

**National HIV Behavioral Surveillance System:
Injection Drug Users
(NHBS-IDU3)**

**OPERATIONS
MANUAL**



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

Version Date: May 25, 2012

ACKNOWLEDGEMENTS

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

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Suggested Citation:

Centers for Disease Control and Prevention. *National HIV Behavioral Surveillance System in Injecting Drug Users – Round 3: Operations Manual. May 25, 2012.* Available from: Gabriela Paz-Bailey (gpazbailey@cdc.gov).

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1.1 Overview

The *NHBS-IDU3 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 3 Model Surveillance Protocol* in order to prepare for NHBS activities. Copies of the operations manual and the protocol should also be available for reference at each field site and at the project office.

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

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

1.2 Justification

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

1.3 Staff Responsibilities

CDC staff are responsible for writing the *NHBS-IDU3 Operations Manual* and providing technical assistance to project sites during implementation. Local NHBS staff are responsible for conducting the project using the procedures described in the manual and

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

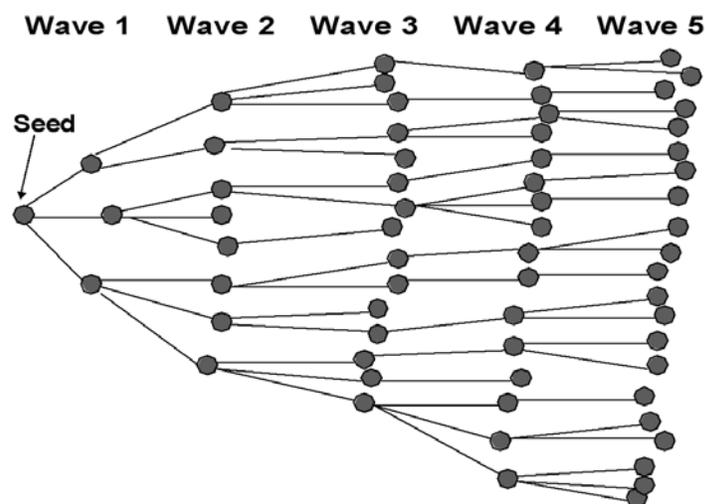
1.4 Respondent-Driven Sampling

The sampling method used during the IDU cycles of NHBS is RDS, a type of peer-driven chain-referral sampling (Heckathorn 1997, 2002). Although there are biases associated with chain-referral sampling that can affect the composition of the sample achieved, RDS can control for these biases through its methods of data collection and analysis. In addition, RDS is capable of producing population estimates when the data are analyzed with the RDS Analysis Tool (RDSAT) software program. 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 an encoded number on the recruitment coupons, and they are limited in how many people they can recruit based on the number of recruitment coupons they are given. In NHBS, the maximum number of coupons that can be distributed to each participant is five.

Figure 1.1 – RDS recruitment waves



Source: *Behavioral Surveillance Introduction to Respondent-Driven Sampling Participant Manual*, CDC Global AIDS Program, September, 2007

1.4b RDS theory and assumptions

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

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

One of the concerns with chain-referral sampling is that the final sample will be composed of individuals with characteristics similar to those of the seeds. However, the RDS method minimizes this limitation. RDS follows a mathematical process which causes the sample to approach an “equilibrium” in composition as recruitment chains become longer with each wave of recruitment. 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.

1.4c RDS and bias

One bias with chain-referral sampling is that people with large personal networks (i.e., who know many other people) are more likely to recruit participants, and are therefore more likely to be overrepresented in the sample. A second bias with chain-referral sampling is that people tend to know others who are like themselves. This tendency for “within-group” association is called “homophily” and affects recruitment because participants often recruit people who have similar characteristics to themselves. These biases can be minimized by limiting the number of coupons given to each recruiter and generating long chains of recruitment that approach equilibrium. In addition, by conducting data analysis in RDSAT, data are weighted by the participant's personal network size (those with smaller networks are given more weight than those with larger networks) and by the probability of one sub-population recruiting another (e.g., men

recruiting women). This weighting further reduces some of the biases associated with chain-referral sampling and is how RDS is able to produce population estimates.

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



The NHBS questionnaire has a series of “Network Questions” that ask participants to 1) estimate their personal network size, and 2) describe their relationship to their recruiter. Since these questions measure adherence to some of the RDS assumptions, it is important for interviewers to clarify any potentially inaccurate responses to these questions.

1.5 Operations Checklist

The Operations Checklist is found in **Appendix A** (in prior rounds of NHBS this document was referred to as the Pre-implementation Checklist). Project sites should complete the checklist, along with the requested attachments, and send them to their CDC project officer at least *two weeks* before the planned start of data collection. If they choose, project sites can also send draft sections of the checklist to their CDC project officer as soon as the sections are completed. Once the checklist has been finalized, the CDC project officer will set up a conference call with the project site to review the checklist to ensure that all preparatory activities have been satisfactorily completed. Data collection *cannot* begin until the CDC project officer has given approval. Over the course of data collection, project sites should revise the checklist whenever there are any changes to operations (e.g., new staff, new field sites, etc.) and they should promptly send the revised version of the checklist to their CDC project officer.

1.6 References

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

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

Heckathorn D. Extensions of respondent-driven sampling: analyzing continuous

variables and controlling for differential recruitment. *Sociological Methodology* 2007; 37(1):151-207.

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

2

Staffing, Training, and Evaluation

2.1 Overview

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

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

2.2 Staffing

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

2.2a Management staff

Each project site should have the following management positions: principal investigator, project coordinator, and field supervisor. Each position is discussed below. Management staff are responsible for implementing project operations in compliance with all NHBS guidance (e.g., *NHBS Round 3 Model Surveillance Protocol*, *NHBS Formative Research Manual*, *NHBS-IDU3 Operations Manual*, and *Round 3 NHBS Interviewer Guide*) and locally developed policies.

Principal investigator

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

Project coordinator

The project coordinator is responsible for the day-to-day management of the project including providing support for key administrative functions. Project coordinators will spend up to 100% of their time on the project. Generally, the project coordinator and

Table 2.1 – Recommended positions and responsibilities for management staff

| Responsibilities | Principal Investigator (PI) | Project Coordinator | Field Supervisor |
|----------------------------------|---|---|---|
| <p>Administrative</p> | <ul style="list-style-type: none"> • Oversee the hiring and supervision of project staff. • Tailor <i>NHBS Round 3 Model Surveillance Protocol</i> per site-specific needs. • Apply for and obtain Institutional Review Board (IRB) approval(s), inform IRB(s) of procedural changes and other revisions, and send IRB approval letters to CDC. • Ensure all subcontracting agencies having contact with human subjects have a Federalwide Assurance (FWA) number. (Health department only) • Review, monitor, and assure compliance with established Notice of Award guidelines to provide fiscal administration and management of federal funds. This includes administrative supervision to investigate and report financial irregularities. (Health department only) • Oversee preparation and submission of annual cooperative agreement reports, including interim or annual progress reports and financial status reports, to CDC Procurement and Grants Office (PGO). (Health department only) • Oversee the development of local use questions. • Respond to CDC’s requests for input on revisions to the NHBS questionnaire and other supporting documents. • Participate in CDC site visits, PI meetings, conference calls, and national calls. | <ul style="list-style-type: none"> • Manage contracts related to the project (as applicable). • Assist PI with the hiring and supervision of project staff. • Assist PI with IRB-related activities, cooperative agreement reports and other key administrative functions. • Participate in CDC site visits, trainings, national calls, and regular conference calls. • Act as the primary point of contact between the NHBS and CDC in matters that relate to the project. • Respond to CDC’s requests for input on revisions to the NHBS questionnaire and other supporting documents. • Coordinate the development of local use questions | <ul style="list-style-type: none"> • Participate in CDC site visits, trainings, regular conference calls, and, as available, monthly calls. |
| <p>Project management</p> | <ul style="list-style-type: none"> • Serve as back-up for project coordinator in event of absence or appoint a designee. • Collaborate with local stakeholders and disseminate information and data from the project to garner community support. | <ul style="list-style-type: none"> • Provide overall project management. • Maintain inventory of supplies, materials, incentives, and equipment. • Oversee ongoing formative research efforts. • Serve as back up for the data manager and field supervisor. | <ul style="list-style-type: none"> • Ensure adequate preparations, including supplies, materials, and equipment for field sites. • Assist with field staff-related issues (i.e., training and development, scheduling, team building). • Coordinate ongoing formative research efforts and implement changes based upon findings. • Manage operations and data collection at field sites. |

(Table continues on the next page)

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

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

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

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

field supervisor positions comprise 1.5-2.0 full-time equivalents (FTEs).

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

Field supervisor

The field supervisor is responsible for assisting with the day-to-day management of the project, particularly overseeing the non-management 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 comprise 1.5-2.0 FTEs.

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

2.2b Field staff

Project sites should designate staff for the following field positions: interviewer, coupon manager, and HIV test counselor. Each position is discussed below. It is useful for field staff to be trained to perform multiple positions to maximize the flexibility of operations. Field staff are expected to adhere to procedures in accordance with NHBS guidance (e.g., *NHBS Round 3 Model Surveillance Protocol*, *NHBS Formative Research Manual*, *NHBS-IDU3 Operations Manual*, and *Round 3 NHBS Interviewer Guide*) and locally developed policies.

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

Interviewers

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

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

Coupon manager

The coupon manager is responsible for participant check-in and check-out, recruiter training, coupon distribution, distributing recruiter rewards, and monitoring coupon activity using the CMP.

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.

HIV test counselors

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

standards and NHBS HIV testing guidelines. HIV test counselors are also responsible for providing tailored prevention messages to each participant based upon risk behaviors identified during the interview or counseling session, as well as referrals for medical or social services as needed.

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

2.2c Data manager

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

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

2.3 Spanish-speaking Staff

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

2.4 The Importance of Skill Standardization and Quality Assurance

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

implementation and ongoing evaluation recommendations, and (5) retraining recommendations.

2.4a What is standardization?

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

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

2.4b What is measurement error?

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

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

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

Table 2.3 – Evaluation and retraining recommendations

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

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

2.5 Project Staff Training

Project managers are responsible for conducting a field operations training at each site to ensure that all staff members have:

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

2.5a Required trainings

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

Field Operations Training

The CDC-sponsored Field Operations Training should be attended by the field supervisor and one additional senior field staff member. These individuals will, in turn, conduct field operations training at their project site.

Required participants: *Field supervisor and a senior field staff member*

HIV/AIDS surveillance data security and confidentiality

In accordance with the Assurance of Confidentiality for HIV/AIDS Surveillance Data, all project staff must adhere to the security and confidentiality standards for HIV/AIDS surveillance data that were approved by the Overall Responsible Party (ORP) at their state or local health department. Information on this training requirement can be found at: www.cdc.gov/hiv/topics/surveillance/resources/guidelines/guidance/training.htm.

Required participants: *All project staff*

DCC data management training

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

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

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

Project staff should be trained in general field safety and emergency situations. They should be taught how to handle challenges involving the general public, field sites, weather, and participants (in particular, de-escalation techniques for unruly participants

and emergency procedures for participants who have a negative reaction to the survey or their HIV test result). Trainers should also discuss procedures for handling and reporting field incidents and adverse events, as well as a communication plan for alerting project staff in case of an emergency. Throughout the project cycle, the field supervisor should review safety procedures with the project staff at least once a month to ensure that they can successfully handle difficult situations.

Required participants: All project staff

HIV counseling and testing

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

Required participants: All HIV test counselors

2.5b Recommended trainings

Recommended trainings for project staff are described below and can also be found in **Table 2.4**. As with the required trainings, completed trainings should be documented in the Operations Checklist (**Appendix A**).

Human subjects and scientific ethics training

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

Recommended participants: All field staff

Cultural diversity course

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

Recommended participants: All field staff

Table 2.4 – Pre-implementation knowledge and trainings

| | Guidance Documents | | | | | | | Required Trainings | | | | | Recommended Trainings | |
|----------------------------|-----------------------------|-------------------|---------------------------|-------------------|---------------|---------------------------------|-------------------------------------|--|---|-------------------------------|---|---------------------|---------------------------|---------------------------------|
| | Model Surveillance Protocol | Operations Manual | Formative Research Manual | Interviewer Guide | Questionnaire | Data Management Training Manual | Site-specific HIV testing documents | Confidentiality for HIV/AIDS surveillance data | Emergency procedures, field safety, adverse events, and field incidents | CDC Field Operations Training | Project site and job-specific trainings | DCC Data Management | Cultural diversity course | Human subjects ethical training |
| Project Coordinator | X | X | X | X | X | X | X | X | X | | X | X | X | X |
| Field Supervisor | X | X | X | X | X | X | X | X | X | X | X | | X | X |
| Interviewers | X | X | X* | X | X | | | X | X | 1 senior field staff member | X | | X | X |
| Coupon Manager | X | X | X* | | | X | | X | X | | X | | X | X |
| HIV Counselors | X | X | X* | | | | X | X | X | | X | | X | X |
| Data Manager | X | X | X* | X | X | X | | X | X | | X | X | | |

*if assisting

2.6 Project Staff Evaluations

To help project sites evaluate pre-implementation and ongoing staff performance, **Table 2.3** outlines pre-implementation evaluation and performance recommendations, an ongoing evaluation schedule, retraining recommendations, and a retraining evaluation schedule. In addition, evaluation forms for each staff position can be found in **Appendices B** thru **G**.

2.6a Pre-implementation evaluation and performance recommendations

Prior to implementation, each staff member should meet all the performance recommendations for their position. Ensuring that all project staff have demonstrated mastery of their position's skillset prior to implementation is critical to ensuring the standardization of skills within and across project sites from the onset of data collection.

Performance recommendations are the suggested quality standards that each staff position should attain prior to working in the field and should *maintain* throughout the project cycle. When a staff member no longer performs at the recommended skill level, retraining should occur immediately.

2.6b Ongoing evaluations

All project staff should be evaluated on a regular basis to ensure that standardization and quality data collection are maintained throughout the project cycle. Over time, it can be expected that project staff, even those with much experience, will begin to drift from the NHBS performance recommendations, resulting in lack of study standardization. If these deficiencies are not identified and corrected, data quality will be compromised. Routine evaluations will identify when a staff member has drifted from NHBS performance recommendations, allowing the deficiency to be quickly corrected.

2.6c Recommended ongoing evaluation schedule and retraining procedures

The importance of ongoing evaluations and its positive impact upon the reliability of NHBS data cannot be overstated. Retraining should occur each time a staff member has been identified as not having maintained a performance recommendation.

2.6d Evaluators

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



The principal investigator or project coordinator should conduct most ongoing evaluations since the field supervisor will be busy managing field site operations.

When conducting an evaluation, it is critically important that the evaluator has a thorough understanding of the duties and responsibilities for the position, performance recommendations, and criteria for evaluation (evaluation form). When evaluating interviewers, it is often helpful to have a portable computer to follow along with the survey.

Recommendations for evaluators:

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

2.6e Project staff

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

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

2.6f Interviewer Improvement Report

To help project sites assess the interviewers and provide feedback for improving their techniques, the DCC will produce an Interviewer Improvement Report containing the

following tables: *Interviewer Capacity, Signs and Knowledge of Drug Injection, Response Validity, HIV Test Consent, Hepatitis Test Consent, and Coding of “Other” Insurance*. Information on each table is provided in **section 10.3i** of this manual. Project sites should review the report at least once a week and discuss the findings with the interviewers to identify strengths and areas for improvement.

3.1 Overview

The purpose of this chapter is to describe the preparations that should be made prior to starting data collection. These preparatory tasks include: 1) developing a project logo and marketing materials, 2) requesting access to the Data Coordinating Center (DCC) data portal, 3) obtaining project supplies, and 4) establishing local safety and field incident reporting procedures.

3.2 Project Logo and Marketing Materials

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

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

3.3 Access to the Data Coordinating Center Data Portal

Project sites will need to regularly submit the QDS™ Warehouse with their core surveys to the DCC data portal (see **section 11.2** of this manual). They will also use the data portal to enter data into the online HIV Test Results Log (see **sections 9.8a and 11.2** of this manual) and the online Data Error Log (see the *NHBS-IDU3 Data Management Training Manual*). Project staff that need access to the data portal should first receive approval from the principal investigator of the directly funded health department and then apply for access following the instructions in the *NHBS-IDU3 Data Management Training Manual*.

3.4 Project Supplies

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

3.4a Portable computers and survey software

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



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

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

Project sites must upgrade all QDS modules used to collect and manage NHBS data to version 2.6.1. These modules include the Design Studio, Warehouse Manager, and HAPI™ (if handhelds are used). QDS modules using version 2.6.1 may not function properly on computers that also contain earlier versions of the modules, such as versions 2.4 and 2.5. Project sites should therefore remove earlier versions of the modules from any computers that will be using version 2.6.1. In addition, project sites that are replacing their handhelds with a laptop or tablet will need to convert HAPI™ modules to CAPI™ modules.

3.4b Materials

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

3.4c Forms and logs for project management

To ensure successful project management and quality data collection, project staff 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 will

be responsible for completing, reviewing, correcting, and updating forms in accordance with their local procedures and the *NHBS Round 3 Model Surveillance Protocol*. Project sites are encouraged to develop additional forms to manage project activities as needed.

Table 3.1 summarizes some forms and logs that are recommended.



CDC recommends the forms and logs listed in **Table 3.1** for better managing NHBS operations, but CDC does not systematically collect the information contained in them. The forms and logs are not federal data collection systems, and they have not received Paperwork Reduction Act (PRA) or Office of Management and Budget (OMB) approval.

Project staff should use a binder to store forms and logs in a central and easily referenced location. Project sites providing HIV test results over the phone should refer to the HIV Phone Result Protocol (Appendix I) of the *NHBS Round 3 Model Surveillance Protocol* and develop a Phone Results Log (see **Appendix I** of this manual). Hard copies of forms that contain confidential information (e.g., Reminder Call Forms, HIV Test Results Log, and Phone Results Log) should be stored in a locked file cabinet and handled in a manner which complies with the *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action* (available at <http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>). In addition to the aforementioned forms and logs, project staff may want to keep other materials and information in the project binder for easy reference, such as memorandums of understanding (MOUs).

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

| Form or Log | Purpose | Location |
|--|---|--|
| <i>Appointment Log</i> | Schedule and track appointments. | Chapter 4 |
| <i>CMP Log</i> | Log coupons distributed to each recruiter. | Appendix J |
| <i>Appointment Reminder Call Forms (if applicable)</i> | Schedule a call to remind participants to obtain their HIV test results. | Appendix K |
| <i>HIV Test Results Log</i> | Record HIV testing data. | Chapters 9 and 11 |
| <i>Phone Results Log (if applicable)</i> | Record information for returning HIV test results over the phone. | Appendix I |
| <i>Specimen Transport/Shipping Log</i> | Track the transport and shipment of laboratory specimens. | Appendix L |
| <i>Data Error Log</i> | Record errors that occur during data collection for later entry in the DCC data portal. | <i>NHBS-IDU3 Data Management Training Manual</i> |
| <i>Project Staff Evaluation Forms</i> | Observe and evaluate project staff. | Appendices B - G |

3.4d Prevention and referral materials

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

- **Informational and educational pamphlets.**
 - Data describing the current state of the HIV, STD, and hepatitis epidemics.
 - Modes of transmission for HIV, STD, and hepatitis.
 - Strategies for preventing HIV infection through sex and drug use.
 - HIV testing, hepatitis testing, and other testing services.
 - Alcohol and drug treatment services.
- **List of referral agencies** and contact persons to provide to participants who are HIV-positive so that they can receive medical care and case management services. Also, so that project sites can readily make any necessary referrals, they should maintain a list of the names and contact information of health and social service providers in their communities. This list should include HIV and STD clinics, substance abuse treatment centers, mental health service providers, and agencies that offer free HIV, STD, and hepatitis testing.
- **Supplies** used to reduce HIV risk, such as condoms and lubricant. Project sites are *not* allowed to distribute syringes due to the ban on using federal funds for this purpose. This is true even if the project site does not use NHBS funds to purchase the syringes. Similarly, NHBS funds cannot be used to purchase bleach or injection equipment, like cookers, cotton, and sterile water. However, project sites are allowed to distribute bleach and injection equipment (other than syringes) if the items are *not* purchased with NHBS or any other federal funds.



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

3.4e Other supplies and materials

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

3.5 Local Safety Procedures

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

It is important for project staff to prevent problems by using common sense and advance planning. Project staff must be alert to their own safety and to that of their co-workers at all times. A basic awareness of one's surroundings is critical when working in the field. Each staff member is also responsible for maintaining a safe working environment. The field supervisor is generally responsible for crowd control and overall safety. The field supervisor must have emergency contact information for each staff member working in the field and he must have this information readily available at all times.

3.5a General principles of field safety

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

- Call 911 without hesitation if danger is present.
- Always carry a project or health department identification card.
- Plan ahead, be alert, and use common sense.
- Have a first aid kit available.
- Always have at least 3 staff members at each field site during the hours of operation.

3.5b Steps for field safety

Project sites should consider the following steps for field safety:

Plan ahead

- Have an emergency action plan.
 - Know what you are going to do ahead of time in case things go wrong.
 - Know who to contact in case of emergency.
 - Always know the location of all exits at the field site.
- During interviews, always position yourself closest to the door; you do not want an unruly participant between you and the exit.

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

Be alert

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

Use common sense

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

3.5c Techniques for handling dangerous or difficult situations

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

Aggressive or threatening individuals

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

Sexual harassment

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

Inebriated, high, or drowsy participants

A participant may not be able to complete the interview or give accurate responses for a variety of reasons. For example, he may be unable to give intelligible answers to the questions or he may nod off during an interview if he has had little sleep or has recently used alcohol or drugs. If the participant is unable to provide coherent answers during eligibility screening, then he should be made ineligible; and if he cannot provide coherent answers during the core survey, his interview should be stopped (see **section 7.4** of this manual for further guidance).

3.5d Safeguarding portable computers

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

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

3.6 Field Incident Reporting Procedures

Project sites should create field incident reporting procedures and include them in the Operations Checklist (**Appendix A**). These procedures should adhere to all local IRB requirements. A model field incident report is provided in **Appendix M**. In the event that an incident occurs, project staff should notify their field supervisor within 24 hours.

The field supervisor or project coordinator should then notify CDC within 48 hours and complete a “Field Incident Report” and send it to their CDC project officer. Project sites should then discuss the field incident with their CDC project officer to determine whether it is an adverse event and should be reported to the local IRB(s) (see Chapter 9 of the *NHBS Round 3 Model Surveillance Protocol*).

4.1 Overview

During RDS cycles, data collection activities are conducted at fixed locations called field sites. Field sites are usually existing or rented office space or vans parked at specific places. Findings from formative research will help project sites decide the optimal number and location(s) of their field sites. This chapter provides specific guidance on selecting and managing these field sites.

4.2 Field Site Location

Project sites should consider several factors when selecting a field site location. Ideally, the field site should be centrally located and easily accessible by foot, car, or public transportation. Multiple field sites may be needed in project sites that have limited public transportation or cover large geographic areas. A field site must also be accessible to all major sub-populations of IDUs. It should not be located in an area where certain sub-populations of IDUs would not be willing or able to safely go. The best location is one that serves as a “bridge” between the major sub-populations of IDUs. If formative research indicates that confidentiality is a concern among potential participants, project sites should choose a nondescript location for their field site.

4.2a Restrictions on field sites

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

- Field sites should not be located in facilities or near areas where *large* numbers of IDUs congregate. This will minimize the likelihood that participants distribute coupons to IDUs hanging around the field site rather than to IDUs they know personally.
- Field sites should not be placed in substance abuse treatment centers or methadone clinics. People attending these facilities may not have injected drugs in the past 12 months, but they would have sufficient knowledge of injection practices to pass the “knowledge” questions in the eligibility screener.
- Field sites should not be located in facilities that serve the homeless population or near areas where *large* numbers of homeless people congregate. The incentives provided in RDS studies are extremely attractive to economically disadvantaged populations, like the homeless; and as a result, they may be more likely to participate in the project, biasing the sample. Another potential problem is that homeless people who are not IDUs could fraudulently claim to

be IDUs in order to participate in the project and collect the incentive.

Single-service facilities

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

Nevertheless, there is an exception to the prohibition on facilities with primary or exclusive services. With approval from their CDC project officer, project sites can place a field site in a facility that provides a specific service if there is *no* stigma associated with that service and the field site is able to operate separately from the facility, such as on different days or at different times. For example, if a syringe exchange operates in a facility Monday thru Friday from 10 am to 5 pm, a field site could operate in the facility on weekends or in the evening.

Multi-service facilities

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

4.2b Additional considerations for vans

Project sites that plan on using a van must identify fixed locations where the van will be parked on each day of project operations. They should also create a set schedule of hours of operation at each location. Fixed locations and schedules are essential for ensuring that people always know where to go to participate in the survey and at what times. Depending on parking regulations and availability, it may be necessary to obtain a parking permit for each location or to reserve the location in advance. As mentioned above, vans should not be parked near facilities or in areas where large numbers of IDUs or homeless people congregate, near substance abuse treatment centers or methadone clinics, or near facilities that primarily or exclusively provide a specific service.

4.3 Multiple Field Sites

Since more than one field site may be necessary to reach all the major sub-populations of IDUs in a large city, project sites have the option of using multiple field sites for conducting operations. However, project sites should not operate an additional field site

merely to reach a small, insular sub-population of IDUs or a sub-population of IDUs that does not contribute substantially to the local HIV epidemic.

When deciding whether to use multiple field sites, project sites should consider the resources and logistical issues involved in operating multiple sites. Furthermore, while multiple field sites can facilitate enrollment by making it more convenient for people to participate, they can also create an enrollment barrier if people have to wait too long for the opportunity to participate. For example, in previous RDS cycles, some project sites that operated in each field site just once per week had difficulty generating recruitment chains because people had to wait too long before they could participate and lost interest in the survey.

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

4.3a Cross-recruitment

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

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

During formative research, project sites considering multiple field sites must assess whether cross-recruitment is likely to occur among the planned field sites. If cross-recruitment is not likely to occur with a particular field site, operations should not be conducted there. Otherwise, two separate RDS samples would be generated in the project site and the data would not be able to be analyzed as a single sample using the RDS Analysis Tool (RDSAT).

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, 1 to 3 interview areas, and a waiting area for potential participants. Interviews should be conducted in private offices or rooms to provide privacy and protect participant confidentiality. Alternatively, partitions could be used to divide an open space and white noise machines could be used to mask voices. If there is not sufficient space inside the

field site for a waiting area, project sites may be able to set up a makeshift waiting area outside the field site using folding chairs. Project sites that have separate interviewers and HIV testing staff will also need space for HIV counseling and testing. Furthermore, the spaces used for specimen collection and rapid test processing must comply with all quality assurance requirements.

4.4a Talk with neighbors and local police

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

4.4b Field site safety

Project sites are responsible for the safety of both their staff and the participants while at the field site. They should develop local safety procedures for their staff and train them how to respond to threatening situations and other field incidents (see **section 3.5** of this manual). To prevent theft, project sites should store incentives, computers, supplies, and other potentially valuable items in safe locations that are not visible to participants. Most importantly, file cabinets that contain data collection forms should be in limited-access areas and must remain locked when not in use. Protecting participant confidentiality should always be a primary objective. Project sites that use a van should have one staff member monitor the area immediately surrounding the van, as well as control who is allowed to enter the van.

