedule your appointment?	
Your appointment is scheduled for:	
_____ day	_____ date at _____ AM PM
_____ time	
<i>Hand the Appointment Card to the participant and verbally explain the process:</i> To make sure we are returning test results to the right person, you will need to provide us with the identification number on this card to receive your results.	
<i>For project areas that are also providing results over the phone:</i> If you change your mind and would like to receive your test results over the phone, call the number on this card and we can assist you.	
OPTION B: PHONE - YOU CALL US	
5. <i>Hand the Phone Results Card to the participant and verbally explain the process:</i> You can call the phone number on this card to obtain your test results. To make sure we are returning results to the right person over the phone, you will need to provide us with the identification number on this card and answer a security question that you will set up today.	
5a. Some examples of security questions are "What is your mother's date of birth?" or "What is the name of your first pet?" What would you like your security question to be?	

5b. What is the answer to your security question? _____	

OPTION C: PHONE - WE CALL YOU	
6. What is your phone number? (_____) _____ - _____	
7. What are the best days and times to call you?	Days: _____ Times: _____
8. Is it okay for us to identify ourselves as [project name] when we make the phone call? ☐ Yes ☐ No	
9. We will not leave any voice mail messages with test results, but we may leave a voicemail reminding you to call us back for your results. Unless we are instructed otherwise, our standard phone message is:	
<i>Hello, this is [project name] calling to provide you with your results. Please call us back at [phone number] [hours of operation] [days of operation]. If you reach a busy signal during these times, please call back in several minutes. Thanks and have a great day.</i>	
If no one answers, is it okay to leave this message on your voicemail? ☐ Yes ☐ No	
10. <i>Hand the Phone Results Card to the participant and verbally explain the process:</i> To make sure we are returning test results to the right person over the phone, you will need to provide us with the identification number on this card and answer a security question that you will set up today.	
10a. Some examples of security questions are "What is your mother's date of birth?" or "What is the name of your first pet?" What would you like your security question to be?	

10b. What is the answer to your security question? _____	
11. Remember that test results will be ready about [# days/weeks] from today. If you do not get a call back from us by then, you can call us at the phone number on the card I gave you.	
STAFF USE ONLY	
1st Call: Date of Call: _____ Time of Call: _____ ☐ AM ☐ PM Outcome of Call: _____ Is another call necessary? ☐ Yes ☐ No If Yes: Call-back Date: _____ Call-back Time: _____ ☐ AM ☐ PM	
2nd Call: Date of Call: _____ Time of Call: _____ ☐ AM ☐ PM Outcome of Call: _____	
3rd Call: Date of Call: _____ Time of Call: _____ ☐ AM ☐ PM Outcome of Call: _____	

If a participant opts to receive test results **over the phone** (either by calling the project phone or by providing a phone number for staff to call them), staff must verify that the person on the phone is the appropriate participant while still protecting the participant's anonymity. Therefore, staff should ask participants to provide a security question, such as their mother's date of birth, the name of their first pet, or their favorite sports team, along with the answer. Staff should then record each participant's security question and answer on the Return of Lab Results Log or Form.

Because contact information cannot be stored with test results, project areas must use the survey ID, the laboratory ID, or a proxy ID to link a participant's contact information to their test results. If project areas choose to use a proxy ID, they should discuss methods of creating the ID with their CDC project officer. Most notably, proxy IDs should be sufficiently different from survey IDs to avoid any confusion between the two types of IDs. Project areas should describe their plans for linking contact information and test results in the Operations Checklist ([Appendix A](#)), and they should obtain their CDC project officer's approval for the plan. If project areas are using a proxy ID for linkage, they should include the method of creating the ID in the plan as well.

If the NHBS survey is offered in both English and Spanish, the return of test results should also be available in English or Spanish. Whenever participants complete the survey in Spanish, they should be asked if they would also like to receive their test results in Spanish.

Step 3 – Providing an Appointment or Phone Results Card

If participants choose to receive their laboratory-based test results **in-person** by appointment, staff should provide the participants with cards to remind them of their appointments. A model Appointment Card can be found in [Appendix M](#) of this manual. The card should have the project name, phone number, and days and hours of operation on it. The Appointment Card should also list the field site address or have a space to record the address of a field site where the appointment is scheduled.

If participants choose to receive their laboratory-based test results **over the phone**, staff should provide them with a Phone Results Card with the project name, phone number, and days and hours of operation on it. A model Phone Results Card can be found in [Appendix M](#) of this manual. Project areas should anticipate that participants will call for test results outside of the days and hours of operation and they should use the Operations Checklist to describe their plans for handling these calls via voicemail.

Since all testing conducted as part of NHBS must be anonymous, an ID number should be written on the card and used to locate and confirm participants' test results. This could be the survey ID, the laboratory ID, or a proxy ID. Staff should inform participants that they **must** provide the ID number on the card and, if applicable, the answer to their security question to obtain their test results. Participants can choose to take a photo of their Appointment Card or Phone Results Card to save it electronically, but staff cannot send the cards to participants electronically.

Step 4 – Returning the Test Result

When returning laboratory-based test results **in person**, project staff should ask participants for the ID number on their Appointment Cards so that the staff can look up their test results. To return laboratory-based test results **over the phone**, project areas should have a project phone that is staffed at pre-defined times for returning results. Personal phones or other devices should **never** be used to make phone calls to participants.

If the NHBS survey is offered in both English and Spanish, project areas should make an effort to have interpretation services available when test results are returned to participants. This includes having a plan for accessing interpretation services when Spanish-speaking participants call for their results. Since calls for test results are unscheduled, project areas must decide prior to starting data collection how they will provide interpretation services when a Spanish-speaking participant calls for results. For example, participants who prefer to have their results returned in Spanish could be encouraged to call during a time when an interpreter will be present. Some health departments and universities have interpretation services available in-person or through a 3-way call with a contracted interpretation service. Spanish-speaking NHBS project staff can also be utilized. Care should be taken to ensure that security and confidentiality are maintained when using non-NHBS staff.

