National HIV Behavioral Surveillance: Transgender Women (NHBS-Trans)

Operations Manual

Behavioral Surveillance Team
NCHHSTP/DHAP/BCSB

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Acronyms

Acronym:	Definition:
AFAB	Assigned female at birth
AMAB	Assigned male at birth
CAPI	Computer Administered Personal Interview
CBO	Community-based Organization
CDC	Centers for Disease Control and Prevention
CITI	Collaborative Institutional Training Initiative
CLIA	Clinical Laboratory Improvement Amendments
CMP	Coupon Manager (software) Program
DBS	Dried Blood Spot
DCC	NHBS Data Coordinating Center
DHAP	Division of HIV/AIDS Prevention
EIA	Enzyme Immunoassay
FTE	Full-time Equivalent
FWA	Federalwide Assurance
GNC	Gender Nonconforming
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration
IFA	Immunofluorescent Antibody
IRB	Institutional Review Board
MOU	Memorandum of Understanding
MSA	Metropolitan Statistical Area
NAT	Nucleic Acid Testing
NB	Nonbinary
NGA	Notice of Grant Award
NHBS	National HIV Behavioral Surveillance
NHBS-Trans	National HIV Behavioral Surveillance, Transgender Women
NIH	National Institutes of Health
OFR	Office of Financial Resources

OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
PHRP	(National Institutes of Health) Protecting Human Research Participants
PI	Principal Investigator
PRA	Paperwork Reduction Act
QDS™	Questionnaire Development System
RDS	Respondent-driven Sampling
RDS-A	Respondent-driven Sampling Analyst (software)
RDSAT	Respondent-driven Sampling Analysis Tool (software)
SRP	Self-reported (HIV) Positive
TG	Transgender
TGW	Transgender Women
TGM	Transgender Men

1 Introduction

1.1 Overview

The *NHBS-Trans 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 among Transgender Women 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 and other 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 NHBS. The manual ensures operational standardization of NHBS activities across all project areas who are conducting surveillance of trans women.

1.3 Staff Responsibilities

CDC staff are responsible for writing the *NHBS-Trans Operations Manual* and providing technical assistance to project areas during implementation. Local NHBS staff are responsible for conducting the project using the procedures described in the manual and for submitting all required data to CDC in a timely manner through the NHBS Data Coordinating Center (DCC) data portal.

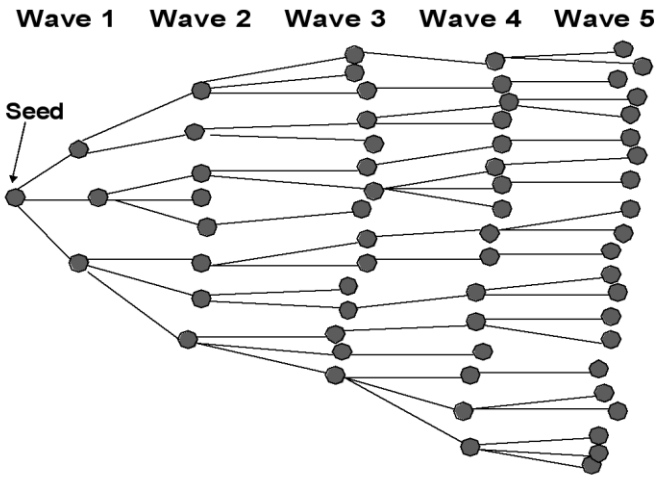
1.4 Respondent-Driven Sampling

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

1.4a RDS methods

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

Figure 1.1 – RDS recruitment waves



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

1.4b RDS assumptions

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

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

1.4c RDS and bias

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

The biases associated with chain-referral sampling can be minimized with RDS by limiting the number of coupons given to each recruiter and by generating long chains of recruitment. As recruitment chains become longer with each wave of recruitment, the sample approaches an "equilibrium" in composition. Equilibrium is the point at which the composition of the sample no longer changes, even with further waves of recruitment. At equilibrium, the characteristics of the sample become independent of those of the seeds. In addition, by conducting data analysis using RDS analysis software, 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., younger persons recruiting older persons). This weighting further reduces some of the biases inherent in chain-referral sampling and is the means by which RDS produces population estimates.

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

1.5 Operations Checklist

The Operations Checklist is found in **Appendix A**. Project areas 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 areas 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 staff 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 areas should update the checklist whenever there are any operational changes (e.g., changes to staff, field site hours or locations, number of coupons distributed) and they should promptly send a copy of the revised checklist to their CDC project officer.

1.6 References

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

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

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

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

2 Staffing, Training, and Evaluation

2.1 Overview

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

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

2.2 Staffing

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

Guidance on creating job descriptions for hiring NHBS-Trans staff

In addition to recommending that all project areas hire women that are part of the local trans community whenever possible, the following is general language to include when creating job descriptions for hiring NHBS-Trans staff. Including the following, or similar, language is especially important when hiring a project coordinator, field supervisor, and other field staff. Project areas may adapt the following language based on local project needs.

Job qualifications that may be demonstrated through employment, volunteerism, activism or community works include:

- A commitment to transgender equality
- A commitment to full social justice and an understanding of health issues affecting transgender women, including transgender women of color and those with low- or no-income
- A strong understanding of the issues and health needs of transgender women in the United States and in your local community
- Skills in speaking sensitively about issues of gender, sexuality, and other aspects of diversity
- A demonstrated interest in transgender, health, HIV or related issues

If possible, do not limit gender identity fields included on job applications for hiring any staff (including health department and contract staff) to binary options only.

2.2a Management staff

Project areas should, at a minimum, have the following management positions: principal investigator, project coordinator, and field supervisor. Each of these positions is discussed below. Management staff are responsible for implementing project operations in compliance with all NHBS guidance (e.g., *Model Surveillance Protocol, Formative Assessment Manual, Operations Manual,* and *Interviewer Guide)* and locally developed policies. Substantial deviations from the roles listed below should be discussed with your CDC project officer.

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.

Project coordinator

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

A successful project coordinator has considerable knowledge of HIV/AIDS and surveillance activities, is familiar with or part of the local population of trans women, has 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).