4.5 Hours of Operation

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

change.

4.5a Additional considerations for vans

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

4.6 Crowd Control

As the study becomes established in the community and recruitment increases, more and more IDUs will be interested in participating. These potential participants may crowd the field site or line up outside it. To help control these crowds, project sites should develop plans for managing large numbers of potential participants. For example, they could employ an appointment system, whereby a participant could only be interviewed at a scheduled time (see **section 4.7**). If project sites do not wish to schedule appointments, they could use a "take-a-number" system to see participants on a first-come, first-served basis. With this system, project staff would determine how many interviews they could conduct each day and then hand out the corresponding number of tickets. Rather than using tickets, project staff could also track participants by listing their survey IDs (coupon numbers) in the order that they arrived at the field site. Potential participants should be told how long they will have to wait to be interviewed, and if the wait will be long, they could be told to return at a later time that day.



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

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

interview. The policy on children should be posted at the field site and reinforced during recruiter training and the scheduling of appointments.

4.7 Appointment System

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



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

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

4.7a Scheduling appointments

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

- 1) Greet the potential participant and ask him for his coupon. Check the “Activation Date” (if applicable) and the “Expiration Date” on the coupon to verify that the coupon is valid before scheduling the appointment. If the potential participant does not have his coupon with him, instruct him to return with his coupon or call the field site to schedule an appointment over the phone. When scheduling over the phone, ask the potential participant for his coupon information (the coupon number to schedule the appointment and the activation and expiration dates to verify the validity of the coupon).
- 2) Record all appointments in a single appointment book or log kept at the field site. To schedule an appointment, write the potential participant’s coupon number next to his appointment time. *Never* collect or write the potential participant’s name or personal identifying information in the appointment book or log.
- 3) Tell potential participants the approximate time required to complete the survey and HIV test.

- 4) Make sure potential participants are aware that they must first answer some background questions to determine if they have been selected to participate in the survey. They should also understand that if they are not selected for the survey or do not complete the interview, they will not be paid an incentive.
- 5) Emphasize that potential participants should be on time for their appointment. If they need to reschedule their appointment, they should call before the scheduled appointment time.
- 6) Tell potential participants that children are not permitted to sit in on their interview, and they should therefore arrange for someone to watch their children at home or at the field site.
- 7) Remind potential participants that they must bring their coupon to the appointment or they cannot be interviewed.



Project sites should not reserve appointment spots for members of any specific IDU sub-population. Denying available appointment spots to IDUs who are not members of the specific sub-population would undermine the RDS sampling method and bias the sample.

4.7b Standby appointments

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

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

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

- 5) If the standby appointment time did not become available, ask the potential participant if he would like to schedule a different standby appointment time or schedule a guaranteed appointment time.

5.1 Overview

Seeds are non-randomly selected members of the target population who initiate the RDS chain-referral process. They are usually chosen by referral from key informants or during outreach by project staff. After a seed completes an interview, he is asked to recruit up to five people he knows who inject drugs and live in the project area. From each seed, a recruitment chain is then expected to grow. Because seeds start the recruitment process, they play a critical role in RDS studies and should be selected very carefully.

5.2 Identifying and Recruiting Seeds

Key informants consulted during formative research can be the starting point for identifying and recruiting seeds. Key informants serve as “cultural experts,” providing insight into the characteristics, behaviors, and social networks of local IDUs. Examples of key informants include community leaders, persons doing outreach work among IDUs, staff from organizations providing services to IDUs, and current or former IDUs. Enlisting the assistance of a diverse group of key informants will help project sites identify a diverse group of seeds.

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

- a current IDU,
- at least 18 years old,
- a resident of the project area, *and*
- male or female (although transgender persons are eligible to participate in NHBS, they are not the target population for this cycle and cannot be selected as seeds).

Since seeds who do not meet the eligibility criteria could provide false answers during screening, key informants should be asked to not reveal the eligibility criteria to potential seeds. If a seed is referred by a key informant, the seed must contact the project staff to participate in the survey; the project staff should *never* contact the seed. This way, project sites will not maintain any personal identifying information on potential participants. Seeds may also be recruited directly by project staff during outreach activities, or alternatively, key informants who are current IDUs could serve as seeds.

When potential seeds are referred or recruited, the project staff should briefly describe the survey to them using the information in their local consent form or in the Model

Recruiter Training Script (**Appendix Q**). Without revealing the eligibility criteria, project staff should also make it clear to potential seeds that their participation is not guaranteed. In prior RDS cycles, project 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.

5.2a Seed characteristics

The ideal seed is someone who has a large personal network of IDUs (i.e., knows many IDUs) and is well respected in the community. These characteristics increase the likelihood that the seed will be able to recruit other IDUs to participate in the survey. Moreover, seeds should be diverse with respect to factors such as age, race/ethnicity, drug preference, geography, and any other factors that may create more insular social networks. For example, if younger IDUs do not interact with older IDUs in a project area, cross-recruitment between these groups would be very limited or non-existent. Accordingly, the project site should select younger seeds and older seeds to ensure that both sub-populations are represented. Similarly, if methamphetamine users do not interact with heroin users, the project site should select some seeds that are methamphetamine users and some that are heroin users.

Seeds should also reflect the sub-populations which contribute most significantly to the local HIV epidemic among IDUs. During formative research, project sites should identify those IDU sub-populations from which seeds should be chosen to yield a representative sample of at-risk IDUs.

5.2b Number of seeds

There is no specific number of initial seeds that will guarantee project sites reach the sample goal of 500 eligible IDUs. However, based on prior RDS cycles, it is recommended that project sites select 3-10 seeds to initiate the recruitment process. To determine the most appropriate number of seeds, project sites should consider how closely IDU sub-populations are networked in their local community. If two or more sub-populations are *not* closely networked, project sites will need to select a small number of seeds (2-3) from each of the sub-populations. On the other hand, if two or more sub-populations are closely networked, a small number of seeds from any of the closely-networked sub-populations will be sufficient to start recruitment.

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

5.2c Selecting additional seeds

If the initial seeds do not recruit participants or if enrollment is halted because all the recruitment chains have “dried up” (i.e., stopped recruiting), then additional seeds will need to be selected. With RDS, seeds do not all have to be chosen at the beginning of the study or at the same time. Before selecting additional seeds, project sites should first conduct ongoing formative research to determine if there are any barriers to study 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. All decisions about recruiting more seeds must be made in consultation with the site’s CDC project officer.

5.3 Assessing Seeds

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

- **Connected to many other people in the community:** A good seed will know many other IDUs living in the project area. If one imagines a social network with lines drawn between people to show relationships, a seed is someone with a lot of lines radiating out; that is to say, a focal point of the network.
- **Respected and well-liked:** People who are considered “opinion 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 study to others.

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

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

- *Do you know many people who inject drugs and live in [the project area]?*
- *Are you willing to recruit other people you know who inject drugs and live in [the project area] for the study?*

- *Of the people you know who inject drugs and live in [the project area], can you think of 3 to 5 you have seen in the past 30 days that you could recruit for the study? Do you think these people would be willing to participate in the study?*
- *Are you familiar with the injection drug community in [the project area]?*
 - *Do you know where most people buy drugs?*
 - *What are the prices of the drugs?*
 - *What is the most commonly injected drug?*
 - *How do people inject here?*
- *Have you been involved in any other injection drug studies before?*

5.4 Screening and Interviewing Seeds

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

5.4a Screening and interviewing by appointment

If a project site does not screen potential seeds in the field (see **section 5.4b**) or if a potential seed is not available to be screened when he is approached, the project site should make an appointment to screen and interview the potential seed at a field site at a mutually convenient time. Project staff who are recruiting seeds in the field should maintain a list of possible appointment dates and times or they should call the staff at the field site to schedule appointments. The day of the week, the date, and the time of the appointment should be recorded on a referral card. To avoid any confusion, the appointment information should be written out completely (e.g. Monday, June 7, 2010 at 1:00 pm). The day, date, and time of the appointment should also be recorded in an appointment book or log, along with the survey ID (pre-printed number on the referral card).

When giving the referral card to the potential seed, project staff should review the appointment information on the card and the directions to the field site. Project staff should also tell the potential seed that he should call the project phone number on the referral card if he needs to reschedule his appointment. Because NHBS is an anonymous survey, project sites should never contact potential seeds to remind them of their

appointments or to follow-up with them if they miss their appointments. Project sites may want to include an expiration date on their referral cards to motivate potential seeds to keep their appointments or to promptly reschedule them. To achieve this goal, expiration dates should be no later than 1 to 2 weeks after a scheduled appointment. Of further benefit, expiration dates ensure that potential seeds enroll at the very beginning of the project cycle when they are needed to initiate recruitment chains.

5.4b Screening and interviewing in the field

If a potential seed is available to be screened when he is approached, project sites may interview him in the field. To do this, project sites must have all the materials and equipment needed to conduct an interview, test for HIV, and provide recruiter training. They will need referral cards, portable computers with the survey, consent forms, HIV test kits, incentives, recruitment coupons, and a computer with the Coupon Manager Program (CMP). To operate in the field, project staff must protect the confidentiality of the potential seed at all times; no one outside of the project should be able to hear or observe any proceedings. If confidentiality cannot be guaranteed in the field, project staff cannot interview potential seeds there. Instead, they will have to schedule an appointment to screen and interview the potential seed at a field site.

5.5 Referral Cards

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



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

5.5a Making referral cards

Project sites may have their referral cards professionally printed or they may make the cards themselves by following the instructions in **Appendix O**. Referral cards may be designed however a project site wishes, but they must contain specific information on their front and back as illustrated in **Figures 5.1** and **5.2**.

Figure 5.1 – Example of the front of a referral card

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

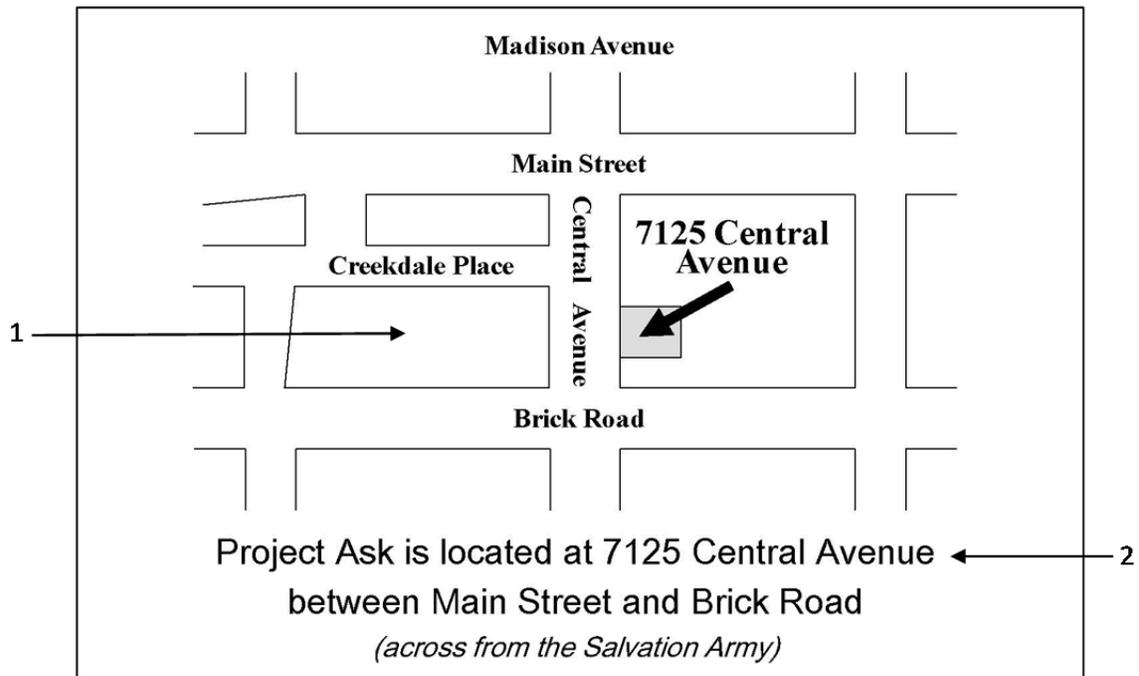
- 1 → 0001
- Project ASK
- 0001 ← 2
- You have an appointment on
- 3 → Day: _____ Date: ___ / ___ / ___ Time: __ : ___
- at 7125 Central Avenue, 2nd Floor. ← 4
- (Directions are on back.)
- 5 → Please call 1-888-865-4327 if you have any questions or if you need to reschedule.
- Coupon expires on: ___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

1. Referral card number ranging from 0001 to 0888.
2. Name of the local NHBS project.
3. Space to record the day, date, and time of the potential seed’s screening appointment.
4. Address of the field site.
5. Phone number to call for project information or to reschedule an appointment.
6. **Optional:** Space to record an expiration date.
7. **Optional:** Space for project staff to record any information that would help with operations. In this example, there is a field for the interviewer to record his Interviewer ID and checkboxes to indicate whether the participant completed the survey (S) and had an HIV test (HT). If required, project sites should obtain local IRB approval for any supplemental information collected on the referral card.



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

Figure 5.2 – Example of the back of a referral card



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



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

To help project staff distinguish between referral cards and recruitment coupons, cards should be printed on different colored paper and have a different size.

6.1 Overview

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

6.2 Coupon Number

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



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

6.3 Coupon Options

Based on their experience from prior RDS cycles and their findings from formative research, project sites should decide how many coupons to distribute to seeds and other participants. They should also determine whether or not to include an activation date or an expiration date on their coupons. Activation and expiration dates define a period when coupons are valid for project participation.

6.3a Number of coupons distributed

Project sites may give up to 5 coupons to each participant who completes the survey and agrees to recruit others (see the *NHBS Round 3 Model Surveillance Protocol*). The number of coupons given to each recruiter will vary from project site to project site depending on the likelihood that one of the distributed coupons will yield a participant who completes the survey. The lower the likelihood that a coupon will yield a participant, the greater the number of coupons a project site must give out to ensure that

enrollment does not decrease with successive recruitment waves and eventually die out. During previous RDS cycles, project sites found that giving 2 or 3 coupons to each recruiter was usually sufficient for enrollment to progress successfully. Giving more coupons than this is likely to negatively impact data quality, as well as any RDS analyses performed on the data. Nevertheless, project sites may want to give the maximum of 5 coupons to seeds, and then reduce the number of coupons given to subsequent participants. Since recruiting seeds requires a considerable investment of time and effort, giving the maximum number of coupons to seeds will optimize the chance that they yield participants.

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

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

If participation by a specific sub-population is less than what is expected based on formative research, project sites can increase the number of coupons given to recruiters from the underrepresented sub-population to improve their enrollment. Likewise, if a specific sub-population starts to dominate enrollment, project sites can decrease the number of coupons given to recruiters from that sub-population to reduce any bias in the sample, or if necessary, they can even stop giving coupons to that sub-population altogether. As mentioned above, this is referred to as differential coupon distribution. Differential coupon distribution is a drastic action, however, and should only be used when the sample would not represent those sub-populations most affected by the local HIV epidemic without intervention. Before increasing the number of coupons given to a select sub-population, project sites must first conduct ongoing formative research to determine why participation by that sub-population is low and they must address any recruitment or participation barriers identified (see **section 10.4** of this manual). If these

actions do not improve enrollment by the underrepresented sub-population, project sites may then distribute more coupons to them. The under- or overrepresentation of a sub-population often requires immediate intervention. Accordingly, project sites should discuss any potential recruitment problems with their CDC project officer as soon as possible to prevent them from escalating into irreversible recruitment problems.

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

6.3b Coupon activation dates

A coupon activation date is a date when coupons become valid for participation in NHBS. On or after the coupon activation date, a potential participant may bring his coupon to one of the field sites to begin the check-in process. Project sites should decide whether or not 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 sites set an activation date that was one day after the coupon was distributed.

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

On the other hand, some project sites have found that activation dates hinder recruitment. This was especially true for project sites that had several field sites far apart from one another and only operated in each field site once a week. Even with a short one-day activation period, recruits at these project sites had to wait a week before they could participate in the survey at a convenient location. As a result of the long delay between the time they were recruited and the time they were able to participate, many recruits lost interest in the project and never tried to participate.

Changing activation dates

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

6.3c Coupon expiration dates

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

Changing expiration dates

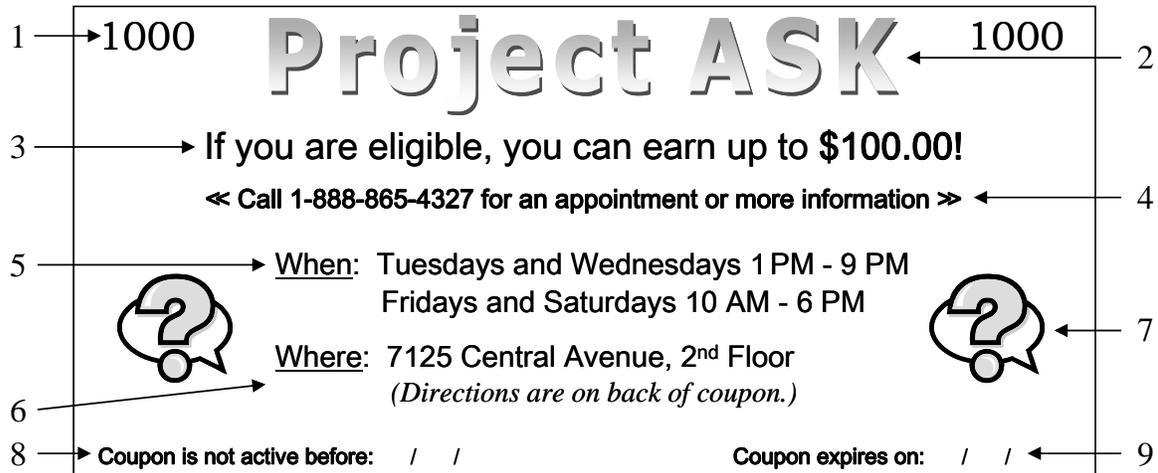
As with activation dates, project sites may change the interval before their coupons become invalid if they think it will improve recruitment or operations. Expiration dates may be made earlier or later, but they may not be eliminated. As mentioned above, at the very least, coupons must expire on the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

6.4 Making Coupons

Coupons can be professionally printed or project sites can make the coupons themselves by following the instructions in **Appendix O**. Coupons may be designed however a project site wishes, but they must contain specific information on the front and back as illustrated in **Figures 6.1** and **6.2**. In addition, project sites located in cities that are in close proximity to one another should share their coupon designs and ensure that they are

sufficiently different. This will help alleviate participant confusion if coupons from a neighboring project site become introduced locally.

Figure 6.1 – Example of the front of a coupon

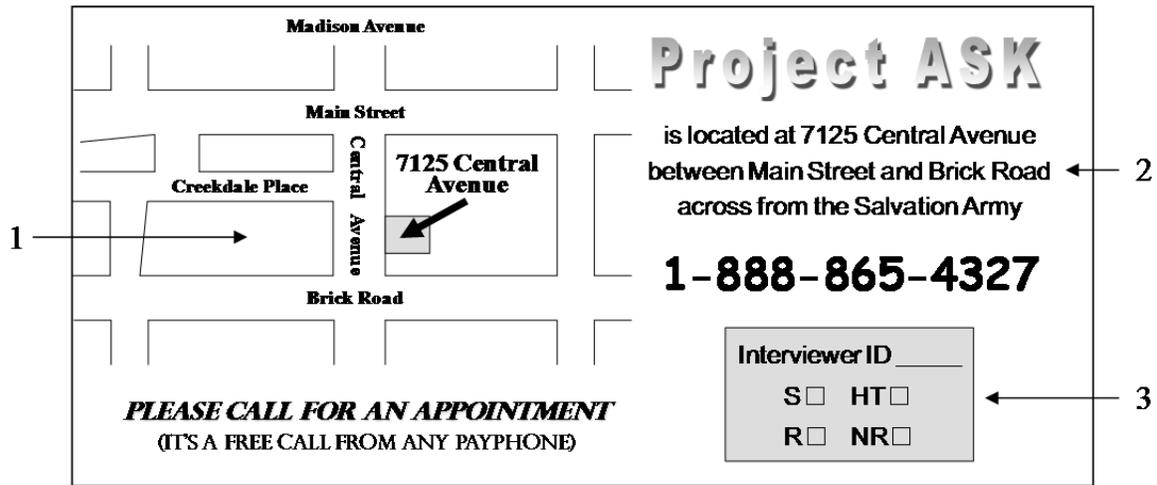


1. Coupon number ranging from 1000 to 8888.
2. Name of the local NHBS project.
3. Incentive type and amount for eligible participants completing the survey.
4. Phone number to call for project information and if applicable, to schedule appointments. It is best to have a toll-free number because of the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



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

Figure 6.2 – Example of the back of a coupon



1. Map showing location of the field site.
2. Directions to the field site.
3. **Optional:** Space for project staff to record any information that would help with operations or coupon tracking. In this example, there is a field for the interviewer to record his Interviewer ID and checkboxes to indicate whether the participant completed the survey (S), had an HIV test (HT), and was eligible (R) or not eligible (NR) to recruit. If required, project sites should obtain local IRB approval for any supplemental information collected on coupons.



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

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

6.5 Coupon Tracking System

To help monitor how well recruitment and enrollment are progressing over the course of the project cycle, project sites should develop a system for tracking the coupons distributed and returned each week. The CMP can output much of the needed information, such as the number of coupons distributed and the number of coupons returned, but some of the information will have to be collected by project staff in logs and files.

6.5a Tracking coupons distributed

Project sites should use a log to keep track of the numbers on the coupons given out each week. **Table 6.1** provides an example of a simple coupon distribution log that project sites can customize to meet their local needs. Since coupons should always be given out in order of their coupon numbers, any break in the series of coupon numbers should be documented in the log and a reason for the break provided. For example, project staff could lose or misplace some coupons. If this were to occur, the lost coupon numbers should not be replaced; the numbers should be made void and recorded in the log. In contrast, if coupons are merely damaged, replacement coupons should be made with the same coupon numbers and the damaged coupons destroyed.

Table 6.1 – Coupon Distribution Log

| Week | Dates | Coupon Numbers Distributed | | Comments |
|------|-------------|----------------------------|------|--------------------------------------|
| | | First | Last | |
| 1 | 6/1 - 6/7 | 1000 | 1008 | |
| 2 | 6/8 - 6/14 | 1009 | 1037 | <i>Coupons 1018 - 1028 were lost</i> |
| 3 | 6/15 - 6/21 | 1038 | 1061 | |
| | | | | |

6.5b Tracking coupons returned

Project sites should keep track of the coupons returned by participants each week, including coupons from ineligible participants and expired coupons. An easy way to manage returned coupons is to have a set of file folders or envelopes labeled with the dates for each week that data are collected (e.g., Week 1: 6/1 – 6/7, Week 2: 6/8 – 6/14, and so on). When a participant returns a coupon, the coupon should be marked “*USED,*” “*VOID,*” “*EXPIRED,*” or with similar terms to indicate that the coupon is no longer valid and the reason why. The coupon should then be placed in the folder or envelope labeled with the week the coupon was returned.

7

Check-in, Interviewing, and Check-out

7.1 Overview

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

The person's coupon (or referral card if a seed) will be used to track the participant throughout the enrollment process. In addition, project sites may want to use the Participant Tracking Form (**Appendix P**), or a similar instrument, to document the operational activities completed by each participant. The tracking form is useful because it provides a hard copy of completed activities in the event of data loss, facilitates communication among field staff, and assists with data management.

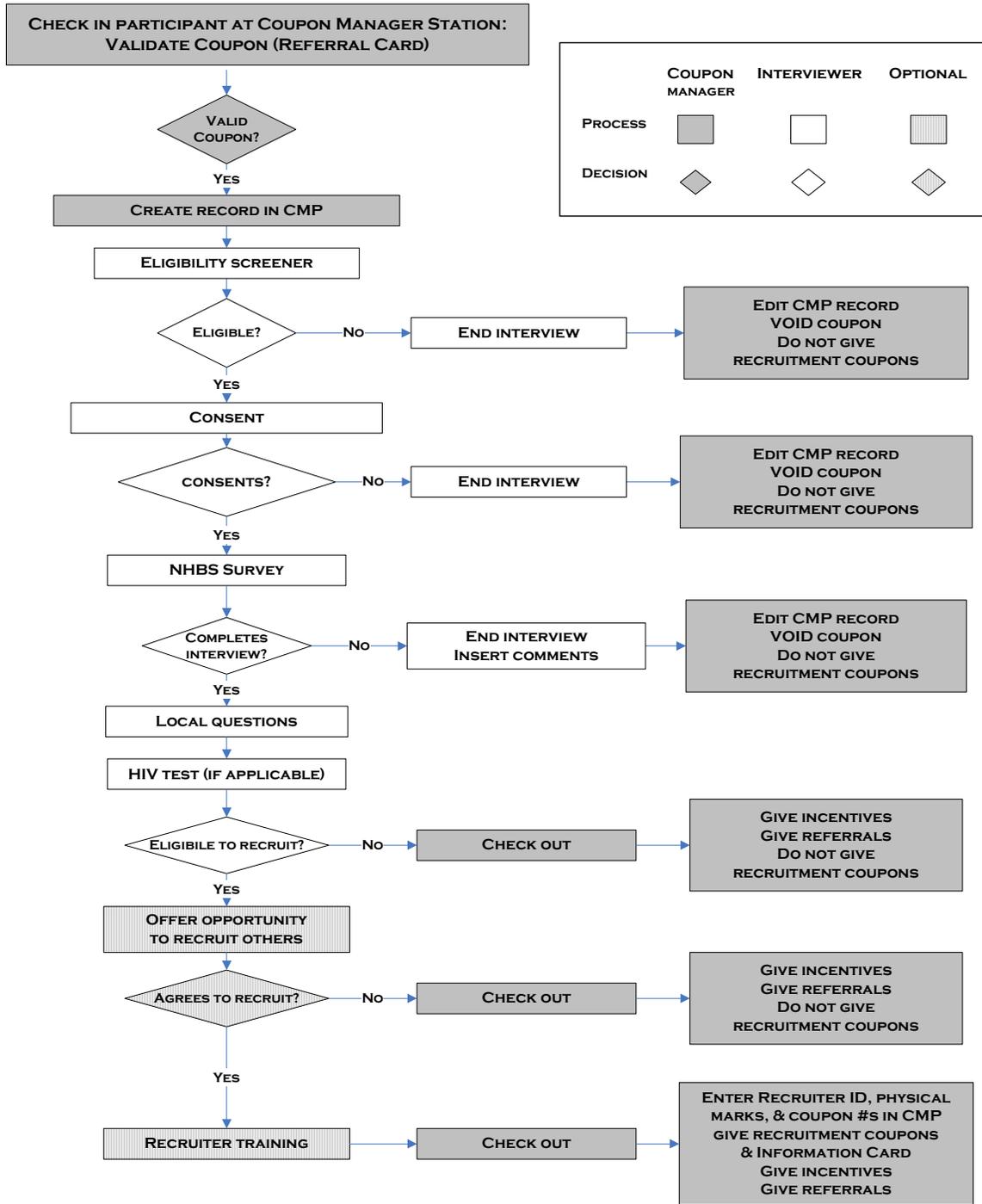
7.2 Coupon Manager Program

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

- 1) **Link recruiters with their recruits:** Each participant's data is linked to that of his recruits by their coupon numbers. This link is necessary to monitor the growth of recruitment chains and to analyze data using 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 ineligible or do not complete the interview.
- 3) **Collect responses to the Recruiter Questions:** The *Recruiter Questions* are used to measure non-response bias by asking about the demographic characteristics of individuals who refused to take coupons from the participant and the reasons why they refused. The CMP displays these questions when a participant returns to claim his rewards for recruiting others. The *Recruiter Questions* will be discussed further in **section 8.3** of this manual.