Once new laboratory-based test results are available, staff should check the participants' preferred method of receiving their results to see if any participants need to be called. If a participant prefers to call the project for their results, then the staff **cannot** call the participant; they must abide by the participant's preference and wait for the participant to call them. Note that some participants may call the project office before their test results are available. In these cases, participants should be told to call back when their results are expected to be available or, if locally permitted, they could be offered the option to have the staff call them when the results are ready. Participants who call the project to receive their results should call during pre-defined phone results hours. Participants who call outside of these hours should be transferred to the project voicemail and asked to call back during the scheduled phone results hours. Below is an example voicemail message for the project phone:

Hello, you have reached [project phone number]. We are available [days and hours of operation] to give results. If you have a question or want a result, please call back during these times. If you reach a busy signal during these times, please call back in a few minutes. Messages cannot be left on this voicemail system.

Participants who provided their phone number to receive their test results should be called as soon as their results are available. Attempts to call participants who have not responded should be limited to three times. If a staff member knows a participant outside of NHBS, that staff member should not call the participant; another staff member should call them. Before making each call, staff should review the information provided by the participant to ensure that they follow the participant's instructions (e.g., preferred

language, use of project name, and whether to leave a voicemail message). Furthermore, when calling participants, staff should first confirm that the person is okay talking at that time and should reschedule the call if requested. If someone other than a participant answers the phone, staff should not provide any additional information about NHBS or the participant. If staff are told not to call back by a participant or someone other than the participant, they should note that in the “Staff Use” section of the Return of Lab Results Form, and they should not call back in the future. If staff call a participant and they do not answer, the staff cannot leave test results on the participant's answering machine or voicemail. Below is an example message that can be left on a participant’s answering machine or voicemail:

Hello, this is [project name] calling to provide you with your results. Please call us back at [project phone number]. We are available [days and hours of operation]. If you reach a busy signal during these times, please call back in a few minutes. Thanks and have a great day.

When returning test results **over the phone**, project areas must implement a two-step verification system (e.g., ID number and security question answer) to confirm that the person on the phone is the appropriate participant before returning results. For example, staff should ask the person for their ID number (i.e., survey ID, laboratory ID, or proxy ID on the Phone Results Card). Once the participant’s test information and results have been found, staff should ask the participant their security question and confirm the answer. Participants **must** pass the two-step verification before test results can be given by phone.

It is reasonable to anticipate that those who call the project phone will have their ID number since both the project phone number and ID number are listed on the Phone Results Card. This ID number will be needed to locate their test information and results. On the other hand, it is possible that participants who provided their phone numbers may not have their ID number when staff call to return results, or they may have lost their Phone Results Card with the ID number. If a participant does not have their ID number when staff call but is able to answer their security question, then staff should ask a second (or alternative) question to verify the participant’s identity. Examples of alternative questions include the location where the participant was tested or a description of their interviewer or test counselor. If the participant is able to accurately answer both their security and alternative questions over the phone, then test results may be given as long as staff are reasonably confident that they are talking to the participant. Participants without this information need to call back when they have their ID number available, or they could return for test results **in person** with their ID number. If a participant does not have their ID number and they cannot correctly answer their security and alternative questions, then test results cannot be provided to that participant. In these situations, staff should refer participants to a facility where they can be re-tested and receive their results. **Table N.1** summarizes the information needed to verify a participant’s identity to receive their laboratory-based test results.

Table N.1 – Verifying a participant’s identity

Method of Contact	Required Information for Verification
In-person	ID number on Appointment Card
Participant calls the project office	1) ID number on Phone Results Card AND 2) Security question (preferred) OR Alternative question (e.g., testing location, interviewer description)
Project staff call the participant	1) ID number on Phone Results Card AND 2) Security question (preferred) OR Alternative question (e.g., testing location, interviewer description) OR ----- 1) Security question AND 2) Alternative question (e.g., testing location, interviewer description)

Regardless of how test results are returned, staff should **always confirm** that participants are ready to receive their results before they are provided. If participants are ready and confirm their identity, staff should provide their results and **record the date the results were returned** in the applicable log or form. Participants with positive test results should be linked to care and to any other necessary services. Participants with indeterminate test results or whose specimens were unable to be tested should be linked to follow-up testing. Participants with negative test results should be linked to any other prevention or needed services.



If a staff member is providing a result **over the phone** and believes the participant is not mentally able to handle a positive test result remotely, the staff member should ask the participant to schedule an appointment to obtain their result **in person**.



A participant who becomes upset or angry when they learn their test results should be kept on the phone. Staff should listen to the participant’s concerns and remain with them until they become calm. Staff should also link the participant to follow-up counseling and advise them to seek immediate support from a friend or relative.

Table N.2 contains a phone script with some example language for calling participants with their laboratory-based test results.

N.2 Data Security and Management

If the collection of phone numbers is permitted locally as an option for participants to receive their laboratory-based test results, staff must abide by all guidance pertaining to the collection of contact information in this appendix and in **Sections 3.3b** and **4.6** of this manual. This includes having staff other than an interviewer (e.g., field supervisor or project coordinator) be responsible for collecting and managing contact information from participants and only using the contact information for the purposes for which it was collected. Although survey IDs and laboratory IDs can be stored with contact information, ***no other NHBS data, including test results, can be stored with it.***

Furthermore, any forms or logs containing contact information must be 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 [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 \(cdc.gov\)](#)). Hard copies of forms or logs with contact information should be stored in a ***locked*** file cabinet under the supervision of the field supervisor or project coordinator, and electronic copies should be stored on a ***secure*** network drive. Project areas collecting contact information to return test results must describe their plans for storing and protecting this information in the Operations Checklist, and they must receive their CDC project officer's approval.