Table 2.1 – Recommended positions and responsibilities for management staff

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

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

Responsibilities	Principal Investigator (PI)	Project Coordinator	Field Supervisor
Training and ongoing evaluations	• Ensure required trainings have been successfully completed by all project staff. • Conduct staff evaluations in collaboration with the project coordinator and field supervisor.	• Coordinate and conduct pre-implementation and ongoing trainings for project staff in collaboration with the field supervisor. • Coordinate pre-implementation cultural competency training for staff and ongoing cultural competency training as needed with the field supervisor to be conducted by local community based organization. (See Section 2.5b) • Conduct staff evaluations in collaboration with the PI and field supervisor.	• Coordinate and conduct pre-implementation and ongoing trainings for project staff in collaboration with the project coordinator. • Coordinate pre-implementation cultural competency training for staff and ongoing cultural competency training as needed with the project coordinator to be conducted by local community based organization. (See Section 2.5b) • Conduct staff evaluations in collaboration with the PI and project coordinator.
Data collection, management, analysis, and dissemination	• Ensure timely submission and entry of data to the DCC data portal. • Assume responsibility for quality control and data integrity. • Supervise the implementation of recommendations from CDC or the DCC to improve data quality. • Oversee development of policies pertaining to analyses and dissemination of data. (Health department only) • Oversee analyses of local data. • Ensure data are 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. • Collaborate with local community organizations in dissemination efforts.	• Ensure daily transfer of data from portable computers to the QDS™ Warehouse. • Ensure that QDS™ Warehouse is maintained. • Ensure that coupon manager information, HIV testing data, and data errors are entered into the DCC data portal daily. • Review Process Monitoring Reports, ensure problems are addressed, and improvement seen. • Coordinate and implement policies pertaining to data analysis and dissemination. • Participate in data analysis and dissemination. • Evaluate need for ongoing formative assessment and make changes based upon findings.	• Schedule field site hours. • Review, tabulate, and reconcile forms and logs used in the field. • Review data errors with the coupon manager, interviewers, and HIV test counselors. • Oversee documentation of data errors. • Supervise entry of coupon manager information, HIV testing data, and data errors into the DCC data portal. • Review Process Monitoring Reports, identify issues of concern, and implement changes for improvement.
HIV testing operations	• Develop local HIV testing protocol and oversee HIV testing activities. • Ensure procedures are developed for making appropriate and acceptable (to the population) referrals to care and other services.	• Oversee maintenance of HIV testing supplies. • Ship HIV test specimens. • Receive and log HIV test results from lab. • Obtain CLIA waiver (if applicable). • Develop procedures for making referrals to care and other services.	• Ensure proper documentation of HIV testing activities, including consent. • Ensure adherence to HIV testing procedures. • Ensure adherence to procedures for making referrals to care and other services.

Safety, security, and confidentiality	• Responsible for safety, security, and confidentiality of project staff, participants, materials, and data, including the development of local procedures and policies. • Report field incidents and adverse events to CDC within 48 hours of occurrence and to the IRB(s) per local policy.	• Coordinate development of local procedures for incident reporting, safety, and handling participants known to project staff. For instance, if an interviewer knows the participant they are about to interview, they should either see if another interviewer is available to conduct the interview, or reschedule for later date/time with another interviewer. • Report field incidents and adverse events to CDC within 48 hours of occurrence and to the IRB(s) per local policy.	• Assist in the development of local procedures for incident reporting, safety, and handling participants known to project staff; and ensure adherence to all locally developed procedures. • Report field incidents and adverse events to CDC within 48 hours of occurrence and to the IRB(s) per local policy.

Table 2.2 – Responsibilities for field staff and the data manager

Coupon Manager	Interviewer	HIV Test Counselor	Data Manager
• Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately. • Check in potential participants; provide recruiter training or, if interviewer provides recruiter training, reinforce recruiter training; check out participants; and pay incentives and recruiter rewards. • Manage all operational activities related to the coupon manager station and the Coupon Manager Program (CMP). • Upload CMP data to the DCC data portal daily.	• Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report field incidents and adverse events to the field supervisor immediately. • Accurately document participant information for the eligibility screener, consent form, questionnaire, and Participant Tracking Form. • Maintain data integrity (i.e., all data collected accurately represent the information provided by participants during the interview). • Provide recruiter training (if applicable). • Assist with ongoing formative assessment as necessary. • Be familiar with or part of the target population. • Be knowledgeable about services available to trans women and able to provide referrals.	• 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 project areas with separate interviewers and HIV test counselors: Document communication between interviewer and HIV test counselor to ensure participant consent was provided for HIV testing.	• Comply with guidelines for maintaining safety, data security, and participant confidentiality. • Implement local safety procedures and report adverse events to the field supervisor immediately. • Ensure upload of data from the portable computers to the QDS™ Warehouse. • Ensure daily receipt of forms and logs and review errors or concerns with the field supervisor or project coordinator. • Enter information from forms and logs into the DCC data portal. • Maintain QDS™ Warehouse and submit to the DCC data portal weekly. • Maintain data integrity (i.e., each record in the database represents the data an individual provided to the field team). • Review data reports from the DCC as soon as they are received, and provide requested data edits and explanations to resolve data issues via the DCC data portal. • Perform data analyses as needed.

Field supervisor

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

A successful field supervisor has considerable knowledge of the communities in which NHBS is conducted, HIV/AIDS, surveillance activities and is familiar with or part of the local population of trans women. In addition, a field supervisor should have strong leadership skills, excellent attention to detail, high motivation, trans 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 areas should designate staff for the following field positions: coupon manager, interviewer, and HIV test counselor. Each of these positions is discussed below. It is useful for field staff to be trained to perform multiple positions to maximize the flexibility of operations. Field staff are expected to adhere to procedures in accordance with NHBS guidance (e.g., *Model Surveillance Protocol, Formative Assessment Manual, Operations Manual,* and *Interviewer Guide)* and locally developed policies.

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

Coupon manager

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

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

Interviewers

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

A successful interviewer has strong interviewing and data collection skills and a thorough understanding of the informed consent process. An interviewer should also have excellent communication skills, experience working with populations at risk for HIV infection, and considerable knowledge of the communities in which NHBS is conducted. While we encourage hiring individuals from the local trans community for NHBS-Trans, interview staff should be diverse; we do not expect ALL interviewers to be from the trans community.

Interviewers cannot be part of your Community Advisory Board as it could create a conflict of interest.

When interviewing trans women, interviewers should be able to identify needs for services that women may have, and provide the appropriate referrals.

HIV test counselors

HIV test counselors must be certified to conduct the specific type(s) of HIV test being used by the project area and are responsible for following local HIV counseling and testing standards and NHBS HIV testing guidelines. HIV test counselors are responsible for providing tailored prevention messages to each participant based upon risk behaviors identified during the interview or counseling session. In addition, HIV test counselors must also provide anonymous referrals to medical care and case management and ensure that HIV-positive participants are linked to these services.