Detailed instructions for using the CMP are included in the *CDC Coupon Manager Version 2.5 User Manual*. The CMP should be installed on a laptop or personal computer and kept at the "coupon manager station," an area of the field site designated for checking in and checking out participants. A staff member should be assigned to

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



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

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

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

Since all data collection software can experience errors and data loss, project sites should keep a hard copy log of pertinent information entered into the CMP, such as the date of the interview, the participant’s coupon (or referral card) number, the interviewer ID, and the numbers on the recruitment coupons given to the participant. Please see **Appendix J** for a model CMP Log.



Although the CMP can automatically back-up its database, each night project sites should manually back-up their CMP database to a secure, external database, like a compact disc, thumb drive, or external hard drive.

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 someone in.

7.3a Validate coupon or referral card

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

- ***If the coupon has not yet become active***, the coupon manager should return the coupon to the person and ask him to return after the activation date or on a scheduled appointment date.
- ***If the coupon has expired***, the coupon manager should not return the coupon to the person. Instead, the coupon manager should search the CMP for the

coupon number and once located, record that the “Coupon has expired.” He should then mark the coupon “*EXPIRED*” and file it in the weekly folder or envelope. The coupon manager should explain to the person that his coupon has expired:

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

- ***If the coupon has expired but local guidelines allow people with expired coupons to be interviewed***, the coupon manager should create a CMP record for the person as described in **section 7.3b** below. If the CMP has automatically changed the status of the person’s coupon to “Expired,” the coupon manager will first have to change the status back to “Outstanding” in the CMP by checking the “Outstanding” box and saving the change.

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

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

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

- ***If the person appears too intoxicated to consent to the interview or to complete it***, the person’s coupon should be returned to him and his appointment should be re-scheduled for another day. The coupon manager should use his own judgment as to how to best handle the situation and avoid confrontation. He could politely reply:

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

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

7.3b Create record in the CMP

After validating the potential participant’s coupon (or referral card), the coupon manager should create a record in the CMP for that person.

When creating a CMP record, the coupon manager should enter the following information:

- **Coupon (or referral card) number:** The potential participant's coupon (or referral card) number will be used to start the record creation process.
- **Survey ID:** The potential participant's survey ID will be the same as his coupon (or referral card) number.
- **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).



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

7.3c Escort participant to interviewer

Once the CMP record has been created, the coupon manager should introduce the participant to his assigned interviewer. He should also give the participant's coupon to the interviewer. If the interviewer knows the person, the coupon manager should assign a different interviewer.

7.4 NHBS Interview

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

7.4a Eligibility screener

The eligibility screener is designed to ensure that participants meet the general NHBS eligibility criteria and are recent IDUs. To start the eligibility screener, the interviewer should open the survey file on the portable computer and enter the survey ID (the coupon or referral card number) and his interviewer ID. The portable computer will automatically determine whether someone is eligible to participate based on the following criteria:

- Is 18 years of age or older
- Has not previously participated in the current project cycle

- Lives in the participating MSA or Division
- Has injected drugs that were not prescribed for him in the past 12 months
- Has physical signs of recent drug injection or knows the steps involved in drug injection
- Is able to complete the interview in English or Spanish

Individuals who do not meet at least one of the eligibility criteria will be told “the computer has not selected you to participate in the health survey.” If someone is ineligible, the interviewer should end the interview and thank the person for his time. After the person leaves the field site, the interviewer should tell the coupon manager that the person was ineligible and give him the person’s coupon. The coupon manager should enter “Not eligible” in the person’s CMP record, mark the coupon “VOID,” and file the coupon in the weekly folder or envelope.



Interviewers 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.

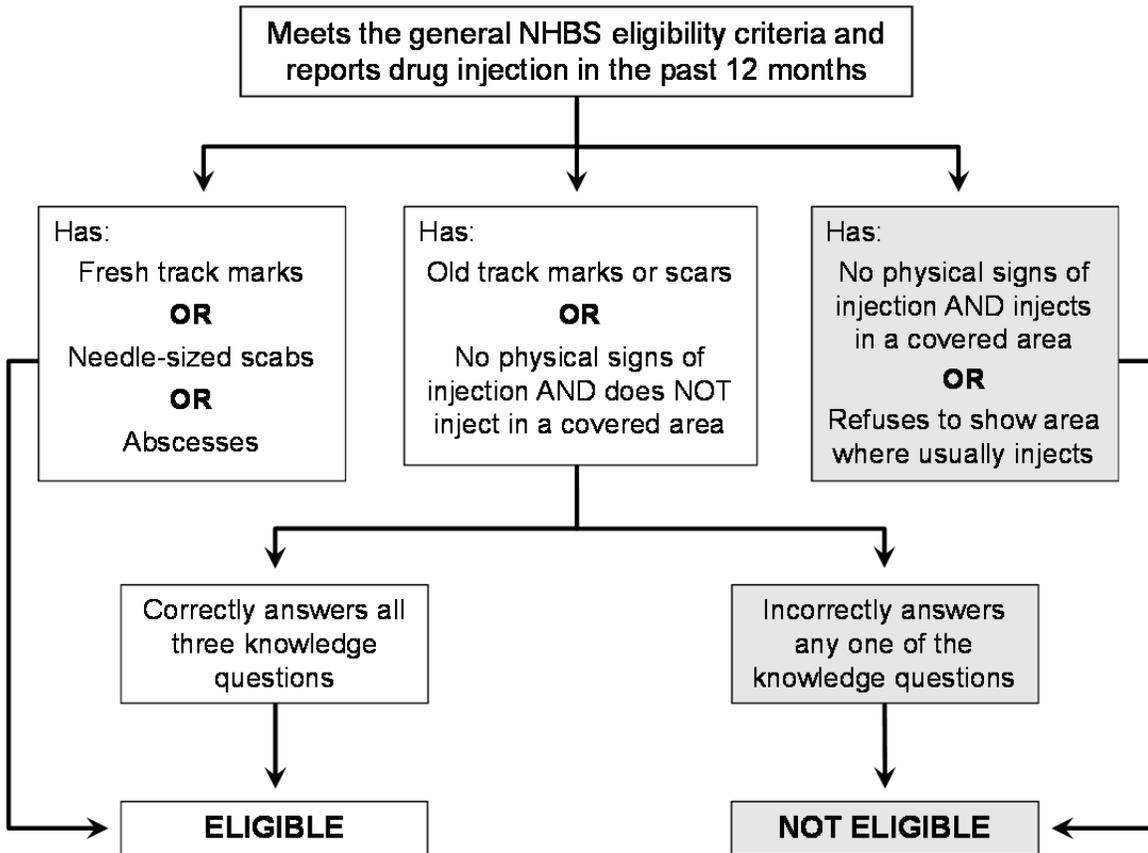
Injection drug use within the past 12 months

NHBS-IDU3 participants must have injected drugs within the past 12 months. To meet this eligibility criterion, participants must report that they have injected drugs that were not prescribed for them in the past 12 months **AND** they must have physical signs of recent injection (fresh track marks, needle-sized scabs, or abscesses) **OR** sufficient knowledge of drug preparation, injection, and syringes. The algorithm for assessing a participant’s physical signs and knowledge of drug injection is illustrated in **Figure 7.2**.

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

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

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



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

Photographic examples of the physical signs of drug injection are available at: <http://www.kap.samhsa.gov/products/brochures/pdfs/SkinLesionchart.pdf>, and additional examples can readily be found on the internet. Project sites should alert CDC to any new resources they identify so that these can be shared with the other sites.

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

- ***If the participant has fresh track marks, needle-sized scabs, or abscesses***, he has evidence of recent injection and the portable computer will skip the injection knowledge questions.
- ***If the participant has old track marks or scars***, he does not have evidence of recent injection and the portable computer will instruct the interviewer to ask the injection knowledge questions to further assess whether the participant is a recent drug injector.
- ***If the participant has no physical signs of injection and DOES NOT inject in a covered area of his body***, he does not have evidence of recent injection and the portable computer will instruct the interviewer to ask the injection knowledge questions to further assess whether the participant is a recent drug injector.
- ***If the participant has no physical signs of injection and DOES inject in a covered area of his body***, he does not have evidence of recent injection. However, in this case, the portable computer will not instruct the interviewer to ask the injection knowledge questions. Because some people who report that they inject in covered areas are fraudulently claiming to be drug injectors so that they can participate in the survey and obtain the incentive, the portable computer will automatically make people ineligible if they inject in covered areas but do not have any recent or old signs of injection.
- ***If the participant refuses to show where on his body he usually injects***, the interviewer will not be able to assess whether he has evidence of recent injection. Since the person is not cooperating with the interviewer, the portable computer will automatically make the person ineligible (it will not instruct the interviewer to ask the injection knowledge questions).

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

- 1) “Step-by-step, tell me how you prepare your drugs?”
- 2) “Step-by-step, tell me how you inject your drugs?”
- 3) “What type of syringe do you usually inject with?”

Project sites should use the information collected during formative research to develop standards for evaluating participants’ responses. Not only will this help the interviewers, but it will also ensure that all participants are assessed in a consistent manner. Based on the local standards established by the project site, the interviewer should determine whether the participant has provided an acceptable response to each of the injection knowledge questions. Since a participant who is asked the injection knowledge questions

does not have to have recent signs of injection, it is important for the interviewer to carefully assess the suitability of the participant's responses. If the interviewer is not completely satisfied with the participant's initial responses, he should probe with additional questions on drug injection and drug use practices until he can confidently determine whether or not the participant is a recent injector. For example, to help differentiate between individuals who are recent injectors and those who injected in the past, interviewers could ask about current "street" names for drugs, drug packaging and pricing, and locations where drugs are purchased and used.



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

Previous participants

The coupon manager can prohibit previous participants from enrolling again if he recognizes them during check-in. Yet, sometimes previous participants are not recognized until after they have been checked in. When this occurs, 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 make him ineligible if he denies previous participation during eligibility screening. If the person responds "No" when asked "During 2012, did you already complete at least part of the health survey that <project name> is conducting? It could have been here or at another location," the interviewer should select the "Known previous participant" response option so that the portable computer will automatically make the previous participant ineligible.



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

Intoxicated participants

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

Underage participants

Project sites that identify a pattern of underage individuals (< 18 years old) attempting to

participate in NHBS should discuss the matter with their CDC project officer. If their CDC project officer agrees that the situation is problematic, then the project site should begin to screen out suspected underage individuals. To do this, project staff should alert the field supervisor whenever they suspect that a potential participant is underage. The field supervisor and the staff member(s) should then discuss whether or not the person appears underage. If the field supervisor and the staff member(s) agree that the person appears to be less than 18 years old, the field supervisor should tell the person's interviewer to make him ineligible if he reports being 18 years of age or older. The interviewer should make the underage person ineligible by recording "No" in the portable computer when asked, "Is this person alert and able to complete the health survey in English or Spanish?" The portable computer will instruct the interviewer to indicate why the person was unable to complete the survey, and the interviewer should select "Thought to be too young." The portable computer will then automatically make the person ineligible.

If the field supervisor and the staff member(s) *disagree* that the person is less than 18 years old, the person's interviewer should *not* make him ineligible based solely on his suspected age. Nonetheless, if the interviewer strongly suspects that the participant is underage, he can express his concerns using the validity question at the end of the survey (see "Core Questionnaire" in **section 7.4c**).

7.4b Consent

The interviewer should read the consent form to each eligible participant and answer any questions the participant may have. Depending on local Institutional Review Board (IRB) requirements, project sites may choose to have the interviewer paraphrase the information in the consent form rather than reading it verbatim. If the local IRB requires informed consent to be obtained before a potential participant is screened for eligibility, project sites must do so. Consent to participate in NHBS should be obtained verbally and recorded in the portable computer (some local IRBs may also require project sites to maintain written documentation of consent). Participants can consent to participate in either: 1) the NHBS survey, or 2) the NHBS survey and an HIV test. If applicable, participants can also consent to other laboratory tests offered locally or to have their blood stored for future tests. Further details of the consent process are provided in the *Round 3 NHBS Interviewer Guide*.



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

All participants in NHBS *must* remain anonymous. Participants cannot be required to provide names or other personal identifiers as a condition of participation. If participants voluntarily disclose their names or personal identifiers, project sites cannot maintain this information nor link it to any survey instruments or forms.

If a person chooses *not* to participate in the survey or is unable to provide consent, the interviewer should end the interview and thank the person for his time. The interviewer should tell the coupon manager that the person has not provided consent and give the person's coupon to the coupon manager. The coupon manager should enter "Did not consent" in the person's CMP record, mark the coupon "VOID," and file the coupon in the weekly folder or envelope.

Participants who change their mind about HIV testing

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

7.4c NHBS survey

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

Interviewing skills

Interviewers and project managers should read the *Round 3 NHBS Interviewer Guide* for explanations of the survey questions and guidance on interviewing. Major areas of focus include:

- **Reading questions and "Say" boxes as written:** To help ensure standard data collection among interviewers and across project sites, interviewers must read survey questions and "Say" boxes completely as written. Nevertheless, if a participant does not understand a survey question as asked, the interviewer can rephrase the question using colloquial language or local terminology.
- **Using flashcards:** Flashcards help participants understand the intent of a question or its responses, thereby facilitating the interview and improving data quality. Interviewers should always use flashcards when indicated by a question and they should read the responses on the cards in case a participant has a low literacy level.
- **Probing:** Interviewers should probe with additional questions whenever a participant cannot remember the answer to a question, gives an unclear response, or gives a response that cannot be coded with one of the available response options. Most often, participants have trouble remembering dates. When this occurs, the interviewer should try to help the participant remember

the date by starting with a broad period and then narrowing the period down. For example, if a participant cannot remember the month that he had his most recent HIV test, the interviewer could start by asking what season he had the test. Once the interviewer has determined what season the participant was tested, he could try to identify the month by anchoring it to a holiday or a special event (i.e., was it before or after the holiday or special event).

Network questions

RDS studies must meet certain assumptions to generate unbiased population estimates (see **section 1.4b** of this manual). Project sites will assess three of these assumptions with the *Network Questions*:

- **Participants know one another as members of the target population:** The first *Network Question* asks the participant to classify his relationship to the person who gave him his recruitment coupon to determine whether the participant and his recruiter know one another or are “strangers” (see **Table 7.1**).
- **Participants randomly recruit other participants from their personal networks:** The second *Network Question* asks the participant to estimate the number of IDUs he knows and has seen in the past 30 days who are male and the number who are female (see **Table 7.2**). The gender composition of the participants’ personal networks can be compared to the gender composition of the sample to help determine whether participants recruit randomly or preferentially from their personal networks.
- **Participants can accurately report their personal network size:** The third *Network Question* automatically sums the number of male and female IDUs the participant knows and asks him to confirm that number (see **Table 7.3**). This is his personal network size. During RDS analysis, participants with smaller networks are given more weight than participants with larger networks to compensate for their having a lower probability of being recruited (participants with smaller networks know fewer people who could potentially recruit them).

Because the *Network Questions* are critical to RDS analysis, it is important that the interviewers ask them accurately and probe if participants provide vague or dubious responses. Some responses, if given, require clarification and the portable computer will automatically instruct the interviewer to follow-up. The first of these responses is recruitment by a stranger and the second is a small personal network size.

Recruitment by a stranger: Recruitment by a stranger violates the RDS assumption that “participants know one another.” For the first *Network Question*, if a participant responds that the person who gave him his coupon was a stranger, the interviewer should probe to determine whether the participant was truly recruited by a “stranger” or by a distant acquaintance. The portable computer will instruct the interviewer to ask:

“***When and where did you first see this person?***”

Table 7.1 – First Network Question

[GIVE RESPONDENT FLASHCARD B.1.] Which of the following describes how you know the person who gave you this coupon? You can choose more than one answer. **[READ CHOICES. CHECK ALL that apply.]**

A relative or family member 1

A person you have sex with..... 2

A person you use drugs with or buy drugs from 3

A friend..... 4

An acquaintance (that is, a person you know, but do not consider a friend)..... 5

A stranger (you don't know the person/just met them).. 6

Refused to answer..... 77

Table 7.2 – Second Network Question

How many males in *[insert project area]* do you know who inject and whom you have seen in the past 30 days? Please include the person who gave you the coupon if they are male.

How many females in *[insert project area]* do you know who inject and whom you have seen in the past 30 days? Please include the person who gave you the coupon if they are female.

Table 7.3 – Third Network Question

So in the past 30 days you've seen _____ people who you know inject and who live in *[insert project area]*. Would you say that _____ people is about right?

Yes, about right..... 0

No, you actually know less people who inject..... 1

No, you actually know more people who inject..... 2

If the participant responds that he *first* saw his recruiter in a situation related to the project, such as when he received his coupon or when hanging around the field site, the interviewer should indicate that the “Recruiter is a stranger.” On the other hand, if the participant responds that he had seen or interacted with his recruiter before he was given his coupon, the interviewer should indicate that that “Recruiter is not a stranger.” When the interviewer selects “Recruiter is not a stranger,” the portable computer will automatically go back to the first *Network Question* so that the interviewer can enter the correct relationship between the participant and his recruiter. The interviewer may also use his own discretion to probe further if he needs more information to determine whether the participant was recruited by a stranger or a distant acquaintance.

Small personal network size: Since data from participants with extremely small personal network sizes are given considerably more weight in RDS analysis, interviewers should confirm a participant’s response whenever he reports that he does not know any other IDUs or he just knows 1 to 3. If a participant responds that he does not know any other IDUs, the portable computer will instruct the interviewer to ask:

“You said you don’t know anyone in [project area] who injects that you have seen in the past 30 days. Is this correct? Did you include the person who gave you the coupon?”

Whereas, if a participant responds that he knows just 1 to 3 other IDUs, the portable computer will instruct the interviewer to ask:

“Is there anyone else you know in [project area] who injects that you have seen in the past 30 days? Did you include the person who gave you the coupon?”

Note that if the participant is a seed, neither question will ask him to include the person who gave him his coupon. When a participant responds that he knows more IDUs than he originally reported, the portable computer will automatically go back to the second *Network Question* so that the interviewer can enter the correct number of male and female IDUs that the participant knows.

Core questionnaire

The core questionnaire consists of several sections: demographics, sexual behavior, alcohol and drug use, HIV testing experiences, health conditions, and exposure to prevention services. Participants are asked all sections, with one exception. Because the sexual behavior section is not designed for use with transgender persons, participants who identify as transgender will not be asked this section.

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

in a participant's responses, then that participant will not be eligible to recruit others.

Additional interviewer instructions, explanations of the core survey questions, and procedures for coding the validity of the participant's responses are contained in the *Round 3 NHBS Interviewer Guide*.

Ending an interview early

If a participant does not want to continue the survey, is too intoxicated to continue, or is behaving inappropriately, the interviewer should end the interview, escort the participant to the coupon manager station, and return the participant's coupon to the coupon manager. The coupon manager should enter "Interview not completed" in the person's CMP record, mark the coupon "VOID," and file the coupon in the weekly folder or envelope. The participant should not be paid an interview incentive and he should not be given coupons to recruit others. Project sites that are required to provide an interview incentive by their local IRB may do so, but they **cannot** distribute recruiter coupons to the participant. When an incentive must be given, the coupon manager should add a note to the CMP record indicating that the "participant did not complete the interview, but the IRB requires that an incentive be paid."

For documentation, the interviewer should record the reason for stopping the interview on the hard copy of the Data Error Log (**section 7.5**) or in the data edits section of the Participant Tracking Form (**Appendix P**). When entering this information into the online Data Error Log on the Data Coordinating Center (DCC) data portal, the data manager should instruct the DCC to add the reason for stopping the interview to the "Comments" field of the participant's survey record (variable= INTTXT).

Participants who have not injected drugs within the past 12 months

In the core questionnaire, participants will again be asked when they last injected any drugs to confirm their eligibility. If a participant has not injected drugs within the past 12 months, the portable computer will automatically jump to the end of the core questionnaire so that the interview can be stopped. The interviewer should use the "Comments" field in the portable computer to enter the reason for stopping the interview and he should use the hard copy of the Data Error Log or the data edits section of the Participant Tracking Form to instruct the DCC to change the participant's eligibility from "eligible" to "ineligible" (the value of the variable EL_IDU should be changed from "1" to "2").

Unlike a participant who has his interview stopped for a reason other than eligibility (see "Ending an interview early" above), a participant found to be ineligible during the core questionnaire can still receive an HIV test if he consented to one and he should be paid interview and test incentives. The participant's recruiter should also be paid a recruiter reward. Nevertheless, since the participant is not a recent drug injector, he should **not** be given coupons to recruit others.

7.5 Data Error Log

The Data Error Log provides documentation of any corrections that need to be made to the data (please see the *NHBS-IDU3 Data Management Training Manual*). At the beginning of each day of field site operation, the interviewers should be given their own hard copy of the Data Error Log. Alternatively, project sites could add a data edits section to the Participant Tracking Form so that they do not have to have a separate log. If mistakes are made or problems occur during an interview, the interviewer should describe them on the log, along with the participant's survey ID and any corrections that need to be made to the data. At the end of each day, the field supervisor should collect all the logs, review them with the interviewers, and make sure they are complete. If the same errors are made repeatedly, additional training should be provided to the interviewers to help them avoid future occurrences.

The information from the Data Error Log or the edits section of the Participant Tracking Form should be entered into the online Data Error Log on the DCC data portal on a *daily* basis. Immediate entry of this information will help the data manager clarify data errors and corrections when an interviewer or the field supervisor needs to recall a specific problem.

7.6 HIV Testing

After the interview is completed, participants who have consented to HIV testing should receive counseling and an HIV test. Project sites must conduct all HIV counseling and testing in accordance with the *NHBS Round 3 Model Surveillance Protocol* and their local testing policies. Most importantly, a participant **cannot** receive HIV counseling or his test result before he finishes the core questionnaire. Some project sites are not required to provide pre-test counseling before they collect a specimen for HIV testing. If these project sites adhere to the prohibition on counseling and providing results before the end of the core questionnaire, they may collect a specimen for rapid HIV testing prior to starting the survey. This will allow these project sites to run a participant's rapid HIV test while he is being interviewed. When the participant completes his interview, he would then receive HIV counseling and his rapid test result. Detailed guidance on HIV testing is provided in **Chapter 9** of this manual.



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

7.7 Recruiter Training

Recruiter training can be provided by the interviewers or the coupon manager. In previous RDS cycles, some project sites had the interviewers provide the recruiter training and then the coupon manager reviewed the instructions with the participant to

reinforce them. If project sites prefer, they can provide recruiter training after conducting the interview but before administering the HIV test.

7.7a Eligibility to recruit others

At the end of the core questionnaire, the portable computer will display a message to the interviewer indicating whether or not the participant can receive coupons to recruit others. Participants can recruit others if: 1) they were eligible and completed the core questionnaire, and 2) they provided valid responses during the interview (i.e., the interviewer did not record his confidence in the participant's responses as "not confident at all").



The message displayed on the portable computer uses the phrases "eligible to recruit others" and "not eligible to recruit others." However, project staff should **never** use the term "eligible" with participants because they may try to ascertain what the criteria are to be a recruiter. Project staff should tell participants that the computer determined whether or not they were selected to recruit others.

7.7b Offering the chance to recruit others

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

- Recruiting is completely **voluntary**. Participants do not have to recruit others if they do not want to, and they will still be paid for completing the interview and testing for HIV.
- Recruiting is **important** to the project. The success of the project depends on people recruiting others to accrue a large sample of people from throughout the city.
- They have a chance to **earn \$10** per person recruited, up to a maximum number of people recruited.

If the interviewer provides the recruiter training and the participant decides not to recruit others, the interviewer will have to tell the coupon manager that the participant does not want to be a recruiter. This can be communicated verbally or through the Participant Tracking Form.

7.7c Conducting recruiter training

During recruiter training, project sites should explain to participants how to properly recruit other IDUs and how to obtain their recruiter rewards. To motivate recruiters and promote community buy-in, project sites should also underscore the benefits of the project to participants and the community. Recruiter training is key to the success of RDS. If training is incomplete or unclear, recruiters will be less effective and recruitment chains may not grow. A model recruiter training script is included in **Appendix Q**, but

project sites may prefer to use talking points instead (see **Appendix R**). Project sites should tailor the script or talking points to match their local operations and, if they plan on conducting interviews in Spanish, they should also translate the recruiter training documents into Spanish. When the interviewers provide the recruiter training, it is helpful to have the coupon manager ask the participants questions about the recruitment process to ensure that they understand what is required.



During recruiter training, project staff should emphasize that participants should only recruit IDUs 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, IDUs.

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

7.8 Check-out

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

7.8a Participant information

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

- Whether the participant was eligible for the survey
- Whether the participant consented to the survey
- Whether the participant completed the survey
- Whether the participant received an HIV test
- Whether the participant is eligible to recruit other IDUs and agreed to do so
- The number of coupons the participant should receive

7.8b Coupon manager duties

The coupon manager's responsibilities during the check-out include editing the CMP record, distributing coupons, distributing incentives, and in some cases, providing

prevention materials and referrals.

Editing the CMP record

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

- ***If the participant was not eligible, did not consent to the survey, or did not complete the survey***, the coupon manager should check the "Interview not completed" box in the participant's CMP record. The coupon manager should mark the coupon "VOID" and file it in the weekly folder or envelope. A project site's IRB may require that the recruiter receive a reward if the participant was eligible and started the interview, but did not complete it. In this case, the coupon manager should check the "Eligible" box in the participant's CMP record instead of the "Interview not completed" box so that the participant's recruiter will be paid a reward. The coupon manager should also add a note to the CMP record indicating that the "participant did not complete the interview, but the IRB requires that the recruiter be paid a reward." Participants who are not eligible, do not consent to the survey, or do not complete the survey **cannot** recruit others and should not be given coupons.
- ***If the participant completed the survey but did not agree to recruit others***, the coupon manager should check the "Eligible" box in the participant's CMP record. The coupon manager should mark the participant's coupon "USED" and file it in the weekly folder or envelope.
- ***If the participant completed the survey and agreed to recruit others***, the coupon manager should check the "Completed interview" box in the participant's CMP record. The coupon manager should mark the participant's coupon "USED" and file it in the weekly folder or envelope. Since the participant agreed to recruit others, the coupon manager should enter the participant's recruiter information into his CMP record:

Step 1) The coupon manager should explain to the participant that he needs to collect some additional information that will be used to identify the participant when he returns for his recruiter rewards. This information will help ensure that no one else can claim the participant's rewards.