Hard or electronic copies of forms or logs containing contact information should only be accessed by a limited number of staff who are responsible for managing this information and returning laboratory-based test results. Contact information must be destroyed once it is no longer needed for the purpose for which it was collected; for the return of test results, this means once the results have been returned to the participant, once staff have attempted to return results to the participant three times, or by six weeks after the end of data collection, whichever comes first.

Table N.2 – Phone script

Initial script:	
Hi, I was given this phone number by the person who participated in our survey a couple of weeks ago. I'm calling with their results. Am I speaking with the person who participated in the survey?	
<i>If yes...</i>	<i>If no...</i>
Are you in a place where you can talk privately? <i>If yes:</i> I want to return some results I have for you. To do this, I need the ID number on the card we gave you. Can you give me that number? <i>If no:</i> When would be a better day and time to reach you this week? <i>Record day and time on form. Thank person and end call.</i>	Is that person available now? <i>If yes:</i> When the participant comes on the phone, repeat the initial script. <i>If no:</i> Is there a day and time this week when it's best to reach that person? <i>Record day and time on form. Thank person and end call.</i>

Note: [Table N.2](#) continues on the following two pages.

Table N.2 – Phone script (continued)

If the participant has their ID number and it matches:	
Now I need to ask your security question. <i>Ask security question.</i>	
<i>If the answer to the security question is correct...</i>	<i>If the answer to the security question is <u>not</u> correct...</i>
<i>Confirm that the participant is ready to receive their test results and if so, provide the results.</i> <i>Negative test results:</i> All of your results were negative, meaning we did not find any <i>[types of infection]</i>. Do you have any questions? <i>Thank person and end call.</i> <i>Positive test results:</i> Your test was positive for <i>[types of infection]</i>. <i>Interpret the test result.</i> Do you have any questions? It's important that you get treated right away and notify your partners. We can set up treatment with <i>[medical facility]</i>. <i>Begin linkage to care plan.</i> <i>If the participant also had negative results:</i> You were also tested for <i>[types of infection]</i> and those results were negative. Do you have any other questions? <i>Thank person and end call.</i>	Since that doesn't match what we have in our system, let me ask you another question to confirm your identity. <i>Ask alternative question.</i> <i>If the answer to the alternative question is correct and negative test results:</i> All of your results were negative, meaning we did not find any <i>[types of infection]</i>. Do you have any questions? <i>Thank person and end call.</i> <i>If the answer to the alternative question is correct and positive test results:</i> Your test was positive for <i>[types of infection]</i>. <i>Interpret the test result.</i> Do you have any questions? It's important that you get treated right away and notify your partners. We can set up treatment with <i>[medical facility]</i>. <i>Begin linkage to care plan.</i> <i>If the participant also had negative results:</i> You were also tested for <i>[types of infection]</i> and those results were negative. Do you have any other questions? <i>Thank person and end call.</i> <i>If the answer to the alternative question is <u>not</u> correct:</i> Unfortunately, that doesn't match what we have in our system. Because we cannot verify your identity, we can't provide your results. We encourage you to get tested for <i>[types of infection]</i> regularly. Here's a place where you can get tested. <i>Facilitate linkage to testing. Thank person and end call.</i>

Table N.2 – Phone script (continued)

If the participant does <u>not</u> have their ID number:	
You did provide a security question. <i>Ask security question.</i>	
<i>If the answer to the security question is correct...</i>	<i>If the answer to the security question is <u>not</u> correct...</i>
Great, now I need to ask one last question. <i>Ask alternative question.</i> <i>If the answer to the alternative question is correct and negative test results:</i> All of your results were negative, meaning we did not find any <i>[types of infection]</i>. Do you have any questions? <i>Thank person and end call.</i> <i>If the answer to the alternative question is correct and positive test results:</i> Your test was positive for <i>[types of infection]</i>. <i>Interpret the test result.</i> Do you have any questions? It's important that you get treated right away and notify your partners. We can set up treatment with <i>[medical facility]</i>. <i>Begin linkage to care plan.</i> <i>If the participant also had negative results:</i> You were also tested for <i>[types of infection]</i> and those results were negative. Do you have any other questions? <i>Thank person and end call.</i> <i>If the answer to the alternative question is <u>not</u> correct:</i> Unfortunately, that doesn't match what we have in our system. Because we cannot verify your identity, we can't provide your results. We encourage you to get tested for <i>[types of infection]</i> regularly. Here's a place where you can get tested. <i>Facilitate linkage to testing. Thank person and end call.</i>	Unfortunately, that doesn't match what we have in our system. Because we cannot verify your identity, we can't provide your results. We encourage you to get tested for <i>[types of infection]</i> regularly. Here's a place where you can get tested. <i>Facilitate linkage to testing. Thank person and end call.</i>

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](#).

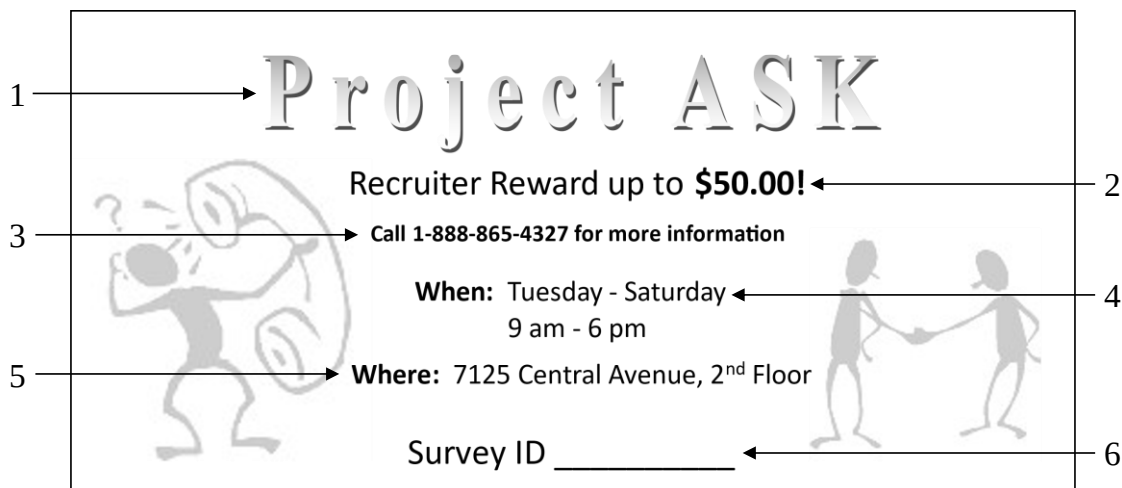
NHBS Field Incident Report	
Project Area: _____	
Name of Person Filing Report: _____	
Position of Person Filing Report (check all that apply):	
☐ Interviewer	
☐ Field Supervisor	
☐ Project Coordinator	
☐ Other (Specify): _____	
Location of Incident (name and address):	