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

2.2c Data manager

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

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

2.3 Spanish-speaking Staff

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

2.4 The Importance of Skill Standardization and Quality Assurance

The quality of NHBS data is dependent upon each staff member's ability to perform their position successfully, consistently, and in the same manner as their NHBS colleagues within their project area and across all the project areas. Standardization of procedures

and quality is an important aspect of all data collection efforts. To ensure standardization of NHBS operations, CDC provides the following tools: (1) NHBS guidance documents, (2) Field Operations Training, (3) project staff evaluation forms with performance recommendations, (4) pre-implementation and ongoing evaluation recommendations, and (5) retraining recommendations. Interview standardization and quality assurance is especially important and is discussed in detail in the *NHBS-Trans Interviewer Guide*.

2.5 Project Staff Training

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

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

2.5a Required trainings

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

Field Operations Training

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

Required participants: *Project coordinator and field supervisor to view webinar sessions. All relevant field staff to attend local training.*

Table 2.3 – Pre-implementation guidance and trainings

		Guidance Documents						Required Trainings						Recommended Trainings	
	Model Surveillance Protocol	Operations Manual	Formative Assessment Manual	Interviewer Guide	IDU5 Data Management Training Manual	Questionnaire	Local HIV testing documents	Field Operations Training	Security and confidentiality of HIV/AIDS surveillance data	Emergency procedures, field safety, adverse events, and field incidents	Project area and job-specific trainings	DCC Data Management training videos	Trans Cultural Competency Training	Human subjects ethical training	Cultural and health diversity course
Project Coordinator	X	X	X	X		X	X	View webinars	X	X	X		X	X	X
Field Supervisor	X	X	X	X		X	X		X	X	X		X	X	X
Coupon Manager	X	X	X*					Attend local training	X	X	X		X	X	X
Interviewers	X	X	X*	X		X			X	X	X		X	X	X
HIV Test Counselors	X	X	X*				X		X	X	X		X	X	X
Data Manager	X	X	X*	X	X	X			X	X	X	X	X	X	

*If applicable.

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

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

Required participants: *All project staff*

HIV counseling and testing

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

Required participants: *All HIV test counselors*

DCC data management training

Representatives from the DCC will train data managers or other designated project staff on best practices for organizing, editing, and submitting data through the DCC data portal. This training will be presented through a series of videos available through the DCC data portal.

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

Trans cultural competency training

Project areas should seek out collaborators at local organizations to provide trans cultural competency training for all staff. Using a variety of methods, cultural competency training could cover topics such as the differences between sex assigned at birth, sexual orientation, gender identity and gender expression. It could also explore respectful terminology and how to be an ally to the community. At a minimum, basic cultural competency training could include establishing pronouns upon greeting participants (if deemed locally appropriate). If local organizations are not able or willing to provide trans cultural competency training, project areas should develop their own training content based on formative findings and staff expertise. If a project area produces its own trans cultural competency training materials, those materials should be reviewed by representatives from local organizations, if possible, or by CDC staff if no qualified local organizations can assist. Whenever possible, trans cultural competency training should be conducted by a member of the local trans women population.

Some free training materials and resources can also be found at The Center of Excellence for Transgender Health website (http://transhealth.ucsf.edu/trans?page=lib-topic-culture). A training video for medical providers can also be rented for $3.99 for 72 hours. Additional resources can be found through the Industry Collaboration Effort, which includes basic LGBT training materials for healthcare providers (https://www.iceforhealth.org/library/documents/ICE_C_L_Cultural_Competency_Provider_Training_Final(1).pdf).

Another resource for you to consider is the first of a 5-module series of trainings specific to competency in the realm of transgender and gender non-conforming people. This was developed by NIH's Division of AIDS in direct consultation with transgender community members.

The learning portal is located at https://daidslearningportal.niaid.nih.gov. From there, you will find instructions for how to request an account –

- For "Site ID", enter "0".
- When filling out your access request form, be sure to mention the Transgender Competency Training, or "Introduction to Transgender Communities", as your reason for applying. The staff have been instructed to approve accounts requested for that reason, as part of an effort to make these modules more widely available.

After 1-2 days, you should receive confirmation that your account has been approved. Once you have access to the portal, search for "Transgender" and you will find "An Introduction to Transgender Communities".

Required participants: *All project staff*

2.5b Recommended trainings

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

Human subjects and scientific ethics training

This free online training covers the historical background of behavioral and biomedical research, the ethical principles for human subject research, and the role of the Institutional Review Board. Online completion time is approximately 30-90 minutes depending upon an individual's familiarity with the material. Courses can be found at either the Collaborative Institutional Training Initiative (CITI) website

(https://www.citiprogram.org) or the NIH Protecting Human Research Participants (PHRP) website (http://phrp.nihtraining.com/users/login.php). Once registered, project staff can complete the course in multiple sittings.

Recommended participants: *All field staff*

Cultural and health diversity course

A cultural and health diversity course is recommended for all project staff who interact with participants. The goals of this training are to increase sensitivity to social, cultural, and linguistic differences among participants and to raise disability awareness. Courses are often offered at local universities, state health departments, medical schools, or companies that specialize in diversity training. Free online courses can also be found, like those available through the Health Resources and Services Administration's (HRSA's) Culture, Language, and Health Literacy Resources webpage (https://www.hrsa.gov/about/organization/bureaus/ohe/health-literacy/resources/index.html). HRSA courses include the curricula developed by the National Center for Cultural Competence: https://nccc.georgetown.edu/.

Recommended participants: *All field staff*

Other trainings

Project areas should consider training staff on how to deal with distressed participants as the NHBS-Trans survey asks questions about potentially distressing experiences such as abuse and harassment. Project areas may seek out collaborators at local organizations to provide this training.

Recommended participants: *All field staff*

2.6 Project Staff Evaluations

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

2.6a Pre-implementation evaluation and performance recommendations

Prior to implementation, each staff member should meet all the performance recommendations for their position to ensure the standardization of skills within and

across project areas 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 to address the identified deficiency.

2.6b Ongoing evaluations and retraining procedures

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

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

2.6c Evaluators

The 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.

Table 2.4 – Evaluation and retraining recommendations

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

Table 2.4 – Evaluation and retraining recommendations (continued)

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

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

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

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

Recommendations for evaluators:

- To ensure the most accurate assessment of a staff member's skill-level, do not serve as a mock participant and evaluator at the same time.
- Unless a major issue arises (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 at the coupon manager station or is conducting an interview or HIV counseling session. If an evaluator needs to interrupt, it should be done discreetly, with communication directed to the staff member and not the participant.
- Provide positive feedback and recommendations for improvement to the staff member following each evaluation.
- Maintain pre-implementation and ongoing evaluation schedules.
- Discuss staff evaluations and retraining needs with the field supervisor.