Step 2) The coupon manager should create a recruiter ID for the participant based on the questions in **Table 7.4** and enter the ID in the participant's CMP record. Since the smallest data entry error can make participant identification difficult or impossible, the coupon manager should be extremely careful entering recruiter

IDs in the CMP and he should double-check the entries. Similarly, the coupon manager should ask participants to be consistent in their responses to the recruiter ID questions, especially if they have multiple aliases. It may be helpful to show the participants a flashcard with the list of questions used to create the recruiter ID to improve the accuracy of their responses.

- Step 3) The coupon manager should ask the participant to show him any distinguishing “physical marks,” like tattoos or birthmarks, that could be used for future identification (see **Table 7.5** for instructions on collecting and recording physical marks). He should also examine the participant’s face, neck, and arms for any other obvious “physical marks.” Relevant “physical marks” should be entered in the participant’s CMP record.
- Step 4) The coupon manager should determine how many coupons the participant should be given to recruit others and enter the numbers on the assigned coupons in the participant’s CMP record.
- Step 5) If necessary, the coupon manager can add comments to the participant’s CMP record that could help with participant identification or project management.

Table 7.4 – Recruiter ID questions

| |
|--|
| <ul style="list-style-type: none">1) What are the FIRST 2 letters of YOUR LAST name?2) What is the FIRST letter of YOUR FIRST name?3) What is the FIRST letter of YOUR MOTHER’S FIRST name?4) In which MONTH were you born? (2 digits)5) What are the LAST 2 digits of your YEAR of birth?6) What is your gender?7) What racial/ethnic group do you consider yourself to be in? |
|--|

Table 7.5 – Collecting and recording physical marks

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

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

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

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

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

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

Distribute coupons

If the participant agrees to recruit others, the coupon manager should give him coupons and reiterate that he will only receive rewards for the people he recruits who are eligible and complete the survey. The coupon manager should also give the participant an information card with the hours, location(s), and phone number of the field site(s).

Participants can call the field site to see if they are owed any recruiter rewards (the coupon manager can use the participant's survey ID to locate his CMP record). Please see **Appendix N** for a model information card and **Appendix O** for instructions on how to create cards. Project sites should keep track of the coupons given out using a Coupon Distribution Log (see **section 6.5a** of this manual) and a CMP Log (**Appendix J**).



Some participants may know fewer IDUs than the number of coupons being distributed. For example, a participant may report that in the past 30 days he has only seen 2 IDUs that he knows, but the project site is giving 3 coupons to each recruiter. Regardless of how many IDUs 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 IDUs they know and have seen in just the past 30 days.

Reinforce recruiter training

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

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

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

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

Distribute incentives

The coupon manager (or field supervisor) should then pay the participant the incentive for completing the survey and if applicable, the incentives for receiving the HIV and other tests. Participants do not have to agree to recruit other IDUs to receive their incentives. After the participant is paid, the coupon manager should document payment of each incentive in the participant's CMP record.



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

Provide prevention materials and referrals

Providing participants with prevention materials and referrals is an important component of NHBS; it facilitates rapport with participants and trust with local communities. Project sites should provide participants with prevention materials such as informational pamphlets on safe drug injection practices and HIV, STD, and hepatitis prevention, as well as condoms, lubricants, and hygiene kits. Please refer to **Appendix S** for guidance on the restriction on using federal funds for the purchase or distribution of needles or

syringes.

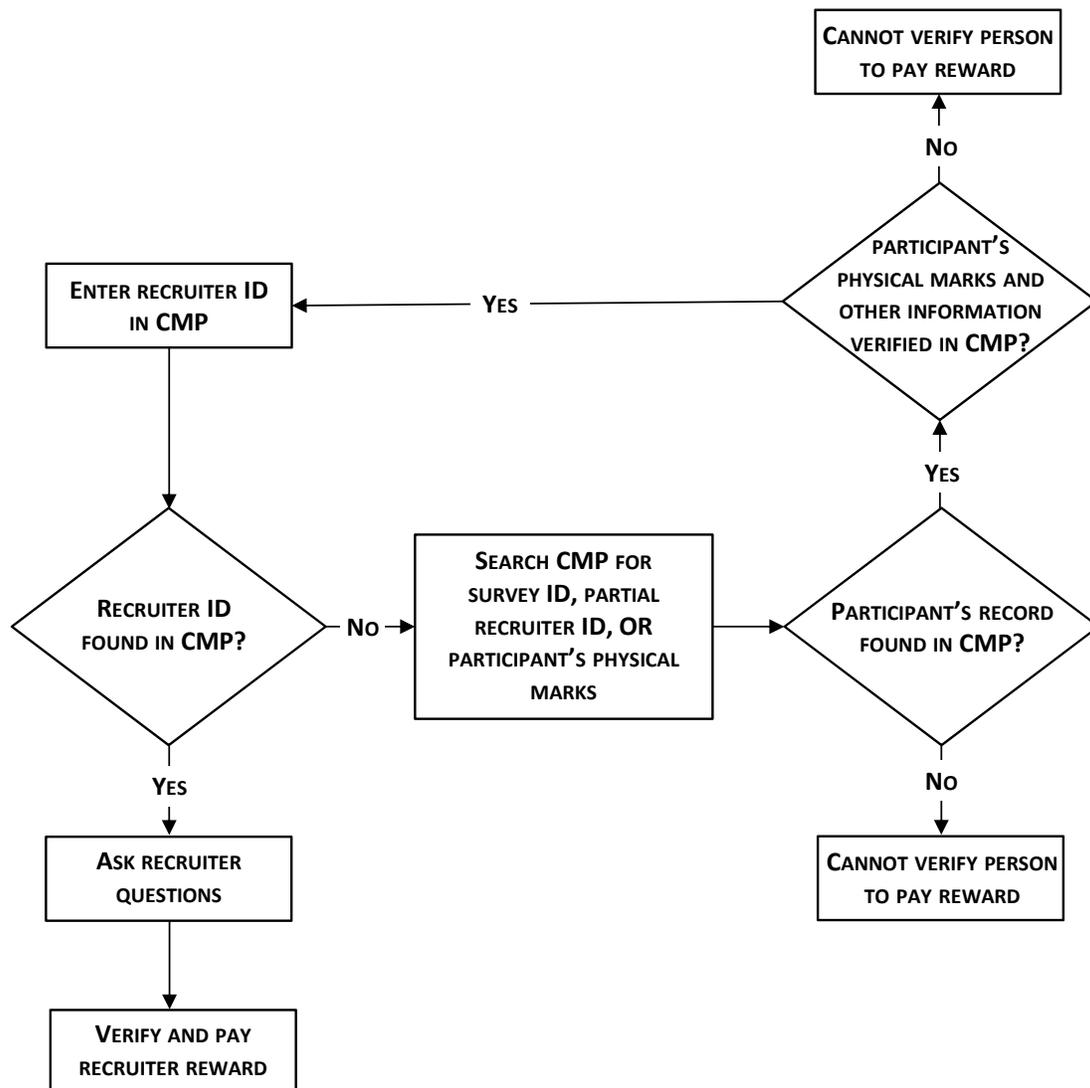
Participants in need of health care or social services should be referred to the appropriate providers in the community. Of utmost importance, participants who are newly diagnosed with HIV infection should be referred for HIV medical care and case management as described in **section 9.7b** of this manual.

Based on their formative research, project sites should identify those health care and social service providers most commonly used by IDUs in their community. Project sites should maintain a list of the names of these providers and their contact information so that they can readily make any necessary referrals. This list should include HIV and STD clinics, agencies that offer free HIV tests, health clinics, mental health service providers, substance abuse treatment centers, domestic violence shelters and programs, housing agencies and shelters, and other social service organizations that provide financial assistance or assistance with food, clothing, utilities, or employment.

8.1 Overview

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

Figure 8.1 – Recruiter Questions and recruiter reward process



8.2 Verify Participant's Identity

The first step in the process of asking the *Recruiter Questions* and paying recruiter rewards is to verify the participant's identity. The coupon manager should enter the recruiter ID into the CMP by asking the series of questions used to initially create the ID (see **Table 7.4** of this manual). The CMP will then locate the participant's record and the coupon manager can ask the *Recruiter Questions* (see **section 8.3**).

8.2a Unable to locate recruiter ID in the CMP

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

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

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

Whenever a record is located by searching for a survey ID, partial recruiter ID, or physical marks, the coupon manager should confirm the participant's identity by checking the rest of the information in the participant's record, including his date of interview, month and year of birth, gender, race/ethnicity, and physical marks. The coupon manager should also correct the recruiter ID in the record, and then repeat the first step of the reward payment process by entering the corrected recruiter ID in the CMP. Re-entering the recruiter ID will allow the CMP to automatically display the *Recruiter Questions*.

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

8.3 Ask Recruiter Questions

The *Recruiter Questions* are used to measure non-response bias by asking the participant about any individuals who refused the coupons they were offered (see **Table 8.1**). Once the CMP has located the participant's record, the coupon manager should ask the *Recruiter Questions* and enter the participant's responses in the CMP. The *Recruiter Questions* should be asked or confirmed **every** time a participant returns to the field site to collect his recruiter rewards or calls the field site to see if he is owed any rewards. Many participants only return to collect their rewards once, so it is important for the coupon manager to always try to ask the *Recruiter Questions* whenever he has the opportunity.

Table 8.1– Recruiter Questions

| No. | Question |
|-----|---|
| 1 | How many of the coupons did you give out? |
| 2 | Has anyone refused the coupons? |
| 3 | Of those who refused coupons, how many were male? |
| 4 | Of those who refused coupons, how many were female? |
| 5 | What is the race or ethnic background of those who refused coupons? That is, how many were white, black, Hispanic, Asian, or another race? |
| 6 | Which of the following are reasons that people who refused gave you about why they did not take a coupon? (<i>The coupon manager should read each response and check all that apply.</i>) <ul style="list-style-type: none"> a. They didn't have time b. They didn't live in the area c. They didn't trust you (recruiter) d. They don't like research/surveys e. They already participated in this survey f. They didn't want to be identified as IDU g. They weren't eligible h. Some other reason (Specify :_____) |



If previous responses to the *Recruiter Questions* show that the participant gave out all his coupons and **NO ONE** refused any of the coupons, then the *Recruiter Questions* do not need to be asked again.

When asking the *Recruiter Questions* a subsequent time, the coupon manager should explain that he may be repeating questions he asked before. If the participant has not given out all his coupons when he is first asked the *Recruiter Questions*, he will be asked if he has given out any more coupons the next time he returns for his recruiter rewards. He will also be asked about people who refused any coupons. The coupon manager can help the participant remember his previous responses by telling him what has already been recorded in the CMP. For example, the first time a participant answers the *Recruiter Questions*, he states that he has given out 2 coupons. When he returns for a second time, the coupon manager could say:

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

If the participant responds that he has given out more coupons, the coupon manager should then ask the remainder of the *Recruiter Questions*. Any inconsistencies in the participant’s responses should also be clarified.

8.4 Verify and Pay Reward

Participants will receive a reward for each eligible recruit who completes the NHBS survey. After the coupon manager asks the *Recruiter Questions*, 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. The participant’s CMP record can then be updated to show that a reward has been paid for the applicable coupon(s). If a participant is not owed a reward, \$0 will be displayed. To determine why a reward is not owed, the coupon manager can check the status of a participant’s coupons by examining his CMP record. The meaning of each coupon status in the CMP and the corresponding reward payment action is shown in **Table 8.2**.

Project sites should consider the following when paying recruiter rewards:

- Reward payments can only be made directly to the participant.
- For safety reasons, rewards should be stored in a locked file cabinet or drawer.
- Participants may call the field site to find out whether they are owed a reward. They can identify themselves by their recruiter ID or their survey ID.
- Participants cannot receive replacement coupons for ineligible recruits or for lost or stolen coupons.
- Some local IRBs may require that the participant still receive a reward when his recruit is unable to complete the survey or chooses to end the interview early.

Table 8.2 – CMP coupon status and recruiter reward payment action

| Coupon Status | UNPAID | VOID | PENDING | PAID |
|--------------------|---|---|---|--|
| Recruitment Status | The recruit has not come to the field site to be interviewed. | The recruit was a previous participant, was not eligible, did not consent to the survey, did not complete the interview, or if applicable, had an expired coupon. | The recruit was eligible and completed the survey. | The recruit completed the survey and the participant was already paid. |
| Payment Action | Tell the participant to encourage the recruit to come to the field site for an interview. | Do not pay the participant for recruits with “VOID” status. | Pay the participant for each recruit with “PENDING” payment status. | No further action. |

9.1 Overview

This chapter provides guidelines for conducting HIV and other tests as part of NHBS. Additional information on testing procedures is contained in Chapter 5 of the *NHBS Round 3 Model Surveillance Protocol*. Before data collection can begin, project sites must document procedures for testing, returning results, and making referrals to care in the Operations Checklist (**Appendix A**). Any locally-developed testing forms or logs (e.g., lab slips, risk assessment forms, etc.) should be included in the checklist as well. Project sites are also responsible for following local laws, guidelines, or requirements for testing and counseling.

9.2 Testing

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

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

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



Project staff are not able to change the consent variable in the Data Error Log. Consent for HIV and other testing can only be recorded in the portable computer.

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

9.2a HIV testing

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

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

Project sites are encouraged to conduct rapid testing if possible. Experience with previous NHBS cycles has shown that many participants do not return for their laboratory-based test results since these are usually not available for one to two weeks. Although a reactive rapid test result is considered preliminary (i.e., a specimen must be collected for confirmatory testing), participants with preliminary positive test results can be immediately referred to care (see **Section 9.7b**). In addition, receipt of a preliminary positive test result may increase a person’s likelihood of seeking additional testing or care, even if he does not return for his final NHBS test result. Project sites offering rapid HIV testing must be prepared to collect confirmatory test specimens from participants with preliminary positive test results.

Rapid HIV testing

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

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

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

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

- The best location for the fingerstick is either the 3rd (middle) or 4th (ring) finger of the non-dominant hand. These fingers tend to be used less often and are thus less likely to have calluses or tough skin.
- Warm the participant's hands and fingers to increase blood flow if possible (an instant hand warmer can be used). To further increase blood circulation and flow, it sometimes helps to massage the whole hand and finger to be stuck, not just the fingertip. It also increases blood flow to have the participant hold his hand below the level of his heart before performing the stick.
- Prior to the stick, clean the fingertip with a 70% isopropanol swab and allow it to air dry completely for a few seconds.
- Using a sterile, disposable lancet, make the puncture just off the center of the finger pad at right angles to the ridges of the fingerprint so that the blood does not run down the ridges. Avoid the tip and center of the finger, as well as the

edge of the nail bed and the side of the finger where there is less soft tissue. It is best to lay the participant's hand flat against a hard surface to ensure a deeper stick.

- Wipe away the first drop of blood, which tends to contain excess tissue fluid, with a sterile gauze or cotton ball. Allow a new drop of blood to form before using the specimen collection device.
- Hold the finger downward. If necessary, the finger can be massaged at the base or pressure can be applied next to the puncture point to increase blood flow. Avoid "milking" or excessive squeezing of the finger because this may dilute the blood with excess tissue fluid. The blood should be free flowing and not "forced" to flow. When applying pressure, provide intermittent pressure rather than constant pressure; apply pressure in a "squeeze, release, squeeze, release" pattern.

During rapid test development, the test face of the device should not be visible to the participant. This is best achieved by conducting testing in an area that is separate from the interview space. If testing is conducted in the same space as the interview, the test face should be turned away from the participant or it should be covered; otherwise, having the test face visible to the participant may cause anxiety or misinterpretation of the test result. Shielding the test face from the participants is particularly important for project sites that collect the specimen before beginning the survey and run the test in the same room as the interview. In these cases, having the test face visible to the participant could also disrupt the interview. Because counseling cannot be conducted until the core questionnaire is completed, test results cannot be disclosed to participants until the end of this section of the survey.



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

Project sites should maintain a Quality Assurance Log to monitor the running of controls, the temperature at which tests are stored and run, and the lot numbers for each batch of test kits used. A good reference guide for Rapid Testing Quality Assurance can be found at http://www.cdc.gov/hiv/topics/testing/resources/guidelines/pdf/qa_guidelines.pdf. Rapid test results must be read within the timeframe indicated in the package insert for the specific test being used. Accordingly, project sites should develop a system for recording the time the test was started and the time the test result was read. For example, these times could be recorded on the HIV Test Results Log, the Participant Tracking Form, or the Quality Assurance Log. All rapid test kits should be stored in accordance with the package insert provided with the kits, and project staff should always check the date on the kits before using them to ensure that they have not expired.

9.2b Hepatitis testing

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

Project sites participating in the CDC-funded supplemental hepatitis testing must incorporate the collection of venipuncture blood specimens into their core NHBS activities. They can accomplish this by either 1) collecting blood specimens for both HIV testing and hepatitis testing, or 2) following their usual HIV testing procedures and obtaining additional consent for blood specimen collection for hepatitis testing. Before specimen collection can begin for hepatitis testing, project sites must discuss their proposed testing method with their CDC project officer and receive his approval.

Appendix T provides additional guidance on testing for HBV and HCV, as well as information on interpreting test results.

9.2c Other and future testing

Project sites may offer other tests, such as for syphilis or herpes simplex virus, or may want to store blood samples for future testing (either locally or at CDC). Options for other and future testing are outlined in the Model Consent Form (see Appendix F of the *NHBS Round 3 Model Surveillance Protocol*).

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



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

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

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

9.3 Staffing and Training

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

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

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

Projects sites collecting blood specimens by venipuncture or fingerstick must adhere to the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard for universal precautions, personal protective equipment, and syringe disposal. The OSHA standards are available at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051. Project sites are responsible for training their staff in these standards, and may be able to get training support from health departments, hospitals, and community-based organizations that perform HIV testing.

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

9.4 Specimen Collection

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

9.4a Venipuncture

Using standard venipuncture procedures, blood specimens should be collected in blood collection tubes appropriate for the type of testing that will be performed. Project sites should check with their local laboratory to determine which collection tubes are indicated for the types of tests they will offer. For example, serum “red top” tubes or EDTA “purple top” tubes are commonly used for HIV testing. Project sites participating in the hepatitis supplement should collect blood in 5 ml red and grey “tiger top” tubes; 1 or 2 tubes should be collected depending on whether the testing will be performed in the same laboratory or in two different laboratories. To ensure an adequate specimen volume for testing, blood collection tubes should be filled completely. If additional tests other than HIV or hepatitis 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.

The date and survey ID number should be recorded on the collection tubes before blood collection begins. If the tubes contain any type of additive, like EDTA, they should be inverted several times immediately after collection to mix the additive with the blood.

9.4b Dried blood spots

A list of supplies needed to create DBS can be found in **Appendix U**. Project sites should begin the DBS collection process by recording the date and the participant’s survey ID number on the DBS card. Those project sites using DBS for laboratory-based HIV testing should record the date and survey ID in two places on the card: 1) the part of the card for the CDC laboratory, and 2) the part of the card for the local laboratory. If the local laboratory uses a separate laboratory ID, that ID should also be included on the part of the card that will be sent to the local laboratory. The laboratory ID should not be written on the part of the card that will be sent to the CDC laboratory. Instructions for dividing DBS cards are described in **section 9.5b**.

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

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

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

DBS from fingerstick

CDC recommends collecting DBS with Whatman cards containing 5 circles, especially if a project site needs to send spots to their local laboratory for HIV testing. Helpful hints for fingerstick blood collection can be found in **section 9.2a** (“Rapid HIV testing”). To obtain a sufficient quantity of blood, the lancets used for fingersticks should be blades rather than needles (see **Appendix U** for recommended lancets). When using the same fingerstick for both DBS and a rapid test, the DBS should be made before the rapid test specimen is collected because the blood at the puncture site could begin to clot while the rapid test is being processed and there would not be enough blood for the DBS. 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 fall from the tip of the finger onto the surface of the card inside the circle. Allow the blood to completely fill the circle before moving on to the next circle. If the circle is not completely filled with one drop, allow a second large drop to fall onto the same circle. Moving from one circle to the next, fill the remaining circles in the same way. When finished, apply cotton to the puncture site until bleeding stops.



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

After the DBS have been collected, avoid touching the part of the blood collection card with the spots. Cards should be dried at least 4 hours in a suspended horizontal position. Nevertheless, since the DBS must be completely dry before packaging, overnight drying is recommended. The drying rack manufactured by Whatman can be used to hold the cards while drying, or the cards can be clipped to test tube racks for drying. If necessary, the Whatman drying racks or test tube racks can be placed in a cardboard box to transport the cards from the field site to the project office for overnight drying and eventual packaging. The cards should remain in the racks until they are completely dry and ready to be packaged.



Drying times will vary depending on the humidity in the project area. Dried blood will appear dark red as opposed to the bright red seen when first collected.

DBS from blood tubes

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

9.4c Oral

Oral specimens for laboratory-based testing are collected via the OraSure Oral Mucosal Transudate (OMT) device. The OMT devices should be stored and used in accordance with the manufacturer’s package insert. Before specimen collection begins, the date and the participant’s survey ID number should be recorded on the OMT device. Project staff should explain to participants how to appropriately swab their mouths and they should monitor the participants to assure that the specimens are collected appropriately. The participant should not speak during specimen collection. As with the oral rapid test, food or drink consumption has **not** been found to interfere with the OMT test, but food particles (e.g., gum, candy) can prevent the test collection device from being placed flat against the gums for appropriate oral fluid collection. Therefore, if a participant has recently eaten something or is chewing gum, project staff should have him rinse his mouth to remove the food particles or have him throw out his gum before oral specimen collection.

9.5 Specimen Storage and Processing

9.5a Venipuncture

The requirements for the temporary storage of blood specimens prior to processing may differ based on the type of blood collection tube (e.g., serum “red top,” EDTA “purple top,” etc.). Additional factors to consider are the time of day and the time of year the specimens are collected. The time of day the specimens are collected in relation to the laboratory’s hours of operation determines how long a delay there will be until the specimens can be processed. Blood specimens should be transported to the laboratory and processed within 24 to 48 hours of specimen collection. The time of year the specimens are collected affects the temperature and humidity in which the specimens are stored and transported. Usually, blood collection tubes should remain at ambient temperature (< 86° F) prior to processing. All precautions should be taken to ensure the quality of the specimens collected. No blood specimen, regardless of type, should ever be subject to extreme hot or cold temperatures during temporary storage or transport to the local laboratory. In addition, all blood specimens should be transported or shipped in containers appropriately labeled according to OSHA guidelines to protect staff and public safety.

9.5b Dried blood spots

It is extremely important that the DBS cards be completely dry before packaging. Once they do become dry, the cards should either be placed in individual glassine envelopes or stacked between sheets of glassine weigh paper so that DBS cards from different individuals do not touch one another. The cards should then be placed in low-gas permeable zip-lock bags. The cards from HIV-positive (i.e., preliminary positive from rapid tests, positive from lab-based testing, and self-reported positive) participants should be packaged separately from the cards of HIV-negative and status unknown participants, and the zip-lock bags should be labeled accordingly (e.g., “HIV pos” or “HIV neg/unk”). The zip-lock bags can be stuffed with as many cards as possible as long as the bag can be sealed tightly and there is no excessive bulging of the bag.

Each zip-lock bag should also contain 5 to 10 desiccant packs to remove any residual moisture from the cards and a humidity indicator card to monitor the humidity in the bag. If the humidity level is high in a project area, more desiccant packs should be added to the zip-lock bag. Press as much air out of the bag as possible and seal it shut. Humidity indicator cards and desiccant packs have a color indicator which changes from blue to pink as humidity within the bag becomes unacceptably high. It is important to monitor the humidity indicator cards in the bags before they are shipped to the CDC laboratory and to replace the desiccant packs if the indicator cards change from blue to pink because of high humidity.



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

Once properly packaged, the DBS cards can remain at ambient temperature in a climate controlled area away from direct sunlight and where they can be monitored for excess humidity. The cards must be shipped to the CDC laboratory within 10 days of specimen collection. They should not be transported to the local laboratory or frozen for storage before shipment to CDC. For project sites that will use DBS for their laboratory-based HIV testing, a section of the card containing no more than 2 spots should be cut from the whole card after it has completely dried and sent to the local laboratory. The remaining spots should then be packaged as described above and shipped to the CDC laboratory. The cards can be cut with a regular pair of office scissors, but the scissors must be cleaned after cutting each card to avoid potential contamination. To clean the scissors, use dish soap and water. The scissors must also be thoroughly rinsed and dried before cutting another card.

9.5c Oral

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

9.6 Specimen Transport and Shipping

9.6a Local transport

As mentioned previously, blood specimen collection and transport should be timed so that specimens arrive at the laboratory and are processed within 24 to 48 hours of specimen collection. Project sites should develop transport procedures in conjunction with their local laboratory. When developing these procedures, they should consider transport time to the laboratory, the days and hours of laboratory operation, specimen intake procedures, and the days and hours of field site operation. A Specimen Transport/Shipping Log (**Appendix L**) should be included with the batches of specimens sent to the laboratory.

9.6b Shipping DBS to CDC

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



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

Because DBS specimens do not need to be processed by the local laboratory, project staff are responsible for mailing them to the CDC. The Specimen Transport/Shipping Log (**Appendix L**) should be used as a CDC shipping manifest and included in the envelope sent to the CDC. In addition, on the day the DBS are shipped to the CDC, an email should be sent to Amanda Smith (zbp9@cdc.gov) and Silvina Masciotra (svm6@cdc.gov) to notify them of the shipment. Overnight mailing should be used and the packages should be timed to arrive at CDC Monday through Thursday.

The DBS must be shipped to the CDC no more than 10 days after the spots are made. Project staff should devise a shipping schedule and record scheduled shipments on a monthly calendar. After arrival at the CDC, the DBS specimens will be stored at the Division of HIV/AIDS (DHAP) laboratory in temperature-controlled freezers until all testing is completed.

9.7 Test Results and Referrals to Care

9.7a Test results

Project sites must make final HIV and hepatitis test results available to participants, and they should keep track of the provision of results. After the NHBS survey is completed, project sites offering rapid testing should provide counseling and return negative and preliminary positive test results to participants. Each box of rapid HIV tests comes with a set of “subject information” pamphlets that should be given to the participants when they receive their rapid test results. For those participants with preliminary positive test results, project sites should also collect specimens for laboratory-based confirmatory testing. Participants can receive laboratory-based test results in person or, if permitted by local policies, over the phone. Project sites planning to provide test results over the phone should refer to the Model HIV Phone Result Protocol in Appendix I of the *NHBS Round 3 Model Surveillance Protocol*, and they should track results given over the phone using a Phone Results Log (see **Appendix I** of this manual for an example of a log). To properly schedule appointments for returning laboratory-based test results, project sites should check with their local laboratory to find out the test turnaround time. Appointments for returning test results should be made with the Appointment or Phone Results Cards in **Appendix V**.

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

keep the participants' confidential information secure. Furthermore, due to the highly sensitive nature of the information being collected, appointment reminder procedures must be approved by the project site's CDC Project Officer before this service can be provided.

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

As discussed in Chapter 5 of the *NHBS Round 3 Model Surveillance Protocol*, test counselors should target prevention messages to specific risks identified during the survey. Project sites that have separate interviewers and testing staff should develop procedures for communicating risk information between staff. For example, test counselors could administer a separate risk assessment or the interviewer could confidentially pass risk information to the test counselor. The collection of any risk information for test counseling must comply with the Assurance of Confidentiality for HIV/AIDS Surveillance data (see appendix K of the *NHBS Round 3 Model Surveillance Protocol*). Project sites conducting hepatitis testing can find resources for counseling participants about HBV and HCV at <http://www.cdc.gov/hepatitis/HBV/TestingChronic.htm> and <http://www.cdc.gov/hepatitis/HCV/PatientEduHCV.htm>.