Date of Incident: ____ / ____ / ____	Time of Incident: ____ : ____ ☐ AM ☐ PM
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
☐ Police	Date: ____ / ____ / ____ Time: ____ : ____ ☐ AM ☐ PM
☐ IRB	Date: ____ / ____ / ____ (attach report)
☐ Other (specify): _____	Date: ____ / ____ / ____ Time: ____ : ____ ☐ AM ☐ PM
Reported to CDC:	Date: ____ / ____ / ____ Time: ____ : ____ ☐ AM ☐ PM
Name of Contact at CDC: _____	
Comments (other information relevant to the incident):	

Participants who agree to be recruiters should be given information cards indicating where and when they can obtain their recruiter rewards. The card should also include the project phone number so recruiters can call to see if they are owed any rewards. Examples of the front and back of an information 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 R](#) of this manual. The color and size of the information cards should differ from those of 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

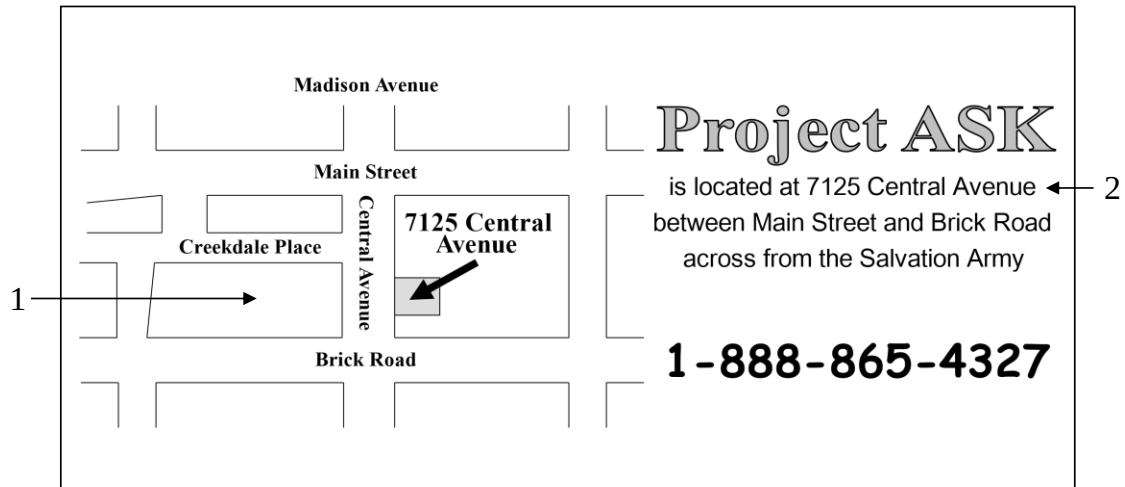


1. Name of the local NHBS project.
2. Maximum recruiter reward a participant could earn.
3. Phone number participants can call for project information or to see if they are owed any rewards. It is best to have a toll-free number because of the likely disadvantaged economic status of many participants.
4. Days and hours of field site operations.
5. Address of the field site.
6. Space to record the participant's survey ID to search for their record in the Coupon Manager Program (CMP).



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.

Appendix Q

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 Q - Recruiter Training Talking Points](#).

Who to Recruit

- We're going to give you **[insert #]** coupons to give to other people who inject drugs, even if they only inject once in a while, so that they can be in the survey 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 survey.

Coupons

- Everyone must have a coupon to be in the survey.
- Tell people you recruit to have their coupon with them when they come in or when they call to schedule an appointment.
- Your coupons cannot be replaced if they are lost or stolen or the person you recruited is not selected for the survey.
- ***If a project area 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 area is using photo coupons:*** Keep the message you send with each coupon 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 area 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 area is using photo coupons:*** Each coupon photo should be sent to one person only. If more than one person tries to use the same coupon photo, just the first person using it will be allowed to participate in the survey.

Process

- ***If a project area is not conducting hepatitis testing:*** The whole process for the survey takes about 1 hour.
- ***If a project area is not conducting hepatitis testing:*** Everyone will get \$[insert interview incentive] for completing the interview and an additional \$[insert HIV testing incentive] for testing for HIV.
- ***If a project area is conducting hepatitis testing:*** The whole process for the

survey takes about *[insert estimated time for interview and HIV and hepatitis testing]*.

- ***If a project area is conducting hepatitis testing:*** Everyone will get \$*[insert interview incentive]* for completing the interview, an additional \$*[insert HIV testing incentive]* for testing for HIV, and an additional \$*[insert hepatitis testing incentive]* for testing for hepatitis.
- ***Optional or as needed:*** 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.
- ***Optional or as needed:*** People who aren't able to complete the interview won't be allowed to participate in the survey. 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 completes the interview; the \$*[insert recruiter reward]* is not guaranteed just for recruiting someone.
- ***Optional or as needed:*** You will not be paid for someone who is not selected for the survey.
- ***Optional or as needed:*** You will not be paid for someone who has already participated.
- ***Optional or as needed:*** You will not be paid for someone who does not complete an interview.
- Coupons will expire and the survey will end at some point.