2.6d Project staff

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

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

2.6e Interviewer Report

To help project areas assess the interviewers and provide feedback for improving their techniques, the DCC will produce an *Interviewer Report* containing the following four tables: Interview Length, Interviewer Confidence in Responses, Testing Consent, and Coding of "Other" Insurance. An explanation of each table is provided in **Section 10.3i**

of this manual. Project areas should review the report weekly and discuss the findings with their interviewers to identify strengths and areas for improvement.

3 Project Preparation

3.1 Overview

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

3.2 Project Logo and Marketing Materials

A project logo and marketing materials (e.g., advertisements, flyers, palm cards) should be created for local project identification and to promote community awareness of the project. Formative assessment should guide the development of these materials and members of the community should be asked about the types of logos and marketing strategies that would be most appealing to potential participants. Moreover, marketing materials should be culturally appropriate and respectful of trans women. Before the logo and marketing materials are printed and distributed, they must be reviewed and approved by the local community advisory board and the project area's CDC project officer. Additional information about developing logos and marketing materials can be found in the *NHBS-Trans Formative Assessment Manual* (section 3.3.3).

Content posted on social media, like a Facebook Page, should be treated the same as all other NHBS marketing materials; it must be reviewed and approved by the local community advisory board and the area's CDC project officer (see **Section 3.3.3** of the *NHBS-Trans Formative Assessment Manual).*

Because respondent-driven sampling (RDS) relies on peer recruitment rather than recruitment by project staff, marketing materials should be used in a limited manner. Marketing materials are best used to garner community support by relaying the project's goals and objectives to local stakeholders. Project areas may also find it helpful to add their project logo to their coupons to promote project identity and to benefit from any name recognition the project has generated in the community.

3.3 Access to the DCC Data Portal

As described in **Chapter 11** of this manual, project areas must regularly submit the

Questionnaire Development System™ (QDS™) Warehouse with their core surveys to the DCC data portal. They will also use the data portal to enter data into the HIV Testing Log, the Hepatitis Testing Log (if applicable) and the Data Error Log. Project staff that need access to the DCC data portal should first receive approval from the principal investigator of the directly funded health department and then apply for access following the instructions in the IDU5 Data Management Training Manual.

3.4 Project Supplies

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

3.4a Portable computers and survey software

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

Project areas must use QDS modules (version 2.6.1) to collect and manage NHBS data. These modules include the Design Studio, Warehouse Manager, and Computer Assisted Personal Interview (CAPI). QDS modules using version 2.6.1 may not function properly on computers that also contain other versions of the modules, such as versions 2.4 or 5.0. Only the CAPI module will be supported for NHBS data collection.

3.4b Materials

Project areas should ensure that they have an adequate number of consent forms, incentives, flashcards, and other materials needed to conduct NHBS activities.

3.4c Forms and logs for project management

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

Project areas can customize the documents for local use and they can develop additional documents to help manage project activities as needed. **Table 3.1** summarizes some forms and logs that are recommended. If your area uses any alternative forms, whether alternatives to those recommended by CDC or in addition to CDC-provided forms, be sure that those forms reflect transgender cultural competency – using forms that validate transgender identity is essential to preventing barriers to participation.

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

Project staff should use a binder to store forms and logs in a central and easily referenced location. Project areas providing HIV test results over the phone should refer to section 5.2d of the NHBS-Trans Model Surveillance Protocol for additional guidance and develop a Phone Results Log (**Appendix N** of this manual). Hard copies of forms that contain confidential information (e.g., HIV Testing Log and Phone Results Log) should be stored in a locked file cabinet and handled in a manner which complies with the *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action* (available at http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf). In addition to the aforementioned forms and logs, project staff may want to keep other materials and information in the project binder for easy reference, such as memorandums of understanding (MOUs) with field site owners or managers.

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

Form or Log	Purpose	Location in This Manual
Project Staff Evaluation Forms	Observe and evaluate project staff.	Appendices B - G
Appointment Book or Log	Schedule and track appointments.	Chapter 4
Participant Tracking Forms	Record participant information, completed activities, and data errors.	Appendix I
CMP Log	Record the numbers on the coupons distributed to each recruiter.	Appendix J
Rapid Testing Quality Control Log	Record external rapid test control results.	Appendix K
Rapid Testing Temperature Log	Record temperatures at which rapid tests and quality controls are stored and run.	Appendix L

Lab slips	Identify specimens.	Chapter 9
HIV Testing Log	Record HIV testing data.	(Appendix L*)
Appointment and Phone Results Cards	Make appointments for returning HIV test results.	Appendix M
Phone Results Log (if applicable)	Record information for returning HIV test results over the phone.	Appendix N
Specimen Transport/Shipping Log	Track the transport and shipment of laboratory specimens.	Appendix O

*Located in the NHBS-Trans Model Surveillance Protocol.

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 areas 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.
  - HIV prevention and treatment.
  - HIV, hepatitis, and other testing services.
  - Syringe services programs (also known as syringe or needle exchange programs).
  - Alcohol and substance use disorder treatment services.
  - Support groups.
  - Medical services, including gender-affirming care.
  - Trans outreach programs.
  - Other services identified during formative as being appropriate for this population such as trans-friendly healthcare providers, housing assistance, legal aid, employment assistance/job placement services, crisis centers, etc.
- **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 areas 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 trans-friendly HIV and STD clinics, substance abuse treatment centers, mental health service providers, and agencies that offer free HIV, STD, and hepatitis testing. The list should also include other services identified during formative research as being appropriate for this population such as trans-friendly healthcare providers, housing, legal aid, crisis centers, etc. It is important that project area staff confirm that all service providers on their referral list are in fact trans-friendly. Further information on referrals to care and services are described in **Section 9.8** of this manual.

- **Supplies** used to reduce HIV risk, such as condoms and lubricant. If a project area is interested in distributing other risk reduction supplies, please check with your Project Officer.

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

3.4e Other supplies and materials

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

3.5 Local Safety Procedures

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

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

3.5a General principles of field safety

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

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

3.5b Steps for field safety

Project areas 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 they are welcoming, but be

cautious if you have concerns about them.

Use common sense

- Limit the amount of cash you carry.
- Do not leave your cell phone unattended.
- Avoid wearing or carrying articles that look valuable. Jewelry, purses, expensive watches, and cameras invite theft.
- Do not wear articles of clothing with political or culturally insensitive images.
- Do not carry illegal weapons.
- Never leave the keys in your car or the doors unlocked.
- Do not use 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 their concerns; avoid becoming defensive; lower your voice, tone, and tempo; and respond to valid complaints. Local safety officials (police, fire, and rescue) may be able to provide de-escalation training.