Project staff should only return test results in a private area to protect participant confidentiality and should never discuss test results publicly.

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

Previous Positive Questions

In prior NHBS cycles, some participants disclosed a previous positive test result during test counseling even though they had not reported a previous positive test result during their interview. To collect this information from participants in a standardized manner, the *Previous Positive Questions* were developed (see **Appendix W** of this manual). These questions should be asked during test counseling to determine whether participants

previously tested positive, and if so, the date they first tested positive. Project sites conducting only laboratory-based HIV tests should ask the *Previous Positive Questions* of participants who do not report a previous positive test result during their interview; whereas project sites conducting rapid HIV tests should ask the *Previous Positive Questions* of participants who do not report a previous positive test result during their interview **and** who have a preliminary positive rapid test result. To ensure consistency in the way these questions are asked, test counselors should follow the script in **Appendix W**.

9.7b Referrals to care and services

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

Project sites cannot provide documentation of an anonymous NHBS test result to any other agency or individual even if a participant requests they do so. The agencies that participants are referred to will have to conduct their own tests to confirm a participant's diagnosis. Furthermore, these agencies should not have access to any NHBS code numbers, such as survey IDs or laboratory IDs, which could link participants to their NHBS data.

An anonymous referral to care or services should involve more than simply telling a participant where to go to receive care or services. Project sites should make an effort to actually link the participant to the needed care or services. For example, project staff could offer to call an agency to schedule a medical appointment for a participant. When making referrals, project sites should always respect the wishes of the participant; participants have the right to decline any referrals to care or services.



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

9.8 Data Management

9.8a HIV testing

While in the field, project sites should record HIV test results on a hard copy of the HIV Test Results Log (see Appendix J of the *NHBS Round 3 Model Surveillance Protocol*). The hard copy of the HIV Test Results Log, as well as any other HIV testing forms or logs, must be secure and in the possession of project staff at all times when in use in the field; otherwise, the forms and logs should be kept locked in a file or file box.

Data from the hard copy of the HIV Test Results Log should be entered into the online HIV Test Results Log on the Data Coordinating Center (DCC) data portal on a **daily basis**. It is important for project sites to enter these data daily so that the process monitoring reports generated by the DCC are up-to-date and reflect each project site's latest data. Project sites should refer to the *NHBS-IDU3 Data Management Training Manual* for specific instructions on data entry, a listing of required variables, a data dictionary, and a hard copy of the HIV Test Results Log for use in the field. Any data collected solely for local use do not have to be entered into the DCC data portal. Accordingly, project sites should consider developing their own electronic systems for storing these data.



For participants who self-report that they are HIV-positive but have a negative or indeterminate NHBS HIV test result, additional test result information, like EIA signal-to-cutoff ratios and Western Blot bands, will have to be entered into the online HIV Test Results Log on the DCC data portal. Guidance for entering this additional testing information is included in the *NHBS-IDU3 Data Management Training Manual*.

9.8b Hepatitis testing

Data management requirements for hepatitis testing are similar to those for HIV testing. While in the field, project sites should record hepatitis test results on a hard copy of the Hepatitis Test Results Log (see Appendix H of the *NHBS Round 3 Model Surveillance Protocol*). The hard copy of the Hepatitis Test Results Log, as well as any other hepatitis testing forms or logs, must be secure and in the possession of project staff at all times when in use in the field; otherwise, the forms and logs should be kept locked in a file or file box.

Data from the hard copy of the Hepatitis Test Results Log should be entered into the online Hepatitis Test Results Log on the DCC data portal on a **daily basis**. It is important for project sites to enter these data daily so that the process monitoring reports generated by the DCC are up-to-date and reflect each project site's latest data. Project sites should refer to the *NHBS-IDU3 Data Management Training Manual* for specific instructions on data entry, a listing of required variables, a data dictionary, and a hard copy of the Hepatitis Test Results Log for use in the field.

10

Process Monitoring and Ongoing Formative Research

10.1 Overview

Process monitoring and ongoing formative research enable project sites to maintain the highest standards for data collection and will help them meet the overall project objective of enrolling a representative sample of 500 IDUs. The information project sites obtain through these assessment methods will complement the information they gathered during the formative research conducted at the start of the project cycle.

10.2 Process Goals

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

- 85% of those who are screened for eligibility meet the eligibility criteria.
- 90% of those who complete an interview agree to recruit other participants.
- 90% of those who complete an interview consent to an HIV test.
- A minimum of 500 IDUs complete an interview.

Achieving these process goals is critical to the success of NHBS. Failure to meet the goals would jeopardize the external validity of NHBS data and would thereby undermine the generalizability of project findings and recommendations. Project sites should continuously monitor their recruitment and enrollment data. If any of the data fall below their target goals, project sites should conduct ongoing formative research to identify the operational problems responsible (see **Section 10.4** for information on ongoing formative research).

10.3 Process Monitoring Reports

The Data Coordinating Center (DCC) will produce the process monitoring reports for project sites to assess recruitment and enrollment, coupon distribution, sample characteristics, HIV and hepatitis testing, seeds, RDS methods, previous participants, and interviewer skills. The reports will be posted on the DCC data portal and should be reviewed by project sites weekly. Project sites should then discuss the findings in the reports with their CDC project officer at least every two weeks. If a problem is identified in the reports, the site's CDC project officer may recommend that they adjust their operations or provide additional staff training to address the problem or that they conduct

ongoing formative research to further evaluate it. If they wish, project sites may also create their own reports to monitor any issues of local interest.

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

10.3a Recruitment Monitoring Report

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

- The number of participants screened.
- The number and proportion of participants who were eligible.
- The number and proportion of participants who completed the interview.
- The number and proportion of participants who consented to HIV testing.
- If applicable, the number and proportion of participants who consented to other testing (e.g., hepatitis).
- If applicable, the number and proportion of participants who agreed to blood storage.
- The number and proportion of participants 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 or other testing, and a low proportion of participants eligible to recruit others.

10.3b Coupon Manager Program Report

The *Coupon Manager Program Report* (**section X.2** of this manual) consists of five tables:

- Coupon Tracking
- Changes to the Number of Coupons Distributed
- Gender of Coupon Refusals
- Race/ethnicity of Coupon Refusals
- Reasons for Coupon Refusals

Project sites should use this report to monitor recruitment, manage coupon distribution, and evaluate participation barriers. The Coupon Tracking table shows the specific number of coupons distributed to each participant, as well as the total number of coupons

distributed and the total number returned. The number of coupons distributed less those returned indicates how many coupons are circulating in the community. This information can help project sites manage coupon distribution, including differential coupon distribution and the phasing out of coupons at the end of the project cycle. The proportion of distributed coupons that are returned is a critical measure; a low value signals a barrier to recruitment or participation.

The Changes to the Number of Coupons Distributed table can also help project sites track and manage coupon distribution. It lists the number of coupons given to each recruiter, the date any changes were made to this number, and the reasons for the changes.

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

10.3c Sample Characteristics – Screened Report

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

- Age
- Gender
- Race/ethnicity
- MSA Resident
- Known Previous Participant
- Able to Participate (i.e., able to complete the survey in English or Spanish)
- Injection Drug Use in the Past 12 Months
- Signs of Drug Injection
- Drug Injection Knowledge
- Type of Drug Injected Most Often

Project sites should review this report to monitor the proportion of participants screened who were ineligible based on key demographic variables and each eligibility criterion.

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

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



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

10.3d Sample Characteristics – Interviewed Report

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

- Age
- Gender
- Race/ethnicity
- Education
- Homeless Status
- Income
- Type of Drug Injected Most Often
- Recruitment by a Stranger
- Geographic Area

Project sites should review the tables in this report to monitor the demographic characteristics of participants who successfully completed the interview, as well as to determine whether recruitment is occurring outside of personal networks (i.e., participants are being recruited by strangers). The demographic characteristics of participants should reflect those of local IDUs who are at increased risk of HIV infection

as described in the project site's formative research reports. If participants are being recruited by strangers, project sites may need to improve their recruiter training so that participants only recruit IDUs they know personally, or they may need to provide additional interviewer training so that interviewers accurately follow-up when a participant responds that he was recruited by a stranger. Interviewers should be able to help participants differentiate between recruitment by a stranger and recruitment by an acquaintance. A high level of recruitment by strangers may also indicate that a "recruitment scheme," like selling coupons or receiving kick-backs from recruits, is occurring in the community.

10.3e Test Results Report

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

- Rapid HIV Test Results
- Self-reported HIV-positive Test Results
- Hepatitis B Test Results
- Hepatitis C Test Results

Using this report, project sites can monitor their HIV and hepatitis test results. The Rapid HIV Test Results table shows rapid test results compared to final test results, and the Self-reported HIV-positive Test Results table shows whether or not the participant self-reported being HIV-positive compared to his final test result. A lack of concordance between rapid and final HIV test results in the Rapid HIV Test Results table may indicate improper specimen collection or the over-reading of rapid test results, necessitating additional staff training. The lack of concordance could also be due to the lower sensitivity of some laboratory-based confirmatory tests, especially those used for oral specimens. In such cases, the additional testing of specimens may be required. Important information provided by the Self-reported HIV-positive Test Results table is the proportion of participants with undiagnosed infection (i.e., did not report being HIV-positive, but had a final HIV test result that was positive), and the proportion of possible false-negative HIV test results (i.e., did report being HIV-positive, but had a final HIV test result that was negative or indeterminate).

The Hepatitis B Test Results table shows the project staff's interpretation of the final hepatitis B test result that they entered into the DCC data portal compared to the interpretation calculated by the DCC from the individual HBsAg, anti-HBs, and anti-HBc values. A lack of concordance between the staff's interpretation of the test result and the calculated interpretation may be due to incorrect data entry or it could indicate an incorrect interpretation by the staff. Project sites should ensure that both interpretations match so that participants are given the correct test result and appropriate counseling and referrals.

All pending test results will be coded as "Unknown" in the tables, and project sites that

do not conduct rapid HIV tests, hepatitis B tests, or hepatitis C tests will have those test results coded as “Not done.”

10.3f Seed Report

The *Seed Report* (section X.6 of this manual) contains two tables:

- Seed Monitoring
- Seed Characteristics

The Seed Monitoring table shows the number of seeds who were screened, found to be eligible, completed an interview, and agreed to be recruiters. These data will help project sites assess the success of seed enrollment. The Seed Characteristics table indicates the gender, race/ethnicity, age, zip code, and drug of choice for each seed who agrees to be a recruiter. If the *Sample Characteristics – Interviewed Report* shows underrepresentation of any sub-populations, project sites should review the Seed Characteristics table to determine whether this lack of sample diversity could be due to a lack of seed diversity.

10.3g Respondent-Driven Sampling Report

The *Respondent-Driven Sampling (RDS) Report* (section X.7 of this manual) includes three tables:

- Field Site Enrollment
- Cross Recruitment
- Recruitment Chains

The Field Site Enrollment table will show enrollment by field site for each day of the week. This table will not only allow project sites to track the pace of enrollment by field site and day of operation, but it will also help them identify incorrect field site IDs. Consider the example in which field site 1 operates on Mondays and field site 2 operates on Tuesdays. If the Field Site Enrollment table indicates that participants were interviewed at field site 1 on a Tuesday, the project site would have to investigate the discrepancy to determine whether the interviewer recorded the wrong field site ID or whether he programmed the wrong date in the portable computer. Correct field site IDs are essential for ensuring the accuracy of the Cross Recruitment table.

One of the assumptions of RDS is that participants are linked together in a single social network. The Cross Recruitment table helps project sites test this assumption by stratifying the number of participants enrolled at each field site by the field site where their recruiter was enrolled. Cross recruitment among field sites occurs when participants are enrolled at a different field site than their recruiter was. A lack of cross recruitment may indicate that participants are not members of a single social network, which may impact the interpretation of data analyzed with the RDS Analysis Tool (RDSAT).

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

10.3h Possible Previous Participant Report

To help project sites identify participants who may have taken or tried to take the survey more than once, the *Possible Previous Participant Report* (**section X.8** of this manual) contains a table listing participants who have the same date of birth, gender, and race/ethnicity. The table shows all participants with matching data even if the interviewer identified the person as a previous participant during eligibility screening or determined that he was not providing honest answers during the interview (i.e., the interviewer coded his confidence in the validity of the participant's responses as "3 – Not confident at all"). By including all participants, regardless of their eligibility and the validity of their responses, project sites can evaluate how well their interviewers are able to identify previous participants.

To further assess whether participants with the same date of birth, gender, and race/ethnicity are the same person, project sites should check the participants' physical marks and recruiter IDs in the Coupon Manager Program (CMP). The participants' educational levels and zip codes listed in the *Possible Previous Participant Report* may help with this assessment. When project sites identify two participants with valid, completed interviews who have the same or similar information, they should discuss their findings with their CDC project officer and decide whether the second record should be treated as that of a previous participant and excluded from the final NHBS dataset.

10.3i Interviewer Improvement Report

The *Interviewer Improvement Report* (**section X.9** of this manual) consists of the following tables:

- Interview Length
- Signs and Knowledge of Drug Injection
- Response Validity
- HIV Test Consent
- Hepatitis Test Consent
- Coding of "Other" Insurance

Project sites should review the tables in this report to identify possible interviewer

deficiencies or areas for improvement. Whenever an interviewer performs below acceptable standards, project sites should provide him with any additional training needed and closely monitor his progress. If the interviewer fails to show improvement, project sites should remove him from his position until he can demonstrate sufficient competence.

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

The Signs and Knowledge of Drug Injection table will help project sites identify interviewers who may not be properly screening potential participants for indicators of recent drug injection. For each interviewer, the table shows the proportion of potential participants who were found to be eligible based on physical signs of recent drug injection, knowledge of injection practices with old signs of drug injection, or knowledge of injection practices with no signs of drug injection. Again, project sites should compare each interviewer's data to the overall data to look for any outliers. In addition, a high proportion of participants who are eligible based solely on their knowledge of injection practices should alert project sites to the possibility that people who are former injectors or those who never injected may be fraudulently claiming to be current injectors so that they can participate in the survey and obtain the incentive.

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

For those participants who completed an interview and had a final HIV test result, the HIV Test Consent table shows whether the interviewer documented HIV test consent in the portable computer. Likewise, the Hepatitis Test Consent table shows whether test consent was documented for participants who completed an interview and had a final hepatitis test result. Since HIV and hepatitis test data cannot be used for analysis if the appropriate consent is not documented, it is extremely important for interviewers to properly record test consent in the portable computer.

Whenever an interviewer selects "Some other health plan" for the type of health insurance that a participant has, the specific name of that "other" plan will be listed in the

Coding of “Other” Insurance table. Project sites should review this table to ensure that interviewers are not selecting “Some other health plan” for a type of insurance that could be coded as one of the existing response options (“Private health plan,” “Medicaid,” “Medicare,” “Some other government plan,” “TRICARE (CHAMPUS),” or “Veterans Administration coverage”). If project sites find “other” health plans that should have been coded as one of the existing response options, they should make the necessary corrections in the Data Error Log on the data portal. Moreover, they should provide their interviewers with a refresher training on the principal health insurance plans in their locality and give the interviewers instructions on how to properly code these plans as one of the available response options.

10.3j Map Report

The *Map Report* (not illustrated in this manual) will map the geographic distribution of participants based on their zip code of residence. This report will help project sites assess whether participants represent the areas in their localities that are most heavily populated by IDUs.

10.4 Ongoing Formative Research

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

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

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

Table 10.1 – Operational problems and potential evaluation methods

| Operational Problem | Potential Evaluation Methods |
|--|---|
| <p>Low or declining enrollment</p> | <p>Quantitative:</p> <p>Project sites should review the Coupon Tracking table in the <i>Coupon Manager Program Report</i> to determine how many coupons have been distributed and the number and proportion of coupons returned. The number of coupons distributed less the number returned equals the number of coupons currently in circulation, a measure of how many potential participants there are in the community. A low proportion of coupons returned indicates a barrier to recruitment or participation, which should be further assessed using the “refusals” tables in the <i>Coupon Manager Program Report</i>. The Recruitment Chains table in the <i>Respondent-Driven Sampling Report</i> will also help project sites monitor the progress of recruitment and enrollment.</p> <p>Qualitative:</p> <p>Project sites should use observations, informal conversations with participants, or street intercept surveys to determine whether enrollment is being hindered by such factors as the field site location or hours of operation, the incentive amount or type, a poor reputation for the project, safety or confidentiality concerns, or the time commitment required.</p> |
| <p>A large proportion of ineligible participants</p> | <p>Quantitative</p> <p>Project sites should review the <i>Sample Characteristics – Screened Report</i> to determine if there are any particular eligibility criteria that potential participants are failing or if certain demographic sub-populations are more likely to be ineligible. If a high proportion of participants are ineligible based on their signs or knowledge of drug injection, project sites should check the Signs and Knowledge of Drug Injection table in the <i>Interviewer Improvement Report</i> to determine whether a particular interviewer is responsible.</p> <p>Qualitative</p> <p>If the proportion of participants who injected drugs in the past 12 months is low, project sites should observe the recruiter training provided by project staff and conduct exit interviews with participants to see if they know that they should only</p> |

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

| Operational Problem | Potential Evaluation Methods |
|---|--|
| <p>A large proportion of ineligible participants (<i>continued</i>)</p> | <p>recruit current IDUs.</p> <p>If a high proportion of participants are ineligible based on their signs or knowledge of drug injection, project sites should observe their interviewers while they assess the signs of recent injection and the steps involved in injection. They should also conduct observations, informal conversations with participants, or street intercept surveys to find out if people in the community are fraudulently claiming to be current injectors so that they can participate in the survey.</p> |
| <p>Demographic characteristics of participants do not match those of the local IDU population</p> | <p><i>Quantitative</i></p> <p>Project sites should review the <i>Sample Characteristics – Screened Report</i> to determine whether members of the underrepresented sub-population are more likely to be ineligible, and they should check the “refusals” tables in the <i>Coupon Manager Program Report</i> to find out if members of the underrepresented sub-population are more likely to refuse coupons. They should also review the Seed Characteristics table in the <i>Seed Report</i> to assess whether a lack of sample diversity could be due to a lack of seed diversity. Using RDSAT, project sites should check the affiliation matrix to see if members of the underrepresented sub-population are substantially less likely to be recruited by members of other sub-populations and they should check the recruitment count to see if members of the underrepresented sub-population are less likely to recruit other participants.</p> <p><i>Qualitative</i></p> <p>If members of the underrepresented sub-population are more likely to be ineligible, project sites should observe the recruiter training provided by project staff and conduct exit interviews with participants from the underrepresented sub-population to see if they understand who should be recruited. Project sites should also use street intercept or key informant surveys to determine whether there are misperceptions in the community regarding the eligibility criteria.</p> <p>If members of the underrepresented sub-population are less</p> |

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

| Operational Problem | Potential Evaluation Methods |
|--|--|
| <p>Demographic characteristics of participants do not match those of the local IDU population <i>(continued)</i></p> | <p>likely to recruit others or more likely to refuse coupons, project sites should have informal conversations with participants or community members from the underrepresented sub-population to determine whether recruitment and participation are being hindered by such factors as the field site location or hours of operation, the incentive amount or type, safety or confidentiality concerns, or a poor reputation for the project.</p> <p>If members of the underrepresented sub-population are substantially less likely to be recruited by members of other sub-populations, project sites should conduct informal conversations with participants, street intercept or key informant surveys, or focus groups to see if members of the underrepresented sub-population are less likely to mix socially with members of other sub-populations.</p> |
| <p>Stranger recruitment</p> | <p><i>Quantitative</i></p> <p>Project sites should review the <i>Sample Characteristics – Interviewed Report</i> to check if a high proportion of participants were recruited by a stranger. They could also analyze their survey data to determine whether certain demographic sub-populations are more likely to recruit people who are strangers.</p> <p><i>Qualitative</i></p> <p>Project sites should observe the recruiter training provided by project staff to see if participants are properly instructed to only recruit IDUs they know personally and they should monitor their interviewers to see if they correctly follow-up when a participant responds that he was recruited by a stranger. Project sites should conduct observations in the area around the field site to determine whether people are congregating outside the field site trying to obtain coupons or if participants are just handing out coupons to people they see on the street. They should also have informal conversations with participants or interview key informants to see if there are any “recruitment schemes” occurring in the community, such as selling coupons or receiving kick-backs from recruits.</p> |

11.1 Overview

The purpose of this chapter is to briefly describe NHBS data submission and management procedures. Project sites will submit their local NHBS data to the ICF International Data Coordinating Center (DCC), which manages all NHBS data at the national level. Specific instructions on how to submit data to the DCC are described in the *NHBS-IDU3 Data Management Training Manual*. The DCC will also provide an in-person training that the data manager from each project site is required to attend.

11.2 Data Submission

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

- QDS™ Warehouse containing the NHBS core interview files
- Coupon Manager Program (CMP) data
- HIV Test Results Log
- Data Error Log

On a *weekly* basis, project sites should submit the QDS™ Warehouse containing the NHBS core interview files through the data portal. On a *daily* basis, they should send the CMP data to the data portal using the automatic upload function in the CMP and also enter HIV test results in the HIV Test Results Log on the data portal. If data in the QDS™ Warehouse need to be corrected, the project site should enter the changes in the Data Error Log on the data portal as soon as the site's data manager becomes aware of them. Project sites should refer to the *NHBS-IDU3 Data Management Training Manual* for additional information on using the data portal to submit and enter their data.

11.3 Data Management

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

local plan is a system for tracking surveys and data corrections. In prior RDS cycles, many project sites used the Participant Tracking Form (**Appendix P**) to track key survey information (e.g., survey ID, interview date, eligibility status, etc.), as well as to record any needed data corrections. Project sites should always review and process their data in accordance with their local plan and the *NHBS Round 3 Model Surveillance Protocol*. Moreover, project sites should *promptly* respond to all DCC communications with either the requested information or a date when the requested information will be sent.

Appendix A

Operations Checklist

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

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

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

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

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

I – IRB Review

a. Was formative research submitted as a separate package to your local Institutional Review Board(s) (IRBs)?

Yes No

a1. ***If Yes:*** Complete the following table on your IRB submission for formative research:

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

Instructions for completing the table:

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

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

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

b. Complete the following table on your IRB submission for NHBS-IDU3:

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

Instructions for completing the table:

Name of IRB: List the name of each IRB that reviewed your NHBS-IDU3 package (do not list an IRB that is deferring to another one).

Date IRB Package Submitted: For each applicable IRB, list the date you sent the NHBS-IDU3 package to the IRB or sent an amended package from a previous NHBS cycle.

Expedited or Full IRB Review: Record *Expedited* or *Full* to indicate whether the NHBS-IDU3 package underwent an expedited or full IRB review.

Date IRB Approval Received: For each applicable IRB, list the date you received approval to conduct NHBS-IDU3.

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

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

Yes No

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

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

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

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

- Read consent form verbatim
- Read summary of consent form (*attach summary*)
- Read bulleted list of key consent elements (*attach bulleted list*)
- Read highlighted excerpts from the consent form (*attach highlighted form*)

g. Will participants provide verbal consent or written consent?

- Verbal consent
- Written consent

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

II – Project Identification

- a. Record your NHBS-IDU3 project name:
- b. Insert or attach your NHBS-IDU3 project logo:

III – Field Sites

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

| Name & Address | Dates of Lease or MOU | Project Staff | Days & Hours | Field Site ID |
|---|-----------------------|---|---|---------------|
| <i>ORP, Inc. 209 Auburn Avenue Atlanta</i> | <i>6/12 – 12/12</i> | <i>Field Supervisor Coupon Manager 2 Interviewers 1 Test Counselor</i> | <i>Mon, Tues, & Thurs 9 am – 5 pm</i> | <i>1</i> |
| <i>Angela's House 7081 Angel Street Decatur</i> | <i>6/12 – 12/12</i> | <i>Field Supervisor Coupon Manager 3 Interviewers 2 Test Counselors</i> | <i>Wed & Fri 11 am – 7 pm</i> | <i>2</i> |

Instructions for completing the table:

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

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

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

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

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

b. Describe the setup of your field site (waiting area, coupon manager station, rooms for interviewing and HIV testing, etc.) and the planned flow of participants:

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

Yes No

c1. **If Yes:** Describe your contingency plans if the van is not available due to mechanical problems (include method of informing participants if operations have stopped):

IV – Seeds

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

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

| # | Gender | Race/Ethnicity | Age Range | Drug of Choice | Geographic Area* |
|---|--------|----------------|----------------|----------------|------------------|
| 1 | | <i>Black</i> | | | <i>Southside</i> |
| 2 | | <i>Black</i> | | | <i>West End</i> |
| 3 | | <i>White</i> | | <i>Heroin</i> | |
| 4 | | <i>White</i> | | <i>Meth</i> | |
| 5 | | <i>White</i> | <i>18 - 29</i> | | |

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

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

V – Coupons

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

Number of coupons distributed to seeds: _____

Number of coupons distributed to non-seeds: _____

- b. Will you use coupon activation dates?

Yes No

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

- c. Will you use coupon expiration dates?

Yes No

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

- d. Insert or attach a copy of your coupon.

VI – Recruiter Training

- a. Attach a copy of your recruiter training script and talking points (if applicable).

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

VII – Phone

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

Phone #: _____

Phone #: _____

Phone #: _____

- b. Is voicemail activated on your project phone?

Yes No

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

VIII – Interview Appointment System

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

Yes No

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

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

IX – Incentives

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

a1. Interview– Amount: _____ Type: _____

a2. HIV testing– Amount: _____ Type: _____

a3. Recruitment– Amount: _____ (per recruit) Type: _____

b. Local compensation policy.

b1. Will minor incentives (< \$5) be given to people who are found to be ineligible?

Yes No

If Yes: Indicate compensation– Amount: _____ Type: _____

b2. Will a participant be compensated if he passes the eligibility screener but only completes part of the interview?

Yes No

If Yes: Indicate compensation– Amount: _____ Type: _____

b3. Will a participant be compensated if one of his recruits passes the eligibility screener but only completes part of the interview?

Yes No

If Yes: Indicate compensation– Amount: _____ Type: _____

b4. Will a participant be compensated if he returns to receive his HIV test result?
NOTE: Compensation for receiving HIV test results can only be provided with non-NHBS funds.

Yes No

If Yes: Indicate compensation– Amount: _____ Type: _____

b5. Will participants be compensated for any other project activities or tests?