Recruiter Information

- We ask questions to create an identification code that is unique to you so that we can identify you when you come to get your rewards. When you come in to get paid, we'll ask you those same questions again to create the code.
- The coupons we give you are linked to you, so we'll know that you are owed a reward.
- Call our office to find out if you are owed a reward.
- We will only pay you. Don't send someone else in to get paid.

Do you have any questions? Remember, give the coupons to people you know and who inject drugs, even if they only inject once in a while. The goal of this project is to improve services for people who inject drugs so it's very important for you to give your coupons just to people who inject.

Thank you for helping your community!

Appendix R Instructions for Creating Referral Cards, Coupons, and Information Cards

Project areas 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. Project areas 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 R - Model Referral Card - Front](#)

[Appendix R - Model Referral Card - Back](#)

[Appendix R - Model Coupon - Front](#)

[Appendix R - Model Coupon - Back](#)

[Appendix R - Model Information Card - Front](#)

[Appendix R - Model Information Card - Back](#)

Project areas should edit the templates to create their own unique designs. Those project areas 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 area 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.

R.1 Using PowerPoint Templates

The Microsoft PowerPoint templates can be edited, copied, and printed as described in the steps below.

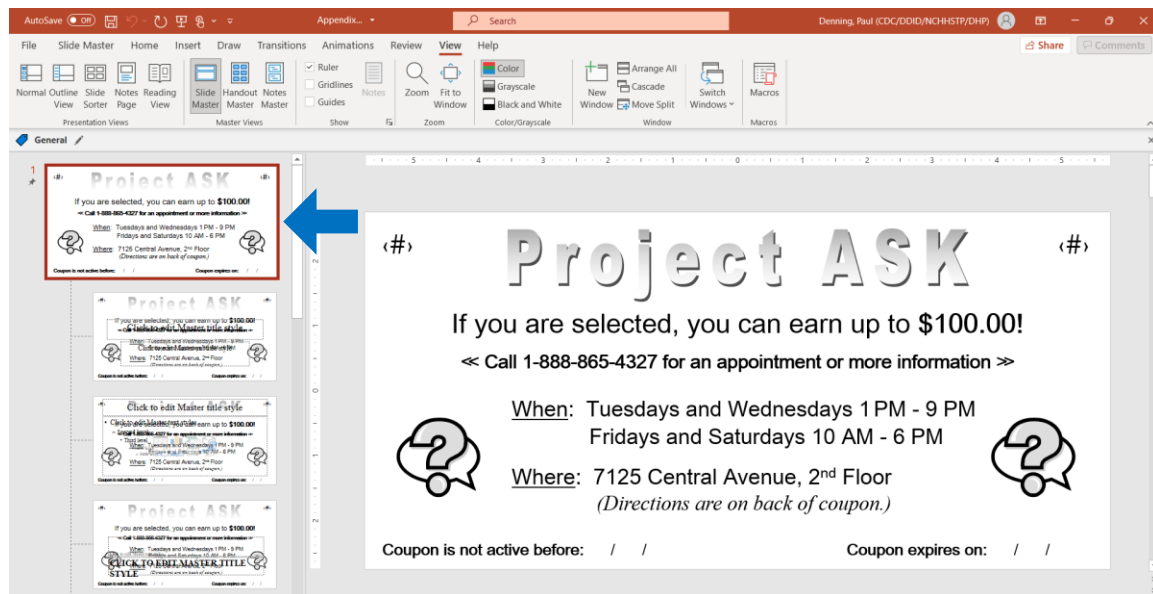
R.1a Editing

The template files were initially saved in the “Slide Master” view and should automatically open in this 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.



When changing to the “Slide Master” view from another view, check the thumbnails on the left side of the pane to make sure that slide 1, which can be edited, is selected (see [Figure R.1](#)).

Figure R.1 – Slide Master view with slide 1 selected



Auto-numbering

The front templates for the referral cards and coupons include auto-numbering (indicated by “<#>”) to automatically number the cards and coupons in sequential order. As described below, some auto-numbering functions can be changed while in the “Slide Master” view and others while in the “Normal” view. To change between these views:

1. Select the **View** tab.
2. Select **Slide Master** view or **Normal** view as needed.

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 the **Slide Number** icon . 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. Use the **View** tab to change from the “Slide Master” view to 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 needed, one of the zeros should be deleted so that the auto-numbering symbols are preceded by two zeros (“00<#>”) and the start number should be changed to “10.” This will allow the numbers “0010” to “0099” to be automatically generated.

R.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** view.
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).
5. After duplicating the cards or coupons, save the file so that the same numbers are not repeated the next time the file is opened and cards or coupons are duplicated.

R.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 area during the NHBS-HET1 pilot.

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

S.1 Hepatitis B Virus Testing

Testing for HBV infection requires 3 laboratory-based tests: 1) hepatitis B surface antigen (HBsAg), a protein on the surface of HBV; 2) total antibody to hepatitis B core antigen (anti-HBc), an antibody to HBV core proteins; and 3) antibody to HBsAg (anti-HBs), an antibody to HBV surface proteins. The presence of each antigen or antibody indicates a different stage of HBV infection. HBsAg indicates current (active) infection, anti-HBc indicates current or past (resolved) infection, and anti-HBs indicates immunity to infection (either from natural infection or vaccination). If a participant is found to be currently infected with HBV, a test for IgM anti-HBc can be performed to help distinguish between acute and chronic HBV infection. [Table S.1](#) outlines the interpretation of HBV test results for counseling participants and linking them to care or services (e.g., treatment for those who are infected with HBV or vaccination for those who are susceptible).