Sexual harassment

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

Inebriated, high, or drowsy participants

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

3.5d Safeguarding portable computers

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

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

3.6 Field Incident Reporting Procedures

Project areas should develop field incident reporting procedures and include them in the Operations Checklist. These procedures should adhere to all local IRB requirements. In the event that an incident does occur, project staff should notify their field supervisor within 24 hours. The field supervisor, project coordinator, or principal investigator should then use a Field Incident Report to notify their CDC project officer of the incident within 48 hours. A model Field Incident Report is provided in **Appendix P** that project areas can customize for local use. Incidents that are adverse events should also be reported to the local IRB(s) within 48 hours or earlier if mandated by local IRB requirements (see Chapter 9 of the *NHBS-Trans Model Surveillance Protocol*).

4 Field Sites

4.1 Overview

During RDS cycles, data collection activities are conducted at fixed locations called field sites. Field sites are usually existing or rented office space or vans parked at specific places. Because all respondents must access a field site to participate in the project, selecting the appropriate number and location(s) of field sites is critical for successfully conducting RDS. Findings from formative assessment will help project areas 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 areas 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 areas that have limited public transportation, cover large geographic areas, or where formative research indicate racial segregation among trans women. If a single field site is used, it should be located in an area where all sub-populations of trans women have equal access and would be equally willing to go, such as a location that serves as a "bridge" between the major sub-populations. Similarly, if multiple field sites are used, at least one of the field sites must be readily accessible to most or all major sub-populations of trans women if possible. Results of formative assessment should be used to determine whether a single field site location is sufficient to reach all the major sub-populations of trans women or whether more than one field site is needed. Furthermore, if formative assessment indicates that confidentiality or group membership is a concern among potential participants, project areas should choose a nondescript location for their field site.

4.2a Restrictions on field sites

- To maintain the integrity of the RDS method, project areas must adhere to some restrictions when choosing field sites. Field sites should not be located in facilities that serve the homeless population or near areas where ***large*** numbers of homeless people congregate. The incentives provided in RDS studies are extremely attractive to economically disadvantaged populations, like the homeless; and as a result, they may be more likely to participate in the project, biasing the sample.

- Field sites should not be placed in substance misuse treatment centers, syringe exchange programs, methadone clinics, or near areas where ***large*** numbers of people who use drugs congregate. Like the homeless, people who use drugs

may be more attracted to the RDS incentives than are members of the broader trans women population, which could bias the sample. The sample could be even further biased if members of the broader at-risk trans women population are reluctant to enter facilities providing services to people who use drugs due to the stigma associated with drug use.

Single-service facilities

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

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

Multi-service facilities

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

4.2b Additional considerations for vans

Project areas that plan on using a van must identify fixed locations where the van will be parked on each day of project operations. They should also create a set schedule of hours of operation at each location. Fixed locations and schedules are essential for ensuring that people always know where to go to participate in the survey and at what times. Depending on parking regulations and availability, it may be necessary to obtain a parking permit for each location or to reserve the location in advance. As was discussed for field sites above, vans should not be parked near facilities or in areas where large numbers of homeless people or people who use drugs congregate; near substance abuse treatment centers, syringe exchange programs, or methadone clinics; or near any other area that would not comply with the restrictions on field sites.

4.3 Multiple Field Sites

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

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

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

4.3a Cross-recruitment

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

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

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

4.4 Field Site Set-up

The field site should be welcoming and comfortable for participants while maintaining their safety and privacy. It should have adequate space for the coupon manager station, 2 or more interview areas, and a waiting area for potential participants. Interviews should be conducted in private offices or rooms to provide privacy and protect participant confidentiality. Alternatively, partitions could be used to divide an open space and white noise machines could be used to mask voices. If there is not sufficient space inside the field site for a waiting area, project areas may be able to set up a makeshift waiting area outside the field site using folding chairs. Project areas 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 Assessing indoor space

The field site should be an environment that is welcoming and comfortable for anyone, but particular care should be taken to assess the field site environment from the perspective of a potential transgender participant. For example, if a field site is established in a healthcare facility during off-hours, consider whether the décor in the field site would be affirming for transgender people from all local sub-populations. If a transgender person is expected to wait comfortably in this space, ask yourself what characteristics of the room and its contents are meant to provide that comfort:

- Are there posters on the walls that depict only white, cisgender, heterosexual people?
- Are bathrooms labeled "Men" and "Women"?
- Do waiting rooms contain reading material that is openly antagonistic towards transgender people?
- Does access to the field site require interaction with non-NHBS staff, and are those staff adequately trained in transgender cultural competency?

Consider that comfort and affirmation for transgender participants may require active measures – the installation or inclusion of trans-targeted materials to engender a supportive environment – as opposed to passive measures, such as simply removing offensive materials or attempting to make a space feel "neutral". Some criticisms of cultural competency suggest that striving for "neutrality" may result in unconscious bias favoring normative characteristics and experiences like cisgender or heterosexual identity. What is perceived as neutral by cisgender, heterosexual men and women may further reinforce uncomfortable norms for a transgender woman.

Where possible, invite your CAB members to inspect field sites so they can help identify ways to make sites welcoming to local transgender women, while also maintaining strong CAB engagement over the project period. If your project area is experiencing issues enrolling in general, or issues enrolling enough members of a specific local sub-

population, it may be particularly valuable to ask CAB members to inspect your field site(s) for any barriers that may be impacting enrollment rates.

4.4b Assessing outdoor space

Your formative findings should provide valuable information regarding how Trans-focused and Trans-serving organizations in your MSA operate, and steps they take to make their own sites attractive and welcoming to Transgender clients.

Follow the example of local organizations and the direction of your CAB and formative informants. If local organizations or services appear to operate with significant discretion or secrecy (e.g. a local service provider doesn't list their address publicly, as a precaution against harassment of their clients; storefront decor does not communicate that the services within are for transgender people) you may wish to operate your field sites with a similar level of discretion. If trans-serving organizations have identified a lack of discretion as a barrier to participating in their services, then it's reasonable to assume that the same barrier may apply to NHBS-Trans activities in your area.

Conversely, if local organizations appear to be open about the identity of their clients (e.g. services that include "Transgender" in the name, have plainly visible signage or advertising which is associated with transgender or related identities; organizations which display pride flags on their exterior), then you may wish to follow suit. In contrast to the previous example, if local organizations are clear about serving transgender clients, loudly and proudly, then your field sites may need to present themselves as explicitly trans-oriented.

4.4c Talk with neighbors and local police

Before setting up the field site, project areas should meet with local police officials to explain the study's objectives and methods and to discuss any safety concerns in the area and to ensure that participating women will not be approached by police. 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, and a letter of support from the local police may be useful to have at the field site. Project areas 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.