Yes No

If Yes: List each activity or test and indicate the amount and type of compensation (add rows as necessary):

| Activity or Test | Amount of Compensation | Type of Compensation |
|------------------|------------------------|----------------------|
| | | |
| | | |
| | | |

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

X – Project Staff Training and Evaluation

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

| Name of Staff Member | <i>Jan Doe</i> | <i>Jen Doe</i> | <i>Jim Doe</i> | <i>Jon Doe</i> |
|--|-------------------------|-----------------------|-----------------------------------|---------------------|
| Position | <i>Field Supervisor</i> | <i>Coupon Manager</i> | <i>Interviewer/Test Counselor</i> | <i>Data Manager</i> |
| ID Code (if applicable) | <i>1</i> | <i>2</i> | <i>3</i> | |
| Received Confidentiality Training? | <i>Yes</i> | <i>Yes</i> | <i>Yes</i> | <i>Yes</i> |
| Date Signed Confidentiality Agreement | <i>4/15/12</i> | <i>4/15/12</i> | <i>4/15/12</i> | <i>4/15/12</i> |
| Read NHBS-IDU3 Operations Manual? | <i>Yes</i> | <i>Yes</i> | <i>Yes</i> | <i>Yes</i> |
| Read NHBS Round 3 Interviewer Guide? (for field supervisor and interviewers) | <i>Yes</i> | | <i>Yes</i> | |

| | | | | |
|--|--|--|---|--|
| Read Package Insert for Rapid HIV Test <i>(for test counselors conducting rapid tests)</i> | <i>Yes</i> | | <i>Yes</i> | |
| Date HIV Counseling and Testing Certification Expires <i>(for test counselors)</i> | | | <i>2/8/13</i> | |
| Attended NHBS-IDU3 Field Operations Training? | <i>Yes</i> | | <i>Yes</i> | |
| Attended NHBS-IDU3 Data Management Training? | | | | <i>Yes</i> |
| Other Training <i>(specify type and dates):</i> | | | <i>HIV Counseling and Testing 2/7/12-2/8/12</i> | |
| Other Training <i>(specify type and dates):</i> | <i>Local Field Ops Training 6/9/12</i> | <i>Local Field Ops Training 6/9/12</i> | <i>Local Field Ops Training 6/9/12</i> | <i>Local Field Ops Training 6/9/12</i> |
| Evaluated and Met Performance Criteria for Position(s)? | <i>Yes</i> | <i>Yes</i> | <i>Yes</i> | <i>Yes</i> |

Instructions for completing the table:

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

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

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

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

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

Read the NHBS-IDU3 Operations Manual: Prior to the start of data collection, all project staff must read the *NHBS-IDU3 Operations Manual*. Record *Yes* to indicate that a staff member read the manual.

Read the NHBS Round 3 Interviewer Guide: Prior to the start of data collection, the field supervisor and all interviewers must read the *NHBS Round 3 Interviewer Guide*. Record *Yes* to indicate that these staff members read the guide.

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

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

Attended NHBS-IDU3 Field Operations Training: Record *Yes* to indicate that a staff member attended this training.

Attended NHBS-IDU3 Data Management Training: Record *Yes* to indicate that a staff member attended this training.

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

Evaluated and Met Performance Criteria for Position(s): Prior to the start of data collection, all project staff must be evaluated and meet the performance criteria for their position(s). See **Appendices B** thru **G** of the *NHBS-IDU3 Operations Manual* for evaluation forms listing the performance criteria for each position. Record *Yes* to indicate that a staff member was evaluated and met these criteria.

- b. Based on the evaluation recommendations in **Table 2.3** of the *NHBS-IDU3 Operations Manual*, describe your plans for evaluating project staff during data collection (specify who will conduct the evaluations and estimate their weekly time commitment for this task):
- c. Since the field supervisor will be busy managing operations during data collection, the principal investigator or project coordinator should ideally conduct staff evaluations. If the field supervisor will also evaluate staff, describe how you will ensure that this added responsibility does not interfere with the field supervisor's ability to manage operations:
(*e.g., assign an experienced staff member to serve as acting field supervisor when the field supervisor is conducting evaluations*)

XI – HIV and Other Testing

a. Rapid HIV Testing

a1. Will you conduct rapid HIV testing?

Yes No

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

a2. Type of specimen collected:

- Blood from fingerstick
 Blood from venipuncture
 Oral

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

a4. Will you use a Rapid HIV Test Algorithm?

Yes No

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

2nd rapid test: _____

3rd rapid test: _____

a5. Do you have a CLIA certificate of waiver?

Yes No

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

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

Yes No

If No: Provide justification why you must run the rapid test in the same room where the participant is being interviewed:

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

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

b1. Type of specimen collected:

Blood from venipuncture

Dried blood spot (DBS)

Oral

b2. Trade name of laboratory-based screening assay: _____

(e.g., *Abott Architect Ag/Ab Combo, Avioq HIV-1 Microelisa, Bio-Rad GS HIV-1/HIV-2 Plus O EIA, Bio-Rad GS HIV Combo Ag/Ab EIA, etc.*)

b3. Trade name of laboratory-based confirmatory test: _____
(e.g., Fluorognost HIV-1 IFA, Gen-Probe APTIMA HIV-1 RNA, GS HIV-1 Western Blot, Multispot HIV-1/HIV-2 Rapid Test, OraSure HIV-1 Western Blot, etc.)

b4. If applicable, trade name of 2nd laboratory-based confirmatory test:

(e.g., Fluorognost HIV-1 IFA, Gen-Probe APTIMA HIV-1 RNA, GS HIV-1 Western Blot, Multispot HIV-1/HIV-2 Rapid Test, OraSure HIV-1 Western Blot, etc.)

b5. If applicable, trade name of 3rd laboratory-based confirmatory test:

(e.g., Fluorognost HIV-1 IFA, Gen-Probe APTIMA HIV-1 RNA, GS HIV-1 Western Blot, Multispot HIV-1/HIV-2 Rapid Test, OraSure HIV-1 Western Blot, etc.)

b6. Name and contact information for the laboratory performing testing:

b7. Attach your laboratory specimen slip or form.

c. Specimen Storage, Transport, and Processing

c1. Have you discussed specimen handling requirements with the laboratory staff for each type of test you are using?

Yes No

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

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

c4. Describe how the specimens will be sent to the laboratory:

(e.g., courier, project staff, FEDEX, etc.)

c5. Describe how project staff will communicate to the laboratory which specimens are from participants who are self-reported HIV-positive:
NOTE: Regardless of the results of any screening tests performed, specimens from self-reported HIV-positive participants must receive confirmatory testing.

c6. Will you obtain consent to store specimens for future testing (e.g., incidence testing)?

Yes No

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

d. HIV Counseling and Testing Procedures

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

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

e. Test Results and Referrals to Care

e1. Describe your procedures for returning either standard or confirmatory laboratory test results:

e2. Will you use the optional phone reminder system (see **Section 9.7a** of the *NHBS-IDU3 Operations Manual*)?

Yes No

If Yes: Attach your Appointment Reminder Call Form.

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

f. Hepatitis Testing

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

Yes No

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

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

f3. Attach your laboratory specimen slip or form.

f4. ***If conducting HCV testing***, insert or attach your laboratory algorithm for HCV testing.

f5. ***If conducting HCV testing***, trade name of HCV screening EIA:

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

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

Nucleic acid test (NAT)

Recombinant immunoblot assay (RIBA)

f7. Describe your procedures for referring HBV- and HCV-positive participants to care:

f8. Describe your procedures for referring participants for hepatitis A and B vaccination:

g. Other Testing

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

Test: _____

Will you return test results to participants?

Yes No

Test: _____

Will you return test results to participants?

Yes No

Test: _____

Will you return test results to participants?

Yes No

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

XII – Local Questions

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

Yes No

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

XIII – Data Management

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

| Name | Phone | E-mail |
|----------------|---------------------|-----------------------------|
| <i>Jon Doe</i> | <i>404-555-9999</i> | <i>jodoe@intertubes.com</i> |

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

| Name | Phone | E-mail | Data Type |
|----------------|---------------------|-----------------------------|---------------------------------|
| <i>Jen Doe</i> | <i>404-555-1111</i> | <i>jedoe@intertubes.com</i> | <i>CMP</i> |
| <i>Jim Doe</i> | <i>404-555-1111</i> | <i>jidoe@intertubes.com</i> | <i>Test Results</i> |
| <i>Jon Doe</i> | <i>404-555-9999</i> | <i>jodoe@intertubes.com</i> | <i>Data Edits & Surveys</i> |

- c. Which QDS™ software program will you use to conduct interviews?

CAPI (*for laptop computers and tablets*)

HAPI (*for handheld computers*)

Both CAPI and HAPI

- c1. **If Both CAPI and HAPI:** Describe your plans for minimizing potential interviewer errors that could result from differences between the CAPI and HAPI interfaces:
(*e.g., ensure that all interviewers are fully trained to use both CAPI and HAPI, have each interviewer conduct interviews using **only** one program [either CAPI or HAPI, but not both], etc.*)

d. Attach the following documents:

d1. Data security policy

d2. Data confidentiality policy

d3. Data transfer protocol (i.e., how data are transferred from the point of collection to the point of upload to the DCC data portal)

XIV – Local Safety and Field Incident Reporting Procedures

a. Attach the following documents:

a1. Local safety protocol

a2. Field incident reporting procedures

XV – Prevention and Other Informational Materials

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

XVI – Public Health Insurance Plans

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

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

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

Instructions for completing the table:

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

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

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

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

Appendix B

Field Supervisor – Project Management Evaluation Form

A model evaluation form is shown below. This form can be printed or modified using the Word file named **Appendix B – Field Supervisor Project Management Evaluation.docx**.

| | | | | | |
|---|---|-------------|---------------|--------------|----------------|
| General Instructions: | | | | | |
| <ul style="list-style-type: none"> To be conducted by the principal investigator or project coordinator. Shaded areas are NHBS performance recommendations. | | | | | |
| Field Supervisor: | Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation | | | | |
| Evaluation Date: | | | | | |
| Evaluator: | | | | | |
| Management of Staff | Rating | | | | |
| 1. Has trained staff members as back-ups for field supervisor, coupon manager, and data manager. | 1 No | 5 Yes | | | |
| 2. Has adhered to evaluation schedule for coupon manager. | 1 No | 5 Yes | | | |
| 3. Has adhered to evaluation schedule for interviewers. | 1 No | 5 Yes | | | |
| 4. Has adhered to evaluation schedule for HIV test counselors. | 1 No | 5 Yes | | | |
| Field Site Operations Setup | | | | | |
| 5. All supplies were prepared and tasks completed per Field Site Checklist. | 1 No | 5 Yes | | | |
| 6. Field site was adequately staffed (a minimum of 2 staff members in addition to the field supervisor). | 1 No | 5 Yes | | | |
| 7. Conducted a staff meeting before opening the field site. | 1 No | 5 Yes | | | |
| Field Site Management | | | | | |
| 8. Managed participant flow by monitoring when the interviewer was available for the next participant. | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 9. Managed participant flow by monitoring when the HIV counselor was available for the next participant. <input type="checkbox"/> N/A | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 10. Managed participant flow by monitoring when the coupon manager was available for the next participant. | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 11. Ensured participants' privacy was protected at all times. | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 12. Remained aware of each team member's whereabouts. | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 13. Maintained security of staff and study materials. | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 14. Monitored staff interactions with participants and the general public. | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 15. Met each potential participant prior to the interview. | 1 Never | 2 Rarely | 3 Sometime | 4 Usually | 5 Always |
| 16. Checked in with interviewers after each interview. | 1 Never | 2 Rarely | 3 Sometime | 4 Usually | 5 Always |
| 17. Assisted field staff when necessary. <input type="checkbox"/> N/A | 1 Never | 2 Rarely | 3 Sometime | 4 Usually | 5 Always |
| 18. Treated participants and staff with courtesy and respect. | 1 Never | 2 Rarely | 3 Sometime | 4 Usually | 5 Always |
| 19. Ensured staff were knowledgeable of safety procedures. | 1 No | | | | 5 Yes |
| 20. Has emergency contact information for each staff member. | 1 No | | | | 5 Yes |

| | | | | | | |
|---|---|-----------------|-------------|-----------|-----------|----------------|
| 21. Scheduled and recorded appointments in the Appointment Log. | <input type="checkbox"/> N/A | 1 No | 5 Yes | | | |
| 22. Maintained Appointment Reminder Form. | <input type="checkbox"/> N/A | 1 No | 5 Yes | | | |
| 23. Made scheduled appointment reminder calls. | <input type="checkbox"/> N/A | 1 No | 5 Yes | | | |
| 24. Maintained Phone Results Log. | <input type="checkbox"/> N/A | 1 No | 5 Yes | | | |
| 25. Adhered to established hours of operation. | | 1 No | 5 Yes | | | |
| Post Operations Management | | | | | | |
| 26. Held debriefing at completion of field site activities. | | 1 No | 5 Yes | | | |
| 27. Reviewed Participant Tracking Forms and Data Error Log. | | 1 No | 5 Yes | | | |
| 28. Reviewed consent forms for each participant. | <input type="checkbox"/> N/A | 1 No | 5 Yes | | | |
| 29. Reviewed HIV Test Results Log. | | 1 No | 5 Yes | | | |
| 30. Reviewed staff evaluation forms from PI or PC. | <input type="checkbox"/> N/A | 1 No | 5 Yes | | | |
| 31. Verified that all participants who consented to HIV testing had either an HIV rapid test conducted or a laboratory specimen collected. | | 1 No | 5 Yes | | | |
| 32. Synched CMP data to the data portal using the CMP automatic upload function. | | 1 No | 5 Yes | | | |
| 33. Portable computers and forms that contain confidential information (i.e., Appointment Reminder Call Forms, HIV Test Results Log, Phone Results Log, and Participant Tracking Forms) were kept in a locked file cabinet. | | 1 No | 5 Yes | | | |
| 34. Demonstrated adherence to <i>NHBS Round 3 Model Surveillance Protocol</i> including RDS methods. | | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| Criterion # | Skill Description, Recommendations, Accolades, and Additional Comments | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| Evaluator: Please ensure that the following steps are completed with the field supervisor. | | | | | | |
| <input type="checkbox"/> Reviewed evaluation form with the field supervisor. | | | | | | |
| <input type="checkbox"/> Provided time for field supervisor to ask questions. | | | | | | |
| <input type="checkbox"/> Provided the field supervisor with recommendations for improvement. | | | | | | |
| <input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard. | | | | | | |

Appendix C

Field Supervisor – HIV Testing Operations Evaluation Form

A model evaluation form is shown below. This form can be printed or modified using the Word file named **Appendix C - Field Supervisor HIV Testing Evaluation.docx**.

| | | | |
|--|---|----------|---------------|
| General Instructions | | | |
| <ul style="list-style-type: none"> To be conducted by the principal investigator or project coordinator. Shaded areas are NHBS performance recommendations. | | | |
| Field Supervisor: | Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation | | |
| Evaluation Date: | | | |
| Evaluator: | | | |
| Specimen Collection, Storage, and Disposal | | | Rating |
| 1. Maintains a paper log (e.g., HIV Test Results Log) with no personal identifying information that links the Survey ID and the Lab ID. <input type="checkbox"/> N/A | 1 No | 5 Yes | |
| 2. Only uses specimen processing and tracking forms approved as part of the NHBS-IDU3 Operations Checklist. | 1 No | 5 Yes | |
| 3. Blood tube specimens are stored in and transported by coolers that are appropriately labeled according to OSHA regulations. <input type="checkbox"/> N/A | 1 No | 5 Yes | |
| 4. DBS are handled, transported, packaged, and stored per the <i>NHBS-IDU3 Operations Manual</i> . <input type="checkbox"/> N/A | 1 No | 5 Yes | |
| 5. All blood collection devices are disposed of in appropriate biohazard containers. <input type="checkbox"/> N/A | 1 No | 5 Yes | |
| 6. Collects all required HIV testing variables per HIV Test Results Log, Specimen Shipping Log, etc. | 1 No | 5 Yes | |
| 7. Tracks whether participants have returned for their results. | 1 No | 5 Yes | |
| 8. Monitors which specimens can be stored and, for the specimens from participants' who don't provide consent to for storage, are disposed of properly. <input type="checkbox"/> N/A | 1 No | 5 Yes | |
| Security and Confidentiality | | | |
| 9. HIV testing forms, logs, lab results, and print outs are kept in a locked cabinet when not in the immediate possession of a staff member. | 1 No | 5 Yes | |
| 10. Uses the DCC data portal to enter data from the hard copy of the HIV Test Results Log. | 1 No | 5 Yes | |
| 11. Sensitive information, such as Appointment Reminder Call Forms, are stored and shredded according to <i>NHBS Round 3 Model Surveillance Protocol</i> . | 1 No | 5 Yes | |
| Rapid Testing <input type="checkbox"/> N/A | | | |
| 12. HIV test package inserts are available for reference at the field site. | 1 No | 5 Yes | |
| 13. Monitors and records temperature at which test kits are stored on Quality Assurance Log. | 1 No | 5 Yes | |
| 14. Monitors and records temperature at which testing is conducted per package insert on Quality Assurance Log. | 1 No | 5 Yes | |
| 15. Runs controls for each new batch of test kits and records the results on Quality Assurance Log. | 1 No | 5 Yes | |
| 16. Runs external controls in accordance with the test package insert. | 1 No | 5 Yes | |
| 17. Monitors data for discordant test results (i.e., reactive rapid test and non-reactive confirmatory test). | 1 No | 5 Yes | |
| 18. Conducts Competency Assessment Tests (CATs) for all new testing staff and every 8 weeks thereafter. | 1 No | 5 Yes | |

| Criterion # | Skill Description, Recommendations, Accolades, and Additional Comments |
|--|--|
| | |
| | |
| | |
| | |
| <p>Evaluator: Please ensure that the following steps are completed with the field supervisor.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Reviewed evaluation form with the field supervisor. <input type="checkbox"/> Provided time for the field supervisor to ask questions. <input type="checkbox"/> Provided the field supervisor with recommendations for improvement. <input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard. | |

Appendix D

Coupon Manager Evaluation Form

A model evaluation form is shown below. This form can be printed or modified using the Word file named **Appendix D – Coupon Manager Evaluation.docx**.

| | | |
|--|--|----------|
| General Instructions: <ul style="list-style-type: none"> To be conducted by the principal investigator, project coordinator, or, if necessary, field supervisor. Shaded areas are NHBS performance recommendations. | | |
| Coupon Manager: | Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. | |
| Evaluation Date: | <input type="checkbox"/> Pre-implementation Evaluation | |
| Evaluator: | <input type="checkbox"/> Ongoing Evaluation | |
| Check-In | Rating | |
| 1. Greeted potential participant appropriately. | 1 No | 5 Yes |
| 2. Established rapport with potential participant. | 1 No | 5 Yes |
| 3. Checked the validity of potential participant's coupon (including activation/expiration dates). | 1 No | 5 Yes |
| 4. Created record in Coupon Manager Program (CMP) for potential participant with a valid coupon. <input type="checkbox"/> N/A | 1 No | 5 Yes |
| 5. Transferred potential participant with valid coupon to interviewer and gave coupon to interviewer. <input type="checkbox"/> N/A | 1 No | 5 Yes |
| 6. Handled ineligible participant in a professional manner. <input type="checkbox"/> N/A | 1 No | 5 Yes |
| 7. Voided and filed invalid coupons appropriately. <input type="checkbox"/> N/A | 1 No | 5 Yes |
| Recruiter Training <input type="checkbox"/> N/A | | |
| 8. Ensured participant was eligible to receive recruitment coupons. | 1 No | 5 Yes |
| 9. Successfully trained recruiter: <i>Instructions were given regarding who to recruit.</i> | | |
| a. People you know who inject drugs. | 1 No | 5 Yes |
| b. People who live in the project area. | 1 No | 5 Yes |
| c. People who have <u>not</u> already participated in the study. | 1 No | 5 Yes |
| d. Do <u>not</u> give coupons to strangers. | 1 No | 5 Yes |
| 10. Successfully trained recruiter: <i>Instructions were given on what to say to person receiving the coupon.</i> | | |
| a. Call for an appointment or visit the field site before the expiration date. | 1 No | 5 Yes |
| b. The process will take about an hour. | 1 No | 5 Yes |
| c. Children can't sit in on the interview. | 1 No | 5 Yes |
| d. Coupons can't be replaced if lost or stolen. | 1 No | 5 Yes |
| 11. Successfully trained recruiter: <i>Rewards.</i> | | |
| a. Rewards will be paid for each person recruited who is selected to participate and completes the interview. | 1 No | 5 Yes |
| b. Rewards will not be paid for someone who is not selected to participate. | 1 No | 5 Yes |
| c. Rewards will not be paid for recruiting someone who has already participated. | 1 No | 5 Yes |
| d. Rewards will not be paid for someone who does not complete the interview. | 1 No | 5 Yes |
| e. Each coupon can only be given to one person. | 1 No | 5 Yes |
| f. A unique identification number will link the recruiter, coupon(s), and reward(s). | 1 No | 5 Yes |

| | | |
|--|---|----------|
| g. Recruiter can call the office to check on any rewards due. | 1 No | 5 Yes |
| 12. Asked questions to recruiter to ensure s/he understands who to recruit and what to do with coupons. | 1 No | 5 Yes |
| 13. Asked recruiter if s/he had any questions. | 1 No | 5 Yes |
| Check-Out | | |
| 14. Ensured participant had completed all applicable steps of the enrollment process (i.e., eligible, provided consent for interview/HIV testing, completed interview/HIV testing, and, if applicable, eligible and willing to recruit). | 1 No | 5 Yes |
| 15. Collected participant's coupon and Participant Tracking Form (if applicable) from interviewer. | 1 No | 5 Yes |
| 16. Marked and filed the coupon and Participant Tracking Form (if applicable) appropriately. | 1 No | 5 Yes |
| 17. Created Recruiter ID and collected physical marks. <input type="checkbox"/> N/A | 1 No | 5 Yes |
| 18. Distributed correct number of coupons and recorded coupon numbers. <input type="checkbox"/> N/A | 1 No | 5 Yes |
| 19. Distributed incentive. <input type="checkbox"/> N/A | 1 No | 5 Yes |
| 20. Distributed local HIV prevention materials and referrals. <input type="checkbox"/> N/A | 1 No | 5 Yes |
| General | | |
| 21. Demonstrated adherence to <i>NHBS Round 3 Model Surveillance Protocol</i> including RDS methods. | 1 No | 5 Yes |
| 22. Maintained an organized Coupon Manager Station (i.e., CMP hard copy, coupons, referral cards, information cards, and incentives). | 1 No | 5 Yes |
| 23. CMP was never left open or unattended. | 1 No | 5 Yes |
| 24. Ensured participant was never able to view the CMP on the computer screen. | 1 No | 5 Yes |
| 25. Was knowledgeable of safety procedures. | 1 No | 5 Yes |
| Criterion # | Skill Description, Recommendations, Accolades, and Additional Comments | |
| | | |
| | | |
| | | |
| | | |
| Evaluator: Please ensure that the following steps are completed with the coupon manager. <input type="checkbox"/> Reviewed evaluation form with the coupon manager. <input type="checkbox"/> Provided time for coupon manager to ask questions. <input type="checkbox"/> Provided the coupon manager with recommendations for improvement. <input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard. | | |

Appendix E

Interviewer Evaluation Form

A model evaluation form is shown below. This form can be printed or modified using the Word file named **Appendix E - Interviewer Evaluation.docx**.

| | | | | | |
|---|--|-------------|-------------------|--------------|-----------------|
| General Instructions <ul style="list-style-type: none"> To be conducted by the principal investigator, project coordinator, or, if necessary, field supervisor. It is recommended that the evaluator have a portable computer or copy of the questionnaire to follow along during the interview. Permission must be obtained from the potential participant before an evaluator joins an interview. The evaluator should only interrupt the interview for major issues, be discreet when doing so, and direct questions to the interviewer. Shaded areas are NHBS performance recommendations. | | | | | |
| Interviewer: | Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. | | | | |
| Evaluation Date: | <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation | | | | |
| Evaluator: | | | | | |
| Time to Complete Survey | Time | | | | |
| 1. Eligibility screener | Start: _____ | | End: _____ | | Length: _____ |
| 2. Consent process | Start: _____ | | End: _____ | | Length: _____ |
| 3. Core questionnaire | Start: _____ | | End: _____ | | Length: _____ |
| 4. Local questionnaire | Start: _____ | | End: _____ | | Length: _____ |
| Set-up | Rating | | | | |
| 5. Checked date and time on portable computer prior to starting. | 1 Not at all | 2 | 3 Some | 4 | 5 Fully |
| 6. All necessary materials were prepared prior to starting (flashcards, consent forms, prevention materials, referral information, pens, etc.). | 1 Not at all | 2 | 3 Some | 4 | 5 Fully |
| 7. Was knowledgeable of safety procedures. | 1 No | | 5 Yes | | |
| Consent Process | | | | | |
| 8. No personal identifiers (e.g., name, address) were recorded. | 1 Recorded | | 5 Not recorded | | |
| 9. All aspects of informed consent were followed per local IRB requirements (i.e., read as written if required; covered all relevant points if summarized). | 1 No | | 5 Yes | | |
| 10. Provided the participant a copy of consent form to follow along. | 1 No | | 5 Yes | | |
| 11. Offered the participant a copy of the consent form to keep. | 1 No | | 5 Yes | | |
| 12. Provided an opportunity for questions about the project and consent process. | 1 No | | 5 Yes | | |
| 13. Obtained a <u>separate</u> consent for the interview. | 1 No | | 5 Yes | | |
| 14. Obtained a <u>separate</u> consent for HIV testing. | 1 No | | 5 Yes | | |
| 15. Obtained a <u>separate</u> consent for specimen storage or additional testing. <input type="checkbox"/> N/A | 1 No | | 5 Yes | | |
| 16. Pace of reading the consent was... | 1 Too slow | | 1 Too fast | | 5 Just right |
| Eligibility and Questionnaire Administration | | | | | |
| 17. Oriented the participant by reading each introductory statement ("SAY" box). | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| 18. Read each question as written. | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| 19. Read definitions as written (e.g., partner types, "sharing," etc.). | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| 20. Read response options as written when instructed ("READ choices"). | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| 21. Did not read response options when instructed ("DO NOT read choices"). | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |

| | | | | | |
|---|---|-------------|----------------|--------------|-----------------|
| 22. Reread and clarified instructions, questions, and responses. <input type="checkbox"/> N/A | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| 23. Recognized inconsistent responses, clarified with respondent, and corrected data in the portable computer or on the hard copy of the Data Error Log. <input type="checkbox"/> N/A | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| 24. Probed incomplete, implausible, unclear, and, as appropriate, "don't know" responses. <input type="checkbox"/> N/A | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| 25. Used neutral probes (i.e., probed without influencing response). | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| 26. Ensured participant was never able to view the portable computer screen. | 1 No | | 5 Yes | | |
| 27. The amount of time given for responses was... | 1 Too short | | 1 Too long | | 5 Just right |
| 28. Pace of reading the screener was... | 1 Too slow | | 1 Too fast | | 5 Just right |
| 29. Pace of reading the questionnaire was... | 1 Too slow | | 1 Too fast | | 5 Just right |
| Flashcards | | | | | |
| 30. Used flashcards when instructed. | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| 31. Oriented the participant to the flashcard response options (i.e., pointed to responses as being read). | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| 32. Read the flashcards as written. | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| Establishing and Maintaining Rapport | | | | | |
| 33. Established and maintained a good yet neutral rapport with participant (i.e., demonstrated interest, empathy, appropriate tone, and, if needed, refocused participant). | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 34. Maintained eye contact with participant throughout interview. | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 35. Provided neutral feedback throughout the interview. | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| 36. Remained engaged with participant and his responses throughout the survey. | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 37. Demonstrated a professional demeanor. | 1 Never | 2 Rarely | 3 Sometimes | 4 Usually | 5 Always |
| Criterion # | Skill Description, Recommendations, Accolades, and Additional Comments | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| Evaluator: Please ensure that the following steps are completed with the interviewer. <ul style="list-style-type: none"> <input type="checkbox"/> Asked the interviewer how any unclear responses were entered into the portable computer. <input type="checkbox"/> Reviewed how the interviewer coded the question regarding the validity of answers. <input type="checkbox"/> Reviewed evaluation form with the interviewer. <input type="checkbox"/> Provided time for interviewer to ask questions. <input type="checkbox"/> Provided the interviewer with recommendations for improvement. <input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard. | | | | | |