S.2 Hepatitis C Virus Testing

This section describes rapid and laboratory-based testing for HCV infection, interpreting test results, and linking participants to care or services.

S.2a Rapid HCV Testing

The FDA has approved a rapid HCV test for use on blood collected through venipuncture or fingerstick. The test is CLIA-waived for use in the field by non-laboratory staff and results are available within 20-30 minutes. A reactive rapid test indicates the presence of HCV antibodies from either a current (active) or past (resolved) HCV infection and is considered a positive test result. A positive test result on a rapid test is equivalent to a positive test result on an enzyme immunoassay (EIA), the standard laboratory-based screening test for HCV infection (see [Section S.2b](#) below). A non-reactive rapid test means that HCV antibodies were not detected and is considered a negative result. Project areas should return rapid HCV test results to participants, and all participants with positive test results should be linked to care to be evaluated for current HCV infection (see [Section S.2c](#) below for guidance on counseling participants and linking them to any needed care or services).

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

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

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

S.2b Laboratory-based HCV Testing

There are 2 types of laboratory-based HCV tests. One type of test is an EIA test, which measures HCV antibodies, and the other is a nucleic acid test (NAT), which measures HCV ribonucleic acid (RNA). Greater detail on each of these tests is provided below.

Enzyme Immunoassay (EIA)

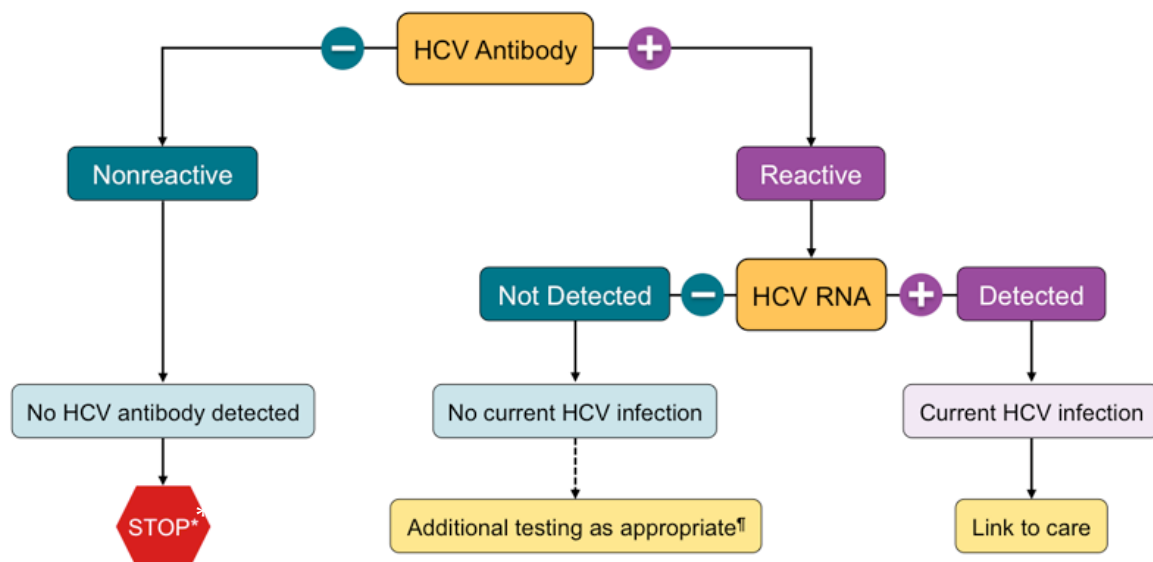
The standard laboratory-based screening test for HCV infection is an EIA test. A reactive EIA test indicates the presence of HCV antibodies from either a current (active) or past (resolved) HCV infection and is considered a positive test result. A non-reactive EIA test means that HCV antibodies were not detected and is considered a negative result.

Nucleic Acid Test (NAT)

A NAT for HCV RNA is the standard supplemental test for someone with a positive antibody test (i.e., a positive HCV rapid or EIA test result). NATs can be used to

determine whether those with positive antibody tests have either current (active) or past (resolved) HCV infection. NATs can also be used to identify acute HCV infections in persons with negative antibody tests. NATs are either quantitative tests, which count the number of hepatitis C virions in a cubic millimeter (mm) of blood, or qualitative tests, which detect the presence of HCV RNA. Qualitative NATs report results as reactive (positive) or non-reactive (negative). Both types of NATs are FDA approved and have similar lower limits of detection. **Figure S.1** shows the CDC-recommended testing sequence for diagnosing current HCV infection using an antibody test and a NAT. By modifying this testing sequence and conducting NATs on those with negative antibody tests, the sequence can also be used to identify acute HCV infections.

Figure S.1 – CDC-recommended testing sequence for diagnosing current hepatitis C virus (HCV) infection



*For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

†To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Sources:

Spach, D. Screening and Diagnosis of Hepatitis C infection: Hepatitis C Diagnostic Testing. *Hepatitis C Online*. 2018. <https://www.hepatitisc.uw.edu/go/screening-diagnosis/diagnostic-testing/core-concept/all>.

Centers for Disease Control and Prevention (CDC). Testing for HCV infection: an update of guidance for clinicians and laboratorians. *MMWR Morb Mortal Wkly Rep*. 2013;62:362-5.

S.2c Interpreting HCV Test Results and Linking to Care and Services

Table S.2 helps project areas interpret the results of HCV tests so that they can properly counsel participants and link them to any needed care or services. Participants with positive antibody tests who have not received NAT should be linked to care to be evaluated for current (active) HCV infection. Even those participants with positive antibody tests who are known to have had a past (resolved) HCV infection should be evaluated for current HCV infection because they could have become re-infected with the virus. All participants with HCV RNA detected by NAT, regardless of their HCV antibody status, should be linked to care to be evaluated for stage of liver disease and treatment.