4.4d Field site safety

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

(see **Section 3.5** of this manual). To prevent theft, project areas should store incentives, computers, supplies, and other potentially valuable items in safe locations that are not visible to participants. Most importantly, file cabinets that contain 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 areas 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 sub-populations of trans women may be less likely to participate, which could bias the sample. Project areas 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 areas 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 areas using vans should also develop contingency plans in case the van is unavailable due to mechanical or staffing problems. For example, they could send project staff to the van's usual location to greet 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 areas must send at least two staff members to notify potential participants; project staff should never work in the field alone.

4.6 Crowd Control

As the project becomes established in the community and recruitment increases, more and more individuals will be interested in participating. These potential participants may crowd the field site or line up outside it. To help control these crowds, project areas 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 areas do not wish to schedule appointments, they could use a "take-a-number" system to see participants on a first-come, first-served basis. With this system, project staff would determine how many

interviews they could conduct each day and then hand out the corresponding number of tickets. Rather than using tickets, project staff could also track participants by listing their survey IDs (coupon numbers) in the order that they arrived at the field site. 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 areas cannot implement any additional sampling strategies to manage enrollment, such as randomly selecting potential participants for each day's available interview spots. Such a system would undermine the RDS sampling method.

In previous RDS cycles, people who were not participants often crowded the field sites. For example, potential participants were sometimes accompanied by their family or friends. If this becomes problematic, project areas 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 an 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 areas should institute a clear policy regarding children at the field site. Since banning children could create a participation barrier, project areas 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 areas to better manage enrollment and may reduce crowding and loitering at the field site. Project areas should develop their appointment system based on the number of interviewers and test counselors they have available and the time required for interviewing and testing. Interviewing and HIV testing should take approximately 1 hour, but additional time may be needed to process rapid tests or conduct other tests. More time may also be necessary at the beginning of data collection when project staff are less accustomed to operations.

Potential participants should be able to schedule appointments by phone (preferably toll-free), but voicemail should ***not*** be activated on the phone to prevent any participants from leaving confidential information, like their name or phone number. If voicemail 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 areas with appointment systems should also consider allowing a limited number of participants to "walk-in" for interviews. "Walk-ins" could be seen on a first-come, first-served basis if someone does not show up for an appointment or cancels one at the last minute.

4.7a Scheduling appointments

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

1) Greet the potential participant and ask them for their coupon. Check the "Activation Date" (if applicable) and the "Expiration Date" on the coupon to verify that the coupon is valid before scheduling the appointment. If the potential participant does not have their coupon with them, instruct them to return with their coupon or call the field site to schedule an appointment over the phone. When scheduling over the phone, ask the potential participant for their 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 their 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 areas should not reserve appointment spots for members of any specific sub-population of trans women. Denying available appointment spots to individuals who are not members of the specific sub-population would undermine the RDS sampling method and bias the sample. Nevertheless, project areas that are having

difficulty enrolling an important sub-population should discuss scheduling options with their CDC Project Officer.

4.7b Standby appointments

Standby appointments allow potential participants to fill in for those who do not show up for their appointments or who cancel them at the last minute. Project areas 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 areas schedule standby appointments is outlined in the steps below:

1) Identify possible standby appointment times by choosing those that generate higher rates of "no-shows" or choosing a few at set intervals throughout the day.

2) Highlight the standby appointment times in the appointment book or log, and create a standby column adjacent to these times.

3) To schedule a standby appointment, write the potential participant's coupon number in the standby column next to their standby appointment time. Explain to the potential participant that they are being scheduled for a standby appointment in the event that someone does not show up for a regularly scheduled appointment.

4) Ask the potential participant to call or return to the field site to see whether their standby appointment time has become available and they can be interviewed.

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

5 Seeds

5.1 Overview

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

5.2 Identifying and Recruiting Seeds

Members of the Community Advisory Board and key informants consulted during formative assessment can be the starting point for identifying and recruiting seeds. These stakeholders serve as "cultural experts," providing insight into the characteristics, behaviors, and social networks of trans women in the project area. Examples of stakeholders include community leaders, outreach workers, staff from organizations that provide services to trans women, and trans women. Enlisting the assistance of a diverse group of stakeholders will help project areas identify a diverse group of seeds.

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

- Have a gender identity of woman or trans woman
- Have been assigned a male or intersex sex at birth
- Be 18 years of age or older
- Live in the participating MSA or Division
- Not have previously participated in NHBS-Trans
- Be able to complete the interview in English or Spanish
- Identify race/ethnicity as Black or Hispanic/Latina*

*Seeds must identify as Black or Hispanic/Latina, however, this is not required of general participants.

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

If acceptable, locally allowable, and approved by the CDC project officer, potential seeds may be given the opportunity to provide a phone number to schedule appointments. If contact information (phone number) is collected, this information will only be available to local staff and will not be submitted to CDC. Participants' contact information will be destroyed prior to data collection so that no survey data can be linked to their phone numbers. Contact information will not be linked to any data and will be maintained in a separate file from any data collection instruments. Phone numbers must be collected directly from the potential seed; phone numbers cannot be obtained from a key informant or any other third party.

Seeds may be recruited directly by project staff during outreach activities, or alternatively, stakeholders who are trans women could serve as seeds. Seeds should be identified through a variety of sources since multiple seeds from the same source would likely be members of the same peer network (the group of people that a person knows in the project area). Ideally, seeds should ***not*** know one another.

We recommend that project areas do not use members of the Community Advisory Board (CAB) as seeds for NHBS-Trans. Although some CAB members may have characteristics we regard as ideal for seeds in RDS, this recommendation is made to reduce potential strain on the relationship between the CAB members and the health department and/or supporting subcontractors. However, there is no issue if a CAB member is recruited to participate in NHBS-Trans through members of their network, provided the project area is able to ensure that they can be interviewed by someone they do not know. CAB members may also provide support to the project through the identification and referral of other members of the community 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 R**). Without revealing the eligibility criteria, staff should also make it clear to potential seeds that their participation is not guaranteed. In prior RDS cycles, staff told potential seeds that a computer would be used to ask them some background questions and then the computer would determine whether they had been selected to participate in the survey.