Appendix F

HIV Counseling and Testing Evaluation Form

A model evaluation form is shown below. This form can be printed or modified using the Word file named **Appendix F – HIV Counseling and Testing Evaluation.docx**.

| | | | | | | |
|---|--|---|---|---|---|------------|
| General Instructions <ul style="list-style-type: none"> To be conducted by the principal investigator, project coordinator, or, if necessary, the field supervisor. Permission must be obtained from the participant before an evaluator joins the HIV testing session. The evaluator should only interrupt the session for major issues, be discreet, and only direct questions to the counselor. Shaded areas are NHBS performance recommendations. This form may be modified to reflect local counseling and testing regulations. | | | | | | |
| HIV Test Counselor: | | Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation | | | | |
| Evaluation Date: | | | | | | |
| Evaluator: | | | | | | |
| Test Preparation | | Rating | | | | |
| 1. All necessary materials were prepared prior to starting (e.g., HIV testing kit, phlebotomy and DBS materials, HIV Test Results Log, referrals, information handouts, personal protective equipment, etc.). | | 1 Not at all | 2 | 3 Some | 4 | 5 Fully |
| 2. Verified on Participant Tracking Form or similar form that consent for HIV testing was provided. | | 1 No | | 5 Yes | | |
| 3. Verified with participant that he is interested in getting tested and has provided appropriate consent(s), including specimen storage and other tests if applicable. | | 1 No | | 5 Yes | | |
| 4. Discreetly obtained relevant behavioral risk information from interviewer. <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| Testing Procedures | | | | | | |
| 5. Test was conducted in an appropriate environment (temperature, lighting, adequate work space, etc.). | | 1 No | | 5 Yes | | |
| 6. All specimens or test devices were labeled with survey ID or lab ID. | | 1 No | | 5 Yes | | |
| 7. No personal identifiers were recorded other than for reminder call. | | 1 Collected identifiable information | | 5 Did not collect identifiable information | | |
| 8. Adequately counseled participant on what to expect during specimen collection. | | 1 No | | 5 Yes | | |
| 9. DBS were collected immediately following fingerstick and according to procedures in the <i>NHBS-IDU3 Operations Manual</i> . <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| 10. OSHA regulations were adhered to with respect to universal precautions (gloves) and waste disposal in approved biohazard and sharps containers. | | 1 No | | 5 Yes | | |
| 11. Appointment card was provided and participant counseled that card must be presented to obtain HIV test results. <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| Rapid Testing <input type="checkbox"/> N/A | | | | | | |
| 12. Oral specimen was collected per package insert and <i>NHBS-IDU3 Operations Manual</i> (e.g., food particles removed from mouth before collection). <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| 13. Appropriate instructions for oral specimen collection were provided (note: collection is different for Oraquick and Orasure). <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| 14. Ensured participant followed specimen collection instructions. <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| 15. Fingerstick specimen was collected per <i>NHBS-IDU3 Operations Manual</i> . <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| 16. Rapid test(s) could not be viewed by participant during test development. | | 1 No | | 5 Yes | | |
| 17. Rapid test results were read within the appropriate time frame for the test performed (Unigold: 10-20 min, Clearview 15-20 min, Oraquick 20-40 min). | | 1 No | | 5 Yes | | |
| 18. Recorded start time for test development and time when results were read. | | 1 No | | 5 Yes | | |
| 19. Confirmatory specimen was obtained if rapid test result was reactive. <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |

| Test Counseling | | | | | | |
|---|--|-----------------|-------------|-----------|-----------|----------------|
| 20. Collected self-reported HIV status according to the guidance in the <i>NHBS-IDU3 Operations Manual</i> . | | 1 No | | 5 Yes | | |
| 21. Pre-test counseling was conducted <i>after</i> the survey was completed. <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| 22. Conducted a risk assessment specific to the participant. | | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 23. Asked questions in an open-ended manner. | | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 24. Developed a risk reduction plan with the participant. | | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 25. Provided HIV information regarding transmission, risk factors, etc. | | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 26. Clarified misconceptions of HIV and corrected false information. <input type="checkbox"/> N/A | | 1 Not at all | | 5 Yes | | |
| 27. Provided a phone number or scheduled an appointment to obtain HIV test result. <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| 28. Offered an appointment reminder call to the participant. <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| 29. Returned test results in a manner that preserved participant's privacy. <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| 30. Ensured participant fully understood his HIV test result. <input type="checkbox"/> N/A | | 1 No | | 5 Yes | | |
| 31. Discussed disclosure of HIV status to partner(s). <input type="checkbox"/> N/A | | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 32. Provided information on where partner(s) can be tested. <input type="checkbox"/> N/A | | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 33. Provided and explained referral and informational resources. | | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 34. Allowed participant to ask questions and raise concerns. | | 1 No | | 5 Yes | | |
| 35. Answered questions and addressed participant's concerns. <input type="checkbox"/> N/A | | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 36. Remained engaged with the participant throughout the counseling session. | | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| 37. Spoke at the participant's level of understanding. | | 1 Not at all | 2 Poorly | 3 Okay | 4 Well | 5 Very well |
| Criterion # | Skill Description, Recommendations, Accolades, and Additional Comments | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| Evaluator: Please ensure that the following steps are completed with the HIV test counselor. <ul style="list-style-type: none"> <input type="checkbox"/> Reviewed evaluation form with the HIV test counselor. <input type="checkbox"/> Provided time for HIV test counselor to ask questions. <input type="checkbox"/> Provided the HIV test counselor with recommendations for improvement. <input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard. | | | | | | |

Appendix G

Data Manager Evaluation Form

A model evaluation form is shown below. This form can be printed or modified using the Word file named **Appendix G – Data Manager Evaluation.docx**.

| | | | |
|---|---|---------------|----------|
| General Instructions <ul style="list-style-type: none"> To be conducted by the principal investigator or project coordinator. Shaded areas are NHBS performance recommendations. | | | |
| Data Manager: | Rating instructions: Circle the number that corresponds with your evaluation for each criterion. For criteria that do not apply, check the "N/A" box. <input type="checkbox"/> Pre-implementation Evaluation <input type="checkbox"/> Ongoing Evaluation | | |
| Evaluation Date: | | | |
| Evaluator: | | | |
| Data Management | | Rating | |
| 1. Ensured daily receipt of the Participant Tracking Form and hard copies of the Data Error Log, the HIV Test Results Log, and other logs, if applicable. | | 1 No | 5 Yes |
| 2. Successfully uploaded data from each portable computer to the desktop computer. | | 1 No | 5 Yes |
| 3. Reviewed QDS™ data files from each portable computer and compared the Survey IDs with the Survey IDs recorded on the Participant Tracking Forms or similar forms. | | 1 No | 5 Yes |
| 4. Transferred records from QDS™ data files (e.g., files with *.QAD extension) to the QDS™ Warehouse successfully. | | 1 No | 5 Yes |
| 5. Did not delete QDS™ data files on the portable computer until after confirming the records were added to the QDS™ Warehouse. | | 1 No | 5 Yes |
| 6. Reviewed data discrepancies and concerns with the field supervisor or project coordinator to determine resolutions. | | 1 No | 5 Yes |
| 7. Documented data discrepancies and their resolution on the hard copy of the Data Error Log. <input type="checkbox"/> N/A | | 1 No | 5 Yes |
| 8. Entered data edits from the hard copy of the Data Error Log into the online Data Error Log on the DCC data portal daily. <input type="checkbox"/> N/A | | 1 No | 5 Yes |
| 9. Successfully entered HIV testing data into the online HIV Test Results Log on the DCC data portal. | | 1 No | 5 Yes |
| 10. Successfully encrypted NHBS data using PGP software. | | 1 No | 5 Yes |
| General | | | |
| 11. Knows how to ask the DCC questions and understands how to access information on the DCC data portal. | | 1 No | 5 Yes |
| 12. (Weekly) Submits QDS™ Warehouse containing core interview files to the DCC data portal. (Note: Please contact the DCC before sending a mock data warehouse to test this procedure.) | | 1 No | 5 Yes |
| 13. (Weekly) Reviews Process Monitoring Reports and communicates discrepancies with DCC. | | 1 No | 5 Yes |
| 14. (Monthly) Reviews DCC Data Management Reports and responds to inquiries on a timely basis. | | 1 No | 5 Yes |
| 15. Responds to DCC communications on a timely basis. | | 1 No | 5 Yes |
| Criterion # | Skill Description, Recommendations, Accolades, and Additional Comments | | |
| | | | |
| | | | |
| | | | |
| Evaluator: Please ensure that the following steps are completed with the data manager. <ul style="list-style-type: none"> <input type="checkbox"/> Reviewed evaluation form with the data manager. <input type="checkbox"/> Provided time for the data manager to ask questions. <input type="checkbox"/> Provided the data manager with recommendations for improvement. <input type="checkbox"/> If applicable, briefly described how each skill was below standard and provided recommendations for meeting the standard. | | | |

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.docx**.

1. General Supplies

Equipment:

- Flashcards for each interviewer
- Portable computers (1 for each interviewer and a backup)
- Laptop computer for the CMP
- AC adaptors for portable and laptop computers
- Communications equipment (e.g., 2-way radios or cell phones)
- Other office equipment (e.g., telephone, printer): _____

Blank forms or logs:

- Appointment book or log (if applicable)
- Consent forms (including copies for participants)
- Participant Tracking Forms (if applicable)
- Hard copies of the Data Error Log (if data errors are not collected on the Participant Tracking Form)
- Hard copies of the HIV Test Results Log
- Specimen Transport/Shipping Log
- Appointment Reminder Cards (if applicable)
- Appointment Reminder Call Forms (if applicable)
- Phone Results Log (if applicable)
- CMP Log
- Seed Referral Cards
- Coupons
- Information Cards
- Recruiter training scripts or talking points
- Receipt book for recording incentive payments (if applicable)
- Other forms or logs: _____

Reference materials:

- NHBS Round 3 Model Surveillance Protocol*
- NHBS Formative Research Manual*
- NHBS-IDU3 Operations Manual*
- Round 3 NHBS Interviewer Guide*
- CDC Coupon Manager Version 2.5 User Manual*
- Other reference materials: _____

Miscellaneous items:

- Interview and test incentives to cover the expected number of participants
- Recruiter rewards
- Envelopes or file folders to store used, voided, and expired coupons
- Signed Memorandums of Understanding (if applicable)
- Marketing materials
- Informational pamphlets on HIV and other medical conditions
- Referral information for HIV care and treatment
- Referral information for health care and social services
- HIV prevention supplies (e.g., condoms, lubricant, hygiene kits)
- Other items: _____

2. HIV Testing Supplies

Rapid testing supplies (if applicable):

- Rapid tests
- Fingertick blood collection devices (e.g., pipettes, loops)
- Test reagents (e.g., developer solution, wash solution, running buffer)
- Other rapid testing supplies: _____

Laboratory-based testing supplies:

- Lab slips
- Oral fluid collection devices (if applicable)
- Phlebotomy equipment (e.g., butterfly needles, tube stopper, tourniquet)
- Whole blood specimen collection tubes (if applicable)
- Whatman protein saver cards
- Other laboratory-based testing supplies: _____

Miscellaneous testing supplies:

- Beckton-Dickinson lancets (for rapid testing and DBS collection)
- Alcohol swabs
- Dry sterile gauze or cotton balls
- Band-aids
- Biohazard (“sharps”) container
- Biohazard bags
- Materials to transfer DBS (e.g., test tube racks, binder clips, box)
- Personal protective equipment (e.g., latex gloves, eye protection, lab coat)
- 5% Lysol disinfectant or germicidal wipes
- Other testing supplies: _____

3. Daily Closeout Activities

Field Supervisor:

From coupon manager–

- Collect coupons returned
- Collect and review the CMP Log
- Collect and review the Coupon Distribution Log

From interviewers–

- Collect and review Participant Tracking Forms (if applicable)
- Collect and review Data Error Logs (if applicable)
- Determine if any unusual events occurred (e.g., participant ended interview early, participant consented to HIV test then changed mind)
- Collect portable computers
- Determine if any problems occurred with the portable computers

From HIV test counselors–

- Collect and review hard copies of the HIV Test Results Log and any other HIV test forms (ensure that there is a specimen for each entry in the HIV Test Results Log and that survey/laboratory IDs are accurate)
- Collect and review Specimen Transport/Shipping Log
- Collect and review Phone Results Log (if applicable)
- Collect and review Appointment Reminder Call Forms (if applicable)

Data Manager:

- Upload data from portable computers
- Back-up CMP data
- Enter data corrections into the Data Error Log on the DCC data portal
- Enter HIV test results into the HIV Test Results Log on the DCC data portal
- Other daily data management activities: _____

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

Step 1. Schedule appointment

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

Step 2. Complete Appointment Reminder Call Form

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

Step 3. File form

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

Step 4. Process reminder calls

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

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

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



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

Step 5. Re-schedule appointment (optional)

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

Appendix L

Specimen Transport/Shipping Log

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

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

Figure L.1 – Local Specimen Transport/Shipping Log

Local Specimen Transport/Shipping Log

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

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

[Project Name] Fax Number: _____

| Lab ID or Survey ID | Date Collected | Specimen Type (Oral or Blood) | Reactive Rapid Test? (Yes or No) | Self-reported HIV-positive? (Yes or No) | Storage for Future Tests? (Yes or No) | Date Sent to Lab |
|---------------------|----------------|-------------------------------|----------------------------------|---|---------------------------------------|------------------|
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Lab Staff: Regardless of the results of any screening tests performed, **ALL** persons who are self-reported HIV-positive must have a confirmatory test (e.g., Western Blot, IFA, NAAT, or other tests that are part of a CDC-approved algorithm).

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

CDC DBS Specimen Transport/Shipping Log

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

[Project Name] Phone Number: _____

[Project Name] Fax Number: _____

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

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 M - Field Incident Report.docx**.

NHBS-IDU3 Field Incident Report

Project Site: _____

Name of Person Filing Report: _____

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

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

Location of Incident (name and address):

Date of Incident: ____ / ____ / ____

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

Description of Incident and Actions Taken:

Reported Locally to (check all that apply):

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

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

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

Name of Contact at CDC: _____

Comments (other information relevant to the incident):

Information cards should be given to recruiters so that they know where and when to return for their recruiter rewards. Examples of the front and back of a card are illustrated in **Figures N.1** and **N.2**. Instructions on how to create cards from a Microsoft Power Point template are provided in **Appendix O** of this manual.

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

Figure N.1 – Example of the front of an information card

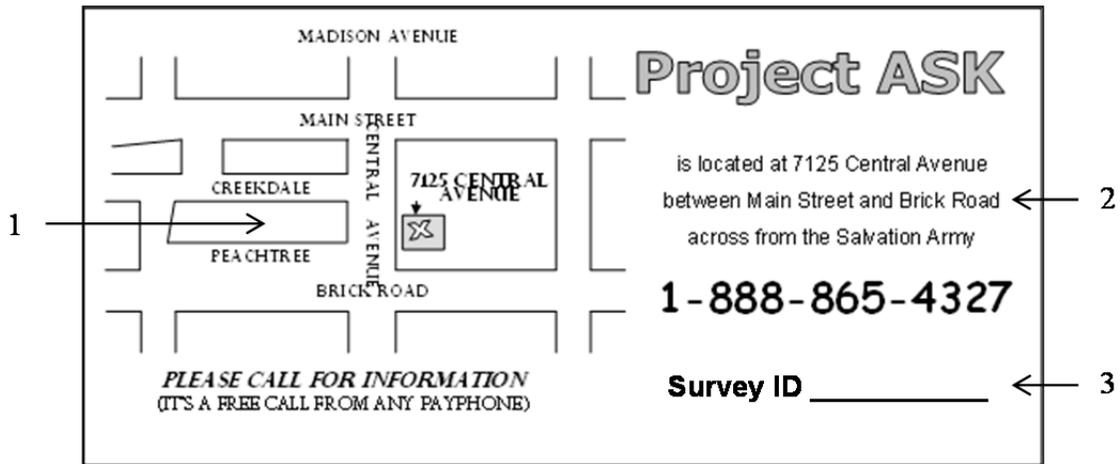


1. Name of the local NHBS project.
2. Description of the type of recruiter reward and the amount.
3. Phone number to call for project information (preferably toll-free).
4. Days and hours of field site operations.
5. Address of the field site.



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

Figure N.2 – Example of the back of an information card



1. Map showing the location of the field site.
2. Directions to the field site.
3. Space to record the participant's survey ID to search for his record in the Coupon Manager Program (CMP).

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

Project sites that wish to create their own referral cards, coupons, or information cards can use the Microsoft PowerPoint templates that were sent electronically with this manual.* These templates are compatible with *PowerPoint 2007* and *PowerPoint 2010*. Project sites using *PowerPoint 2003* should contact their CDC Project Officer to request templates compatible with that version. The template files are named:

Appendix O - Model Referral Card - Front.pptx

Appendix O - Model Referral Card - Back.pptx

Appendix O - Model Coupon - Front.pptx

Appendix O - Model Coupon - Back.pptx

Appendix O - Model Information Card - Front.pptx

Appendix O - Model Information Card - Back.pptx

Project sites should edit the templates to create their own unique designs. Those project sites that are in close proximity to one another should share their coupon designs to ensure that they are sufficiently different. This will help alleviate participant confusion if coupons from a neighboring project site become introduced locally.

To minimize the chance of damage to the cards or coupons, they should be printed on heavy stock paper. It is also helpful to use a different color paper for each of the three types of printouts so that they can be easily distinguished from one another.

0.1 Using PowerPoint Templates

The Microsoft PowerPoint templates can be edited as described in the steps below.

0.1a Opening

Open the file and view the template as a “Slide Master” (the file will automatically open in the “Slide Master” view when using *PowerPoint 2007* or *PowerPoint 2010*).

0.1b Editing

In the “Slide Master” view, use PowerPoint’s editing, inserting, and formatting functions to make any necessary changes to the template. When finished, remember to save the changes.

0.1c Auto-numbering

The front templates for the referral cards and coupons include auto-numbering (indicated by “<#>”) to automatically number the cards and coupons in sequence. The auto-numbering functions can be changed while in the “Slide Master” view.

Auto-numbering can be removed from the templates:

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:

1. Select **Insert**.
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 **Insert**.
5. Select **Slide Number**. The “<#>” symbol will appear in the text box.

Auto-numbering on the referral cards begins with “1” and on the coupons, “1000.” To change these start numbers:

1. Select **Page Setup**. The “Page Setup” window will open.
2. In the “Number slides from” field, enter the desired start number.
3. Select **OK**.



On the referral cards, the auto-numbering symbols are preceded by three zeros (“000<#>”) to automatically create the numbers “0001” to “0009.” If more than nine referral cards are printed, one of the zeros should be deleted so that the auto-numbering symbols are preceded by two zeros (“00<#>”). This will allow the numbers “0010” to “0099” to be automatically created.

O.1d 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 **View**.
2. Select **Slide Sorter**.
3. Copy the template by pressing the **Ctrl** key and the letter **C** key simultaneously.
4. Paste the template by pressing the **Ctrl** key and the letter **V** key simultaneously. The template can be pasted multiple times by holding the **Ctrl** key down and pressing the letter **V** key as many times as needed (holding both keys down simultaneously will generate multiple copies rapidly).

O.1e Printing

The front templates should always be printed first if they include auto-numbering. In addition, when using *PowerPoint 2007*, templates should be printed from the “Slide Master” view for best results.

To select the “Slide Master” view and print using *PowerPoint 2007*:

1. Select **View**.
2. Select **Slide Master**.
3. Select the **Office Button**.
4. Select **Print**. The “Print” window will open.
5. In the “Print what” field, select “Handouts.”
6. In the “Slides per page” field, select “2.” This will print cards approximately the size of an index card and coupons, the size of a dollar bill.
7. Select **OK**.

To print using *PowerPoint 2010*:

1. Select **File**.
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.
7. Select **Print**.

After the front templates are printed, the back templates can be printed on the reverse side of the printouts by following the steps outlined above.



Check the orientation of the printer’s paper feed before attempting to print the back templates. Otherwise, the back templates may be inadvertently printed upside-down or over the front templates.

* The Microsoft PowerPoint referral card and coupon templates were originally provided by Douglas Heckathorn and Robert Broadhead. These templates were further modified by the Detroit project site during the NHBS-HET1 pilot.

Appendix P

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 P - Participant Tracking Form.docx**.

| Participant Tracking Form | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|-------------------------------------|-----------|-----------|--|--------------------------------|---|---|-----|-------------------------------|---|---|--|------------------------------|---|---|--|--------------------------------|---|---|--|--------------------------|---|---|--|-----------------------------|---|---|--|-------------------------|---|---|--|----------------------------|---|---|--|--------------------------------------|--|--|--|---------------------------------|---|---|--|
| Interviewer ID | <input style="width: 95%;" type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Date | <input style="width: 95%;" type="text"/> | Survey ID (Coupon Number) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | <input style="width: 95%;" type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <i>Data Manager Use Only:</i> | | Field Site ID | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Start Time | <input style="width: 95%;" type="text"/> | <input style="width: 95%;" type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | Portable Computer # | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | <input style="width: 95%;" type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| INTERVIEWER: | | Notes: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tbody> <tr> <td style="width: 45%;">1. Passed the eligibility screener?</td> <td style="width: 10%;">Y</td> <td style="width: 10%;">N</td> <td style="width: 35%;"></td> </tr> <tr> <td>2. Consented to the interview?</td> <td>Y</td> <td>N</td> <td></td> </tr> <tr> <td>3. Consented to the HIV test?</td> <td>Y</td> <td>N</td> <td></td> </tr> <tr> <td>4. Consented to other tests?</td> <td>Y</td> <td>N</td> <td></td> </tr> <tr> <td>5. Consented to blood storage?</td> <td>Y</td> <td>N</td> <td></td> </tr> <tr> <td>6. SRP during interview?</td> <td>Y</td> <td>N</td> <td></td> </tr> <tr> <td>7. Completed the interview?</td> <td>Y</td> <td>N</td> <td></td> </tr> <tr> <td>8. Eligible to recruit?</td> <td>Y</td> <td>N</td> <td></td> </tr> <tr> <td style="padding-left: 20px;">If yes, agreed to recruit?</td> <td>Y</td> <td>N</td> <td></td> </tr> <tr> <td style="padding-left: 20px;">If yes, number of coupons due: _____</td> <td></td> <td></td> <td></td> </tr> <tr> <td>9. Received recruiter training?</td> <td>Y</td> <td>N</td> <td></td> </tr> </tbody> </table> | | | 1. Passed the eligibility screener? | Y | N | | 2. Consented to the interview? | Y | N | | 3. Consented to the HIV test? | Y | N | | 4. Consented to other tests? | Y | N | | 5. Consented to blood storage? | Y | N | | 6. SRP during interview? | Y | N | | 7. Completed the interview? | Y | N | | 8. Eligible to recruit? | Y | N | | If yes, agreed to recruit? | Y | N | | If yes, number of coupons due: _____ | | | | 9. Received recruiter training? | Y | N | |
| 1. Passed the eligibility screener? | Y | N | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. Consented to the interview? | Y | N | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. Consented to the HIV test? | Y | N | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. Consented to other tests? | Y | N | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5. Consented to blood storage? | Y | N | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6. SRP during interview? | Y | N | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7. Completed the interview? | Y | N | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8. Eligible to recruit? | Y | N | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| If yes, agreed to recruit? | Y | N | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| If yes, number of coupons due: _____ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 9. Received recruiter training? | Y | N | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| TEST COUNSELOR: | | Notes: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tbody> <tr> <td style="width: 45%;">1. Obtained test specimen?</td> <td style="width: 10%;">Y</td> <td style="width: 10%;">N</td> <td style="width: 35%;"></td> </tr> <tr> <td>2. SRP during counseling?</td> <td>Y</td> <td>N</td> <td>D R</td> </tr> <tr> <td style="padding-left: 20px;">If yes, SRP date: _____</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> | | | 1. Obtained test specimen? | Y | N | | 2. SRP during counseling? | Y | N | D R | If yes, SRP date: _____ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Obtained test specimen? | Y | N | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. SRP during counseling? | Y | N | D R | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| If yes, SRP date: _____ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| DATA EDITS: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Variable Name</th> <th style="width: 25%;">Old Value</th> <th style="width: 25%;">New Value</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> | | | Variable Name | Old Value | New Value | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Variable Name | Old Value | New Value | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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Appendix Q

Recruiter Training Script

A model Recruiter Training Script is outlined below. This script can be printed or modified using the Word file named **Appendix Q - Recruiter Training Script.docx**.

Who to Recruit

We're going to give you *[insert #]* coupons to give to other people who inject drugs so that they can be in the study too. You should give the coupons to drug injectors you know. You should only give the coupons to people who live in *[insert project area]*. Since people can just be in the study once, don't give the coupons to anyone who has already participated. Most importantly, you should NOT give the coupons to strangers. The drug injectors you recruit will have to bring in their coupons and answer questions to determine if they are selected for the study.

Coupons

To be in the study, everyone has to have a coupon. Be sure to tell the people you give a coupon to that they need to have the coupon with them when they come in or when they call to make an appointment. The first thing we'll do is check to see if their coupon is valid.

Your coupons cannot be replaced if they are lost or stolen or if the person you recruited is not selected for the study. A coupon cannot be used more than once. Each coupon has a date when it expires, and after that date, it can't be used anymore. So, you should tell people you give the coupon to that they need to come in or call to make an appointment before the expiration date written on the coupon.

Process

Be sure to tell the people you recruit to come in or make an appointment at a time when they are able to complete the whole survey process, which takes about 1 hour. Children aren't allowed to sit in on the interview, so ask your recruits to have someone watch their children if they have any. People you give coupons to who complete the interview will be given \$25. They will get an additional \$25 for taking an HIV test. We won't do an interview with anyone who is under the influence of drugs or alcohol; people who are not capable of completing the interview will not be allowed to participate in the study.

Reward

You will get paid \$10 for each person you recruit who is selected for the study and who completes the interview. But, it's not guaranteed that you will get the \$10 just for recruiting someone:

- You will not be paid for someone who is not selected for the study.
- You will not be paid for recruiting someone who has already participated in the

study.

- You will not be paid for someone who does not complete an interview.

Not everyone in this study gets the opportunity to recruit others, and not everyone gets the same number of coupons. Who gets to recruit other people for the study and how many coupons they get is determined by the computer. When you give the coupon to someone else and they become part of the study, they might get a different number of coupons than you did. The study is time-limited, so eventually there will be no more coupons given out and no more interviews conducted.

Recruiter Information

In order for us to be sure that we give the reward to the right person, we're going to ask you a few questions and enter the information into the computer to create an identification number that is unique to you. When you come in to get paid, we'll ask you those same questions again to create the number and check it in the computer. The coupons we give you are linked to you so we'll know which ones to pay you for.