Since a person recently infected with HCV may not have developed antibodies at the time of testing, it is possible that a rapid or EIA antibody test may not detect an acute HCV infection (i.e., would produce a false negative test result). Therefore, when project areas are counseling participants with negative antibody tests, they should inform the participants of the possibility of a false negative test result. Moreover, participants with negative antibody tests who are at increased risk of HCV infection, such as persons who inject drugs or HIV-positive MSM, should be advised to get re-tested every 3-6 months.

Table S.2 – Interpretation of hepatitis C virus (HCV) test results

Test Outcome	Interpretation	Further action
HCV antibody nonreactive, HCV RNA not detected or HCV RNA not done	No HCV antibody detected	Sample can be reported as nonreactive for HCV antibody. No further action required. If recent HCV exposure in person tested is suspected, test for HCV RNA.*
HCV antibody nonreactive, HCV RNA detected	Acute HCV infection	Provide person tested with appropriate counseling and link person tested to medical care and treatment.†
HCV antibody reactive, HCV RNA not done	Presumptive HCV infection	A repeatedly reactive result is consistent with current HCV infection, or past HCV infection that has resolved, or biologic false positivity for HCV antibody. Test for HCV RNA to identify current infection.
HCV antibody reactive, HCV RNA detected	Current HCV infection	Provide person tested with appropriate counseling and link person tested to medical care and treatment.†
HCV antibody reactive, HCV RNA not detected	No current HCV infection	No further action required in most cases. If distinction between true positivity and biologic false positivity for HCV antibody is desired, and if sample is repeatedly reactive in the initial test, test with another HCV antibody assay. In certain situations‡ follow up with HCV RNA testing and appropriate counseling.

*If HCV RNA testing is not feasible and the person tested is not immunocompromised, do follow-up testing for HCV antibody to demonstrate seroconversion. If the person tested is immunocompromised, consider testing for HCV RNA.

†Before initiating antiviral therapy, it is recommended to retest for HCV RNA in a subsequent blood sample to confirm HCV RNA positivity.

‡If the person tested is suspected of having HCV exposure within the past 6 months, or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Sources:

Centers for Disease Control and Prevention (CDC). Testing for HCV infection: an update of guidance for clinicians and laboratorians. MMWR Morb Mortal Wkly Rep. 2013;62:362-5.

Appendix T

Fingerstick Quick Reference Guide

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

Valid DBS Specimens...



Supply list...

- Band aids
- Cotton balls
- Alcohol prep pads
- Lancets
- Absorbent paper (e.g., "chux")
- 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 their non-dominant hand
- Assess positioning of the participant to decide the easiest way to collect blood for the rapid test and DBS

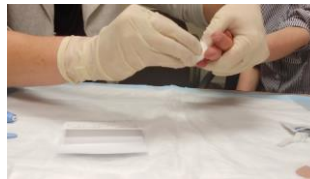


- Assess which finger is free of callouses and has the softest skin – this is typically the ring finger
- Even if the participant's hands are warm, massage the whole hand to increase circulation; hold participant's hand downward (below the heart) while massaging. Circulation can also be increased by asking the participant to pump hand or squeeze a stress ball
- Ask participant to flick their 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 them 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 near (but not directly on top of) the first drop in order to more completely fill the circle
- Continue the above procedures as you move to next circle



- Upon completion, the circles should be full



This appendix contains a list of supplies that project areas will need for creating and shipping dried blood spots (DBS) to CDC, along with some example vendors.



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.

U.1 Supplies for Specimen Collection

Lancets

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

Vendor: Beckton-Dickinson
[BD Microtainer® Contact-Activated Lancet - 366594 | BD](#)

DBS Cards

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

Vendor: Cytiva Life Sciences
[Whatman 903 Proteinsaver Card | Cytiva \(cytivalifesciences.com\)](#)

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

Product: Item # 13-711-9BM
Sterile Disposable Graduated Transfer Pipettes
Capacity: 5.8 mL with 0.25 mL graduations

Vendor: Fisher Scientific
[Fisherbrand Disposable Graduated Transfer Pipettes Capacity: 5.8mL; Sterile; | Fisher Scientific](#)

Note: DBS supplies continue on the following pages.

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

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

Product: Item # 19-240-200
Zip closure; 7 in. x 8 in.

Vendor: Fisher Scientific
[Fisherbrand Bitran Specimen Storage Bags Polyethylene; Size: 7 x 8 in.:Environmental | Fisher Scientific](#)

Desiccant Packets



Desiccant packets from previous NHBS cycles can be used for the current cycle if the pouches containing the packets have not been opened. On the other hand, if the pouches containing the packets have been opened, new desiccant packets must be purchased. Once the pouches are opened, the new desiccant packets should be stored in air-tight containers, with a humidity indicator placed in each container.

Product: Item # 09-928-142
Cytiva Desiccant Packs
1 gram desiccant packs, 100 packs/case

Vendor: Fisher Scientific
[Desiccant Packs, Cytiva](#)

Product: MiniPax Indicating Silica Gel Packets (1.0 Gram)
1 gram desiccant packets with blue indicator that turns pink in high humidity, 1,000/can, sold as 6 cans per case (6,000)

Vendor: Multisorb Technologies
[MiniPax - Compact Cut Desiccant Packets - Multisorb](#)

Humidity Indicator Cards



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

Product: Item # 89024-422
3-Spot Humidity Indicator Cards, Indicates: 30, 40, 50%

Vendor: VWR
[Humidity Indicator, Desco Industries | VWR](#)

Note: DBS supplies continue on the following page.

Envelopes

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

Vendor: Staples

[Staples® Official Online Store](#)

Office Depot

[Office Depot OfficeMax | Official Online Store](#)

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 V

Process Monitoring Reports

The NHBS Data Coordinating Center (DCC) will produce the process monitoring reports and post them on the DCC data portal. Project areas 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.