5.2a Characteristics of seeds

The ideal seed is someone who is motivated to recruit, has a large peer network, and is well respected in the community. These characteristics increase the likelihood that the seed will be able to recruit other individuals to participate in the survey. Moreover, seeds should be diverse with respect to factors such as age, race/ethnicity, geography, and any other factors that may create more insular peer networks. For example, if younger people

do not interact with older people in a project area, cross-recruitment between these groups would be very limited or non-existent. Accordingly, the project area should select some younger seeds and some older seeds to ensure that both sub-populations are represented. Similarly, if trans women who are black do not interact with trans women who are Hispanic, the project area should select some seeds who are black and some who are Hispanic. Nonetheless, selecting seeds by demographic characteristics alone will not guarantee access to diverse peer networks. For example, if a black seed is a member of a Hispanic peer network, they may produce a recruitment chain that is racially and ethnically similar to a chain produced by a Hispanic seed.

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

5.2b Number of seeds

There is no specific number of initial seeds that will guarantee project areas reach the sample goal of 200 eligible trans women. However, based on prior RDS cycles, project areas should select 5-10 seeds to initiate the recruitment process. To determine the most appropriate number of seeds, project areas should consider how closely sub-populations of trans women are networked in their local community. If two or more sub-populations are ***not*** closely networked, project areas will need to select a small number of seeds (2-3) from each of the sub-populations (see **Chapter 4** of this manual for a description of ways to focus on specific sub-populations using field sites). On the other hand, if two or more sub-populations are closely networked, a small number of seeds from any of the closely-networked sub-populations will be sufficient to start recruitment.

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

5.2c Selecting additional seeds

If the initial seeds do not recruit participants or if enrollment is halted because all the recruitment chains have "dried up" (i.e., stopped recruiting), then additional seeds will need to be selected. With RDS, seeds do not all have to be chosen at the same time or at the beginning of data collection. Before selecting additional seeds, project areas should first conduct ongoing formative assessment to determine if there are any barriers to survey participation that have caused recruitment to stall. Please see **Section 10.4** of this manual for additional information on how to assess barriers to participation. Project

areas should note that decisions about recruiting more seeds must be made in consultation with their CDC project officer.

5.3 Assessing Seeds

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

- **Connected to many other people in the community:** A good seed will know many other trans women in the project area. If one imagines a peer 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 charismatic, influential, or considered leaders within their circle of friends or associates will make effective seeds since they can persuade people to participate in the survey and to recruit others. A good seed is someone who others in the community come to for information or advice.
- **Communicates well orally:** Seeds should be able to express themselves clearly when engaged in a conversation; this will give an indication of their ability to explain the project to others.

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

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

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

5.4 Screening and Interviewing Seeds

If a potential seed satisfies the assessment criteria, they should be referred for eligibility screening using a referral card (see **Section 5.5** below). Project areas should use the referral card to make an appointment to screen the potential seed at one of their field sites or, if they are screening the potential seed in the field where they were recruited, they should use the pre-printed number on the referral card as the survey ID. If a potential seed is screened and found to be eligible, they 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 area does not screen potential seeds in the field (see **Section 5.4b** below) or if a potential seed is not available to be screened when they are approached, the project area should make an appointment to screen and interview the potential seed at a field site at a mutually convenient time. Project staff who are recruiting seeds in the field should maintain a list of possible appointment dates and times or they should call the staff at the field site to schedule 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., Wednesday, June 1, 2016 at 1:00 pm). The day, date, and time of the appointment should also be recorded in an appointment book or log, along with the survey ID (pre-printed number on the referral card).

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

5.4b Screening and interviewing in the field

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

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

5.5 Referral Cards

Referral cards serve as both appointment cards and coupons for seeds. They are given to seeds when they are scheduled for an appointment to be screened at a field site or when they are screened in the field at the time of recruitment. Each referral card should have a pre-printed number on it. Referral card numbers must be ***unique*** and ***sequential***. They should be 4-digits long and range from 0700 to 0888. This range is provided so as not to overlap with seed numbers for NHBS-HET5. Project areas 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 areas 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 areas only use numbers that begin with a "9" for practice interviews, the NHBS Data Coordinating Center (DCC) will be able to easily identify any practice interviews that are inadvertently included in the QDS™ Warehouse.

5.5a Making referral cards

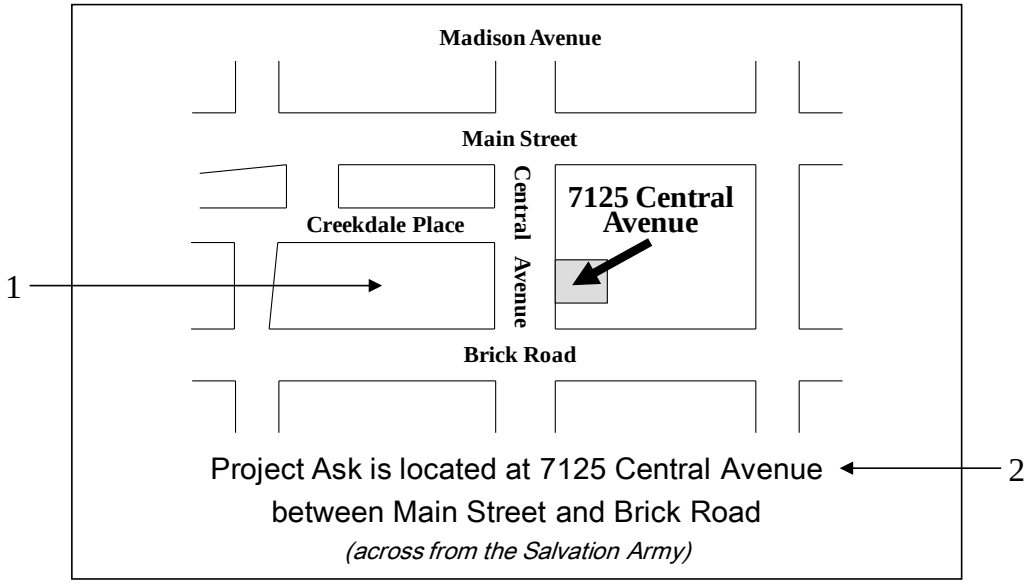
Project areas may have their referral cards professionally printed or they may make the cards themselves by following the instructions in **Appendix T**. Referral cards may be designed however a project area wishes, but they must contain specific information on their front and back as illustrated in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

Figure 5.1 – Example of the front of a referral card

1. Referral card number ranging from 0701 to 0888.
2. Name of the local NHBS project.
3. Space to record the day, date, and time of the potential seed's screening appointment.
4. Address of the field site.
5. Phone number to call for project information or to reschedule an appointment.
6. ***Optional:*** Space to record an expiration date.

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

Figure 5.2 – Example of the back of a referral card



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

During formative assessment, please evaluate the inclusion of terms such as "HIV," "AIDS" or "Trans" on the referral card to ensure acceptability by the community. It is a good idea to share draft versions of the referral card with your CAB for their review and approval.