You can call our office to see if the people you gave coupons to were selected for the study and completed an interview, so that you can come in to get your reward. We can't tell you who came in or not, but we can tell you whether you can get a reward. We will only pay you, so do not send someone else in to get paid.

Wrap-up

Do you have any questions?

Thanks for helping us, and remember, give the coupons to people you know and who inject drugs.

Appendix R

Recruiter Training Talking Points

Model Recruiter Training Talking Points are outlined below. These talking points can be printed or modified using the Word file named **Appendix R - Recruiter Training Talking Points.docx**.

Who to Recruit

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

Coupons

- Everyone has to have a coupon to be in the study.
- Tell people you recruit to have the coupon with them when they come in or when they call to make an appointment.
- Your coupons cannot be replaced if they are lost or the person you recruited is not selected for the study.

Process

- The whole process for the survey takes about 1 hour.
- Children aren't allowed to sit in on the interview, so ask your recruits to have someone watch their children if they have any.
- Everyone who completes an interview will get \$25. Everyone who also does an HIV test will get an additional \$25.
- People who aren't capable of completing the interview won't be allowed to participate in the study. This includes people who are too drunk or high to complete the interview.

Reward

- You will get paid \$10 for each person you recruit who is selected for the study and who completes the interview; the \$10 is not guaranteed just because you give someone a coupon.

- You will not be paid for someone who is not selected for the study.
- You will not be paid for someone who has already participated.
- You will not be paid for someone who does not complete an interview.
- The computer determines who gets to recruit other people for the study and how many coupons they will get.
- Coupons will expire and the study will end at some point.

Recruiter Information

- We ask questions so that we can identify you again when you come to get your rewards.
- We link the numbers on the coupons we give you to the coupon you brought in, so we know who to pay.
- Call the office to find out if you are owed a reward.
- We can't tell you who came in with a coupon from you.
- We will only pay you. Don't send someone else in to get paid.

Do you have any questions?

Thanks for helping us, and remember, give the coupons to people you know and who inject drugs.

Restriction on Using Federal Funds for Needles and Syringes



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Health
Washington, D.C. 20201

March 29, 2012

Dear Colleague:

As you are aware, On December 17, 2011, Congress passed HR 2055, the Consolidated Appropriations Act 2012, which the President signed into law on December 23, 2011. The following language was included in Division F, Title V, Sec. 523: "Notwithstanding any other provision of this Act, no funds appropriated in the Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug."

This act reinstates the ban that was in place prior to December 2009. As a result, using federal funds for the distribution of needles or syringes for the hypodermic injection of any illegal drug is prohibited with fiscal year 2012 funding. Specifically, the following activities are no longer permitted with federal funds:

- Human resources used specifically to distribute needles or syringes
- Delivery modes, e.g. vehicles or rent for fixed sites used specifically for distributing needles or syringes
- Purchase of needles or syringes

This memo replaces any prior HHS agency communication on the reinstated ban.

A handwritten signature in black ink that reads "Ronald O. Valdiserri".

Ronald O. Valdiserri, MD, MPH
Deputy Assistant Secretary for Health,
Infectious Diseases

U.S. Public Health Service

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.

T.1 Hepatitis B Testing

HBV testing requires laboratory-based testing. Project sites should perform three tests for HBV infection: 1) hepatitis B surface antigen (HBsAg), a protein on the surface of HBV; 2) antibody to HBsAg (anti-HBs); and 3) total antibody to hepatitis B core antigen (anti-HBc), an antibody to HBV core proteins. The presence of each antigen or antibody indicates a different stage of HBV infection. HBsAg indicates current infection, anti-HBs indicates immunity to infection (either from natural infection or vaccination), and anti-HBc indicates past or current infection. **Table T.1** describes the interpretation of HBV test results for counseling participants and making any necessary referrals.

T.2 Hepatitis C Testing

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

T.2a Rapid hepatitis C testing

Recently, the FDA approved a rapid HCV test for use on blood collected through venipuncture or fingerstick. The test is CLIA-waived for use in field settings by non-laboratory staff, and results are available within 20 minutes. Project sites may return preliminary HCV test results to participants, but they ***must confirm all*** rapid HCV test results with laboratory-based testing. Accordingly, project sites may wish to use venipuncture to collect blood specimens for rapid HCV testing so that they can use the same specimen for both the rapid test and the laboratory-based confirmatory test. The CDC is currently developing guidance on the interpretation of rapid HCV test results and will share this information with project sites when it becomes available.

T.2b Laboratory-based hepatitis C testing

The standard laboratory-based screening test for HCV infection is an enzyme immunoassay (EIA) test. A negative EIA test result can be considered a final result. Specimens with a positive EIA test result may require further testing depending on the signal-to-cutoff (SCO) ratio set by CDC for the specific EIA test used. If the SCO ratio is above the CDC threshold for the EIA test used, additional testing is not required. However, if the SCO is below the CDC threshold but above the manufacturer's cut-off value (i.e., in the "grey zone"), then additional testing is required. Most laboratories use a recombinant immunoblot assay (RIBA) test for confirmation, while others use a nucleic acid test (NAT). Either method is acceptable for confirming HCV test results in NHBS.

A positive EIA test result with an SCO above the CDC threshold or a positive RIBA test result indicates either current or past (resolved) HCV infection. In contrast, a positive NAT result indicates just current infection. **Figure T.1** provides an algorithm for conducting laboratory-based HCV testing and **Table T.2** describes the interpretation of laboratory-based HCV test results for counseling participants and making any necessary referrals.

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

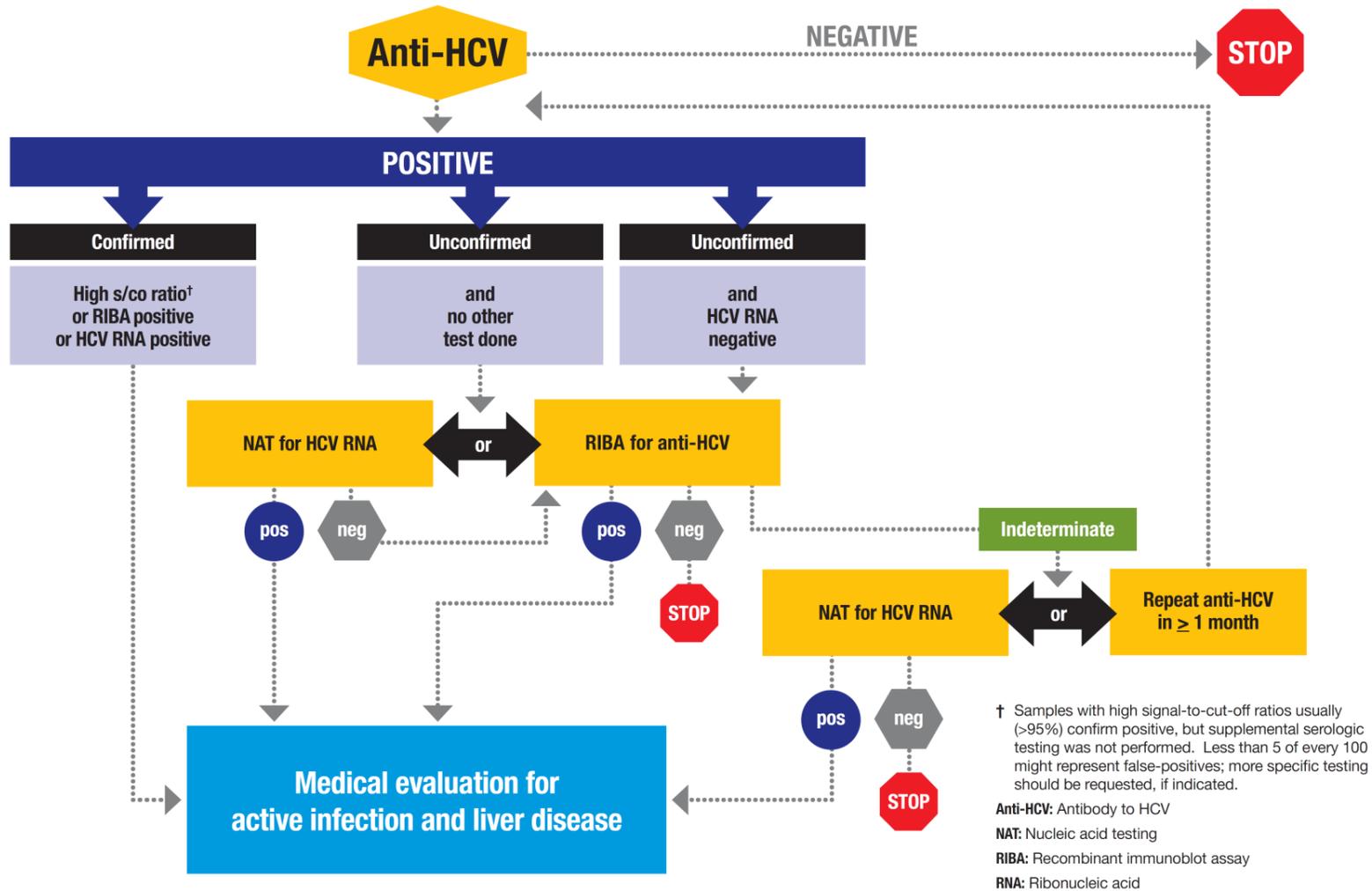
| Test | Result | Interpretation |
|---|--|--|
| HBsAg anti-HBc anti-HBs | negative negative negative | Susceptible |
| HBsAg anti-HBc anti-HBs | negative positive positive | Immune due to natural infection |
| HBsAg anti-HBc anti-HBs | negative negative positive | Immune due to hepatitis B vaccination |
| 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).



The test for IgM anti-HBc will not be performed as part of NHBS. This test may be conducted by a health care provider when a participant is referred for care to help distinguish between acute and chronic HBV infection.

Figure T.1 – Algorithm for laboratory-based hepatitis C virus (HCV) testing



Available at <http://www.cdc.gov/hepatitis/HCV/LabTesting.htm>

Table T.2 – Interpretation of laboratory-based hepatitis C virus (HCV) test results

| If Your HCV Test Result Is: | | | Interpretation | | Action |
|-----------------------------|----------------------------------|------------|----------------|---------------|--|
| Anti HCV Screening Test* | Anti-HCV Supplemental Test RIBA† | HCV RNA | Anti HCV | HCV Infection | Additional Testing or Evaluation |
| Negative | Not Needed | Not Needed | Negative | None | No |
| Positive | Not Done | Not Done | Not Known | Not Known | Supplemental anti-HCV (RIBA) or HCV RNA |
| Positive | Not Done | Negative | Not Known | Not Known♦ | Supplemental anti-HCV (RIBA) |
| Positive (high s/co ratio§) | Not Done | Not Done | Positive | Past/Current | Evaluate for chronic infection and liver disease |
| Positive | Negative | Not Needed | Negative | None | No |
| Positive | Positive | Not Done | Positive | Past/Current | Evaluate for chronic infection and liver disease |
| Positive | Positive | Negative | Positive | Past/Current♦ | Repeat HCV RNA; Evaluate for chronic infection and liver disease |
| Positive | Positive/Not Done | Positive | Positive | Current | Evaluate for chronic infection and liver disease |
| Positive | Indeterminate | Not Done | Indeterminate | Not Known | Test for HCV RNA or repeat anti-HCV testing |
| Positive | Indeterminate | Positive | Positive | Current | Evaluate for chronic infection and liver disease |
| Positive | Indeterminate | Negative | Indeterminate | Not Known♦ | Test for HCV RNA or repeat anti-HCV testing |

Anti-HCV: Antibody to HCV

RNA: Ribonucleic acid

* EIA (enzyme immunoassay) or CIA (enhanced chemiluminescence immunoassay).

† RIBA (recombinant immunoblot assay), a more specific anti-HCV assay.

♦ Single negative HCV RNA result cannot determine infection status, as persons might have intermittent viremia.

§ Samples with high signal-to-cut-off ratios usually (>95%) confirm positive, but supplemental serologic testing was not performed. Less than 5 of every 100 might represent false positives; more specific testing should be requested, if indicated.

Available at <http://www.cdc.gov/hepatitis/HCV/LabTesting.htm>

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



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

DBS Cards

Product: Whatman 903® protein saver card

Vendor: GE Healthcare Life Sciences

<http://www.whatman.com/903ProteinSaverCards.aspx>

(800) 526-3593

DBS Drying Clips

Product: Binder clips for attaching DBS cards to drying racks

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

DBS Drying Racks

Product: Test tube racks for drying DBS cards

Vendor:

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

or:

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

Desiccant Packs

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

Vendor: Poly Lam Products, Corp

(800) 836-9648

<http://www.polylam.com/Desiccant%20Packets%20Dist.pdf>

Envelopes

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

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

Glassine Weigh Paper

Product: Item # 09-898-12C

Vendor: Fisher Scientific
(800) 766-7000

Humidity Indicator Cards

Product: Item # MS20003-2, 125 can

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

Lancets

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

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

Low-gas Permeable Plastic Zip-lock Bags

Product: Item # 11217-106

Vendor: VWR Scientific
(800) 932-5000

Product: Item # 19240127

Vendor: Fisher Scientific
(866) 884-2019

Appendix W

Previous Positive Questions

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

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

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

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

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

Project sites conducting laboratory-based HIV tests can print a copy of the script from the Word file named **Appendix W - Previous Positive Questions for Lab Testing.docx**, and project sites conducting rapid HIV tests can print a copy of the script from the Word file named **Appendix W - Previous Positive Questions for Rapid Testing.docx**.

Responses to the *Previous Positive Questions* should be recorded on the Participant Tracking Form or a similar form. The HIV test counselor should record the participant's answer to the first *Previous Positive Question* under the "SRP during counseling" question (SRP stands for self-reported positive). Responses to the first *Previous Positive*

Question should be coded and recorded as described in the table below:

| If the participant's response to the first <i>Previous Positive Question</i> is... | Circle this response option for the "SRP during counseling" question... |
|---|--|
| Yes | Y |
| No | N |
| Don't know | D |
| Refuses to answer | R |

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

Appendix X

Process Monitoring Reports

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

X.1 Recruitment Monitoring Report

| Recruitment Monitoring Report | | | | | | | | | | | | | |
|-------------------------------|--------------|--------------|------------|-------------------------|-----------------------|---------------------------|-------------------------|-----------------------------|---------------------------|-----------------------------|---------------------------|-------------------------|-----------------------|
| Date | No. Screened | No. Eligible | % Eligible | No. Completed Interview | % Completed Interview | No. Consented to HIV Test | % Consented to HIV Test | No. Consented to Other Test | % Consented to Other Test | No. Agreed to Blood Storage | % Agreed to Blood Storage | No. Eligible to Recruit | % Eligible to Recruit |
| | | | | | | | | | | | | | |
| Total | | | | | | | | | | | | | |

X.2 Coupon Manager Program Report

1 - COUPON TRACKING

| Date | No. Interviewed | No. Agreed to Recruit | % Agreed to Recruit | No. Participants who Received Coupons by No. of Coupons | | | | | | No. Coupons Distributed | No. Coupons Returned | % Coupons Returned |
|--------------|-----------------|-----------------------|---------------------|---|---|---|---|---|---|-------------------------|----------------------|--------------------|
| | | | | 0 | 1 | 2 | 3 | 4 | 5 | | | |
| | | | | | | | | | | | | |
| Total | | | | | | | | | | | | |

2 – CHANGES TO NUMBER OF COUPONS DISTRIBUTED

| Date Change was Made | No. of Coupons Distributed to Recruiter | Reason for Change in Number of Coupons Distributed |
|----------------------|---|--|
| | | |
| | | |

3 - GENDER OF COUPON REFUSALS

| Gender | N | % |
|--------------|---|---|
| Males | | |
| Females | | |
| Total | | |

4 - RACE/ETHNICITY OF COUPON REFUSALS

| Race/Ethnicity | N | % |
|----------------|---|---|
| White | | |
| Black | | |
| Hispanic | | |
| Asian | | |
| Other | | |
| Total | | |

5 - REASONS FOR COUPON REFUSALS

| Reasons for Refusals | N | % |
|---------------------------------------|---|---|
| Didn't have time | | |
| Didn't live in the area | | |
| Didn't trust you (recruiter) | | |
| Don't like research/surveys | | |
| Already participated in the survey | | |
| Don't want to be identified as an IDU | | |
| Not eligible | | |
| Unknown | | |
| Other | | |
| Total | | |

X.3 Sample Characteristics – Screened

1 - ELIGIBLE

| Eligible | N | % |
|----------|---|---|
| Yes | | |
| No | | |
| Total | | |

(Tables in this report continue on the next page)

2 - AGE

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

3 – GENDER

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

(Tables in this report continue on the next page)

5 - MSA RESIDENT

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

6 - KNOWN PREVIOUS PARTICIPANT

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

7 - ABLE TO PARTICIPATE

| | Eligible | | Not Eligible | | Total | |
|---------------------|----------|---|--------------|---|-------|---|
| | N | % | N | % | N | % |
| Able to Participate | | | | | | |
| Yes | | | | | | |
| No | | | | | | |
| Total | | | | | | |

8 - IDU IN PAST 12 MONTHS

| | Eligible | | Not Eligible | | Total | |
|-----------------------|----------|---|--------------|---|-------|---|
| | N | % | N | % | N | % |
| IDU in Past 12 months | | | | | | |
| Yes | | | | | | |
| No | | | | | | |
| Unknown | | | | | | |
| Total | | | | | | |

(Tables in this report continue on the next page)

9 - SIGNS OF DRUG INJECTION

| Signs of Injection | Eligible | | Not Eligible | | Total | |
|--------------------|----------|---|--------------|---|-------|---|
| | N | % | N | % | N | % |
| Covered Area Only | | | | | | |
| No Signs | | | | | | |
| Old Signs | | | | | | |
| Recent Signs | | | | | | |
| Refused | | | | | | |
| Total | | | | | | |

10 - DRUG INJECTION KNOWLEDGE

| Drug Injection Knowledge | Eligible | | Not Eligible | | Total | |
|--------------------------|----------|---|--------------|---|-------|---|
| | N | % | N | % | N | % |
| Yes | | | | | | |
| No | | | | | | |
| Not asked | | | | | | |
| Total | | | | | | |

11 - 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 | | | | | | |
| Crystal, meth, tina, crank, ice | | | | | | |
| Something else | | | | | | |
| Unknown | | | | | | |
| Total | | | | | | |

X.4 Sample Characteristics – Interviewed

1- AGE

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

2 – GENDER

| Gender | N | % |
|------------------------------------|----------|----------|
| Male | | |
| Female | | |
| Other, Includes Transgender | | |
| 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 | | |

(Tables in this report continue on the next page)

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 STATUS

| Homeless | N | % |
|---------------------|---|---|
| Never Homeless | | |
| Previously Homeless | | |
| Currently Homeless | | |
| Unknown | | |
| Total | | |

6 – INCOME

| Income | N | % |
|---------------------|---|---|
| 0 – \$4,999 | | |
| \$5,000 – \$9,999 | | |
| \$10,000 – \$14,999 | | |
| \$15,000 – \$19,999 | | |
| \$20,000 – \$29,999 | | |
| \$30,000 – \$39,999 | | |
| \$40,000 – \$49,999 | | |
| ≥ \$50,000 | | |
| Unknown | | |
| Total | | |

(Tables in this report continue on the next page)

7 - TYPE OF DRUG INJECTED MOST OFTEN

| Type of Drug Injected Most Often | N | % |
|---|---|---|
| Heroin | | |
| Cocaine | | |
| Speedball - Heroin and cocaine together | | |
| Crack | | |
| Crystal, meth, tina, crank, ice | | |
| Something else | | |
| Unknown | | |
| Total | | |

8 - RECRUITMENT BY STRANGER

| Recruited by Stranger | N | % |
|-----------------------|---|---|
| Yes | | |
| No | | |
| Unknown | | |
| Total | | |

9 - GEOGRAPHIC AREA

| Geographic Area | N | % |
|-----------------|---|---|
| | | |
| | | |
| Total | | |

X.5 Test Results Report

1 - RAPID HIV TEST RESULTS

| | Final HIV Test Result | | | | | | | | Total |
|-----------------------|-----------------------|---|----------|---|---------------|---|---------|---|-------|
| | Positive | | Negative | | Indeterminate | | Unknown | | |
| | N | % | N | % | N | % | N | % | N |
| Rapid HIV Test Result | | | | | | | | | |
| Preliminary Positive | | | | | | | | | |
| Negative | | | | | | | | | |
| Unknown | | | | | | | | | |
| Not Done | | | | | | | | | |
| Total | | | | | | | | | |

(Tables in this report continue on the next page)

2 - SELF-REPORTED HIV-POSITIVE TEST RESULTS

| | Final HIV Test Result | | | | | | | | Total N |
|-----------------------------------|-----------------------|---|----------|---|---------------|---|---------|---|------------|
| | Positive | | Negative | | Indeterminate | | Unknown | | |
| Self-Reported HIV Status | N | % | N | % | N | % | N | % | N |
| Self-reported Positive | | | | | | | | | |
| Interview | | | | | | | | | |
| Counseling | | | | | | | | | |
| Not Self-reported Positive | | | | | | | | | |
| Total | | | | | | | | | |

3 - HEPATITIS B TEST RESULTS

| | Interpretation of HBV Tests by DCC | | | | | | | | | | | | Total N % | |
|--|------------------------------------|---|---------------------------------|---|---------------------------|---|----------|---|---------|---|---------|---|--------------|---|
| | Susceptible | | Immune Due to Natural Infection | | Immune Due to Vaccination | | Infected | | Unclear | | Unknown | | | |
| Interpretation of HBV Tests by Project Staff | N | % | N | % | N | % | N | % | N | % | N | % | N | % |
| Susceptible | | | | | | | | | | | | | | |
| Immune Due to Natural Infection | | | | | | | | | | | | | | |
| Immune Due to Vaccination | | | | | | | | | | | | | | |
| Infected | | | | | | | | | | | | | | |
| Unclear | | | | | | | | | | | | | | |
| Unknown | | | | | | | | | | | | | | |
| Not Done | | | | | | | | | | | | | | |
| Total | | | | | | | | | | | | | | |

4 - HEPATITIS C TEST RESULTS

| Interpretation of HCV Test | N | % |
|----------------------------|---|---|
| Antibody positive | | |
| Antibody negative | | |
| Indeterminate | | |
| Unknown | | |
| Not Done | | |
| Total | | |

X.6 Seed Report

1 - SEED MONITORING

| Date | No. Screened | No. Eligible | No. Completed Interview | No. Agreed to be Recruiters |
|--------------|--------------|--------------|-------------------------|-----------------------------|
| | | | | |
| | | | | |
| Total | | | | |

2 - SEED CHARACTERISTICS

| Date | Survey ID# | Gender | Race/Ethnicity | Age | Drug of Choice | Zip Code |
|------|------------|--------|----------------|-----|----------------|----------|
| | | | | | | |
| | | | | | | |

X.7 Respondent Driven Sampling Report

1 - 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 | |
| Monday | | | | | |
| Tuesday | | | | | |
| Wednesday | | | | | |
| Thursday | | | | | |
| Friday | | | | | |
| Saturday | | | | | |
| Sunday | | | | | |
| Total | | | | | |

(Tables in this report continue on the next page)

2 - CROSS RECRUITMENT

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

3 - RECRUITMENT CHAINS

| Chain | Wave | Frequency | Percent | Cumulative Frequency | Cumulative Percent |
|-------|------|-----------|---------|----------------------|--------------------|
| | | | | | |
| | | | | | |

X.8 Possible Previous Participant Report

| Survey ID | Interview Date | Start Time | Interviewer Code | Previous Participant | Eligibility | Validity | Date of Birth | Gender | Race / Ethnicity | Education | ZIP Code |
|-----------|----------------|------------|------------------|----------------------|-------------|----------|---------------|--------|------------------|-----------|----------|
| | | | | | | | | | | | |
| | | | | | | | | | | | |

X.9 Interviewer Improvement Report

1 - INTERVIEW LENGTH

| Interviewer ID | Number of Completed Interviews | Length of Eligibility Screening | | | | | Length of Consent Process | | | | | Length of Interview | | | | |
|----------------|--------------------------------|---------------------------------|------|-----|-----|-----|---------------------------|------|-----|-----|-----|---------------------|------|-----|-----|-----|
| | | Med | Mean | Min | Max | Num | Med | Mean | Min | Max | Num | Med | Mean | Min | Max | Num |
| | | | | | | | | | | | | | | | | |
| TOTAL | | | | | | | | | | | | | | | | |

(Tables in this report continue on the next page)

2 - SIGNS AND KNOWLEDGE OF DRUG INJECTION

| Interviewer ID | Recent Signs of Injection | | Injection Knowledge with Old Signs of Injection | | Injection Knowledge with No Signs of Injection | | No Signs or Knowledge of Injection | | Total |
|----------------|---------------------------|---|---|---|--|---|------------------------------------|---|-------|
| | N | % | N | % | N | % | N | % | |
| | | | | | | | | | |
| | | | | | | | | | |

3 - RESPONSE VALIDITY

| Interviewer ID | Confident | | Some Doubts | | Not Confident at All | | Total |
|----------------|-----------|---|-------------|---|----------------------|---|-------|
| | N | % | N | % | N | % | |
| | | | | | | | |
| | | | | | | | |

4 - HIV TEST CONSENT

| Interviewer ID | HIV Test Consent | | |
|----------------|------------------|----|-------|
| | Yes | No | Total |
| | | | |
| | | | |
| Total | | | |

5 - HEPATITIS TEST CONSENT

| Interviewer ID | Hepatitis Test Consent | | |
|----------------|------------------------|----|-------|
| | Yes | No | Total |
| | | | |
| | | | |
| Total | | | |

6 - CODING OF "OTHER" INSURANCE

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

Appendix Y

Acronyms

| Acronym: | Definition: |
|-----------------|--|
| 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 | (ICF International) Data Coordinating Center |
| DHAP | Division of HIV/AIDS Prevention |
| EIA | Enzyme Immunoassay |
| FWA | Federalwide Assurance |
| HAPI™ | Handheld Assisted Personal Interview |
| HBV | Hepatitis B Virus |
| HCV | Hepatitis C Virus |
| HIV | Human Immunodeficiency Syndrome |
| IDU | Injection Drug User |
| IFA | Immunofluorescent Antibody |
| IRB | Institutional Review Board |
| MOU | Memorandum of Understanding |
| MSA | Metropolitan Statistical Area |
| NGA | Notice of Grant Award |
| NHBS | National HIV Behavioral Surveillance System |
| NHBS-IDU3 | National HIV Behavioral Surveillance System among Injection Drug Users – Round 3 |
| OMB | Office of Management and Budget |
| OMT | Oral Mucosal Transudate |
| OSHA | Occupational Safety and Health Administration |
| PGO | Procurement and Grants Office |
| PHRP | (National Institutes of Health) Protecting Human Research Participants |
| PI | Principal Investigator |
| QDS™ | Questionnaire Development System |
| RDS | Respondent-driven Sampling |
| RDSAT | Respondent-driven Sampling Analysis Tool |
| SRP | Self-reported (HIV) Positive |
| WB | Western Blot |