V.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	Eligible		Completed Interview		Consented to HIV Testing	
			No.	%	No.	%	No.	%
Total								

Consented to STI Testing		Consented to Hepatitis Testing		Consented to Specimen Storage		Eligible to Recruit	
No.	%	No.	%	No.	%	No.	%

V.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 someone who injects drugs		
Other		
Unknown		
Total		

V.3 Sample Characteristics – Screened Report

1. QUESTIONNAIRE VERSION

Questionnaire Version	N	%
Total		

2. AGE

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

3. GENDER IDENTITY/SEX AT BIRTH

Gender Identity/Sex at Birth	Eligible		Not Eligible		Total	
	N	%	N	%	N	%
Man/Male						
Man/Female						
Man/Intersex						
Woman/Male						
Woman/Female						
Woman/Intersex						
Non-binary/Male						
Non-binary/Female						
Non-binary/Intersex						
Unknown						
Total						

4. RACE/ETHNICITY

Race/Ethnicity	Eligible		Not Eligible		Total	
	N	%	N	%	N	%
American Indian or Alaska Native						
Asian						
Black or African American						
Hispanic						
Native Hawaiian or Other Pacific Islander						
White						
Multiple Races						
Unknown						
Total						

5. MSA RESIDENT

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

6. KNOWN PREVIOUS PARTICIPANT

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

7. ABLE TO PARTICIPATE

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

8. TOO YOUNG TO PARTICIPATE

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

9. INJECTION IN THE PAST 12 MONTHS

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

10. TYPE OF DRUG INJECTED MOST OFTEN

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

V.4 Sample Characteristics – Interviewed Report

1. AGE

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

2. GENDER IDENTITY/SEX AT BIRTH

Gender Identity/Sex at Birth	N	%
Man/Male		
Man/Female		
Man/Intersex		
Woman/Male		
Woman/Female		
Woman/Intersex		
Non-binary/Male		
Non-binary/Female		
Non-binary/Intersex		
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

Income	Total	
	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		
Methamphetamine (i.e., crystal, speed, crank)		
Painkillers (e.g., Oxycontin, Dilaudid, Percocet)		
Something else		
Unknown		
Total		

8. ZIP CODE

Zip Code	N	%
Total		

V.5 Test Results Report

1. HIV RAPID TEST RESULT

	Rapid HIV Test Result #1										Total
	Preliminary Positive		Negative		Invalid		Not Done		Unknown		
Rapid HIV Test Result #2	N	%	N	%	N	%	N	%	N	%	N
Preliminary Positive											
Negative											
Invalid											
Not Done											
Unknown											
Total											

2. SELF-REPORTED HIV TEST RESULT

	NHBS HIV Test Result Interpretation										Total
	Positive		Negative		Unknown - Discordant Test Results		Unknown - Unconfirmed Self-Reported Positive		Unknown		
Self-Reported HIV Test Result	N	%	N	%	N	%	N	%	N	%	N
Positive											
Negative											
Unknown											
Total											

3. SPECIMEN COLLECTED FOR CDC LAB

	Self-Reported Positive		Not Self-Reported Positive						Unknown		Total
			At Least 1 Reactive Rapid Test Result		Negative on PrEP		Other				
Specimen Collected for CDC Lab	N	%	N	%	N	%	N	%	N	%	N
Yes											
No											
Total											

4. HEPATITIS C TEST RESULT

	RNA Test Result										Specimen Not Collected		Total
	Positive		Negative		Not Done		Unknown - Specimen Collected >2 Weeks Ago		Unknown				
Rapid HCV Test Result	N	%	N	%	N	%	N	%	N	%	N	%	N
Reactive													
Non-reactive													
Invalid													
Not Done													
Unknown													
Total													

5. RETURNED HEPATITIS C LAB RESULTS

	Returned Hepatitis C Lab Results						Total
	Yes		No		Unknown		
RNA Test Result	N	%	N	%	N	%	N
Positive							
Negative							
Not Done							
Unknown							
Total							

6. HEPATITIS B TEST RESULT

	HBV Test Result Interpretation												Specimen Not Collected		Total	
Returned Hepatitis B Lab Results	Susceptible		Immune Due to Resolved Previous Infection		Immune Due to Vaccination		Current HBV Infection		Not Done		Unknown					
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Yes																
No																
Unknown																
Total																

V.6 Seed Report

1. SEED MONITORING

No. Screened	No. Eligible	No. Completed Interview	No. Eligible to Recruit

2. SEED CHARACTERISTICS

Date	Survey ID	Sex at Birth	Gender Identity	Race/Ethnicity	Age	Drug of Choice	Network Size	Eligible to Recruit

V.7 Respondent Driven Sampling Report

1. RECRUITMENT BY STRANGER

Recruitment by Stranger	N	%
Yes		
No		
Unknown		
Total		

2. FIELD SITE ENROLLMENT

Day of Week	No. of Interviews				Total
	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

	Recruit's Field Site				Total
Race/Ethnicity	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

	Recruit's Field Site				Total
Age	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. NETWORK SIZE BY FIELD SITE

Network Size	Recruit's Field Site				Total
	Field Site ID 1	Field Site ID 2	Field Site ID 3	Field Site ID 4	
0					
1					
2					
3					
4					
5					
6 – 9					
10 – 19					
20 – 39					
≥ 40					
Unknown					
Total					

7. RECRUITMENT CHAINS

Chain	Wave	Frequency	Percent	Cumulative Frequency	Cumulative Percent

V.8 Possible Previous Participant Report

1. POSSIBLE PREVIOUS PARTICIPANTS

Date of Birth	Sex at Birth	Gender Identity	Race/Ethnicity	No. of Records

V.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. INTERVIEWER CONFIDENCE IN RESPONSES

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

3. TESTING CONSENT

Interviewer ID	Consented to HIV Testing		Consented to STI Testing		Consented to Hepatitis Testing		Consented to Specimen Storage		Total
	N	%	N	%	N	%	N	%	N
Total									

4. CODING OF OTHER INSURANCE

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