6 Coupons

6.1 Overview

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

6.2 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 7001 to 8888. This range is provided so as not to overlap with coupons numbers for NHBS-HET5. Project areas should not use numbers less than 7001 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 areas 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 areas only use numbers that begin with a "9" for practice interviews, the NHBS Data Coordinating Center (DCC) will be able to easily identify any practice interviews that are inadvertently included in the QDS™ Warehouse.

6.3 Coupon Options

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

6.3a Number of coupons distributed

Project areas may give up to 5 coupons to each participant who completes the survey and agrees to recruit others (see Chapter 4 of the *NHBS-Trans Model Surveillance Protocol*). The number of coupons given to each recruiter will vary from project area to project area 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 area must give out to ensure that enrollment does not decrease with successive recruitment waves and eventually die out. During previous RDS cycles, project areas found that giving 2 or 3 coupons to each recruiter was usually sufficient for enrollment to progress successfully. Giving more coupons than this is likely to negatively impact data quality, as well as any RDS analyses performed on the data. Nevertheless, sites may want to give the maximum of 5 coupons to seeds, and then reduce the number of coupons given to subsequent participants. Since recruiting seeds requires a considerable investment of time and effort, giving the maximum number of coupons to seeds will optimize the chance that they produce recruitment chains. Additionally, previous NHBS and other RDS studies have found recruitment can be slow to start when the population of interest is not familiar with RDS.

Once steady recruitment is established (i.e. the field sites are conducting interviews at near full capacity) in the entire population or a subset of it, the number of coupons given or given to that subset can be reduced, with project officer approval. If the field staff become overwhelmed with recruits, many recruits would be denied the opportunity to participate in the project. Not only would this undermine the project's credibility in the community, but it would also increase the non-response bias in the sample. A large pool of recruits waiting to enroll could also diminish the effectiveness of differential coupon distribution, whereby different numbers of coupons are given to recruiters from under- and overrepresented sub-populations in order to adjust their enrollment (see below). Lastly, distributing too many coupons to each recruiter may increase the design effect, or variance, in the sample and it could prevent recruitment chains from growing long enough for the sample to reach equilibrium, an essential condition of the RDS method (see **Section 1.4c** of this manual).

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

If participation by a specific sub-population is less than what is expected based on formative assessment, project areas can increase the number of coupons given to recruiters from the underrepresented sub-population to improve their enrollment. Likewise, to help prevent the sample from becoming biased if a specific sub-population starts to dominate enrollment, project areas can decrease the number of coupons given to

recruiters from that sub-population or stop giving coupons to them altogether. As mentioned above, this is referred to as differential coupon distribution. Differential coupon distribution is a drastic action, however, and should only be used when the sample would not represent those sub-populations of greatest importance to the local HIV epidemic without intervention. Before increasing the number of coupons given to a select sub-population, project areas must first conduct ongoing formative assessment to determine why participation by that sub-population is low and they must address any recruitment or participation barriers identified (see **Section 10.4** of this manual). If these actions do not improve enrollment by the underrepresented sub-population, project areas may then distribute more coupons to them. The under- or overrepresentation of a sub-population often requires immediate intervention. Accordingly, project areas should discuss any potential recruitment problems with their CDC project officer as soon as possible to prevent them from escalating into irreversible recruitment problems.

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

6.3b Coupon activation dates

A coupon activation date is a date when coupons become valid for participation in the project. On or after the coupon activation date, a potential participant may bring their coupon to one of the field sites to begin the check-in process. Project areas should decide whether 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, many project areas set an activation date that was one day after the coupon was distributed.

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

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

Changing activation dates

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

6.3c Coupon expiration dates

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

Changing expiration dates

As with activation dates, project areas may change the interval before their coupons 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

areas should discuss any proposed changes to their coupon expiration dates with their CDC project officer and obtain the project officer's approval for the change.

6.3d Photo coupons

Photo coupons are photographs of the fronts of paper coupons that participants can send to their recruits electronically (see **Figure 6.1**). Project areas have the option of allowing participants to use photo coupons in addition to paper coupons. Project areas choosing to permit photo coupons should explain this option to participants after they have been given their paper coupons. Participants would then be able to distribute their coupons either by handing out paper copies or by sending photo copies. Instructions for using the photo coupons can be incorporated into the recruiter training script (**Appendix R**) or talking points (**Appendix S**).

Figure 6.1 – Example of a photo coupon

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

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

Directions to the field site or other information normally found on the back of a paper coupon could be included in the message as well (alternatively, the participant could include a photograph of the back of the paper coupon). Only one coupon should be shown in each photograph and the coupon number must be clearly displayed. No participants should appear in the photographs. To ensure that participants take the photographs correctly, project sites could have the participants take a practice photograph at the field site or have them take all their photographs there. Because participants could

send the same photo coupon to multiple recruits, project sites must accept all coupons on a first come, first served basis. Thus, for each coupon number, the first person who checks in with that number is the only one who can participate in the survey.

6.4 Making Coupons

Coupons can be professionally printed or project areas can make the coupons themselves by following the instructions in **Appendix T**. Coupons may be designed however a project area wishes, but they must contain specific information on the front and back as illustrated in **Figures 6.1** and **6.2**. To reduce the likelihood that recruiters sell their coupons to potential participants, project areas may choose to include the phrase "Not for Sale" on their coupons. In addition, project areas located in cities that are in close proximity to one another should share their coupon designs and ensure that they are sufficiently different. This will help alleviate participant confusion if coupons from a neighboring project area become introduced locally. Project areas must also ensure that their NHBS-Trans coupons differ from HET5 project coupons to make it clear that they are for two different projects.

Figure 6.1 – Example of the front of a coupon

1. Coupon number ranging from 7001 to 8888.
2. Name of the local NHBS project.
3. Incentive type and amount for participants completing the survey.
4. Phone number to call for project information and if applicable, to schedule appointments. It is best to have a toll-free number because of the likely disadvantaged economic status of many participants.
5. Days and hours of field site operations.
6. Address of the field site.

7. Project logo or some other security feature, like a hologram or barcode.
8. ***Optional:*** Space to record an activation date.
9. Space to record an expiration date.

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

Figure 6.2 – Example of the back of a coupon

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

During formative assessment, please evaluate the inclusion of terms such as "HIV," "AIDS" or "Trans" on the coupons to ensure acceptability by the community. It is a good idea to share draft versions of the coupon with your CAB for their review and approval.

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

6.5 Coupon Tracking System

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

6.5a Tracking coupons distributed

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

6.5b Tracking coupons returned

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

7 Check-in, Interviewing, and Check-out

7.1 Overview

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

7.2 Participant Information and Tracking

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

7.2a Coupon Manager Program

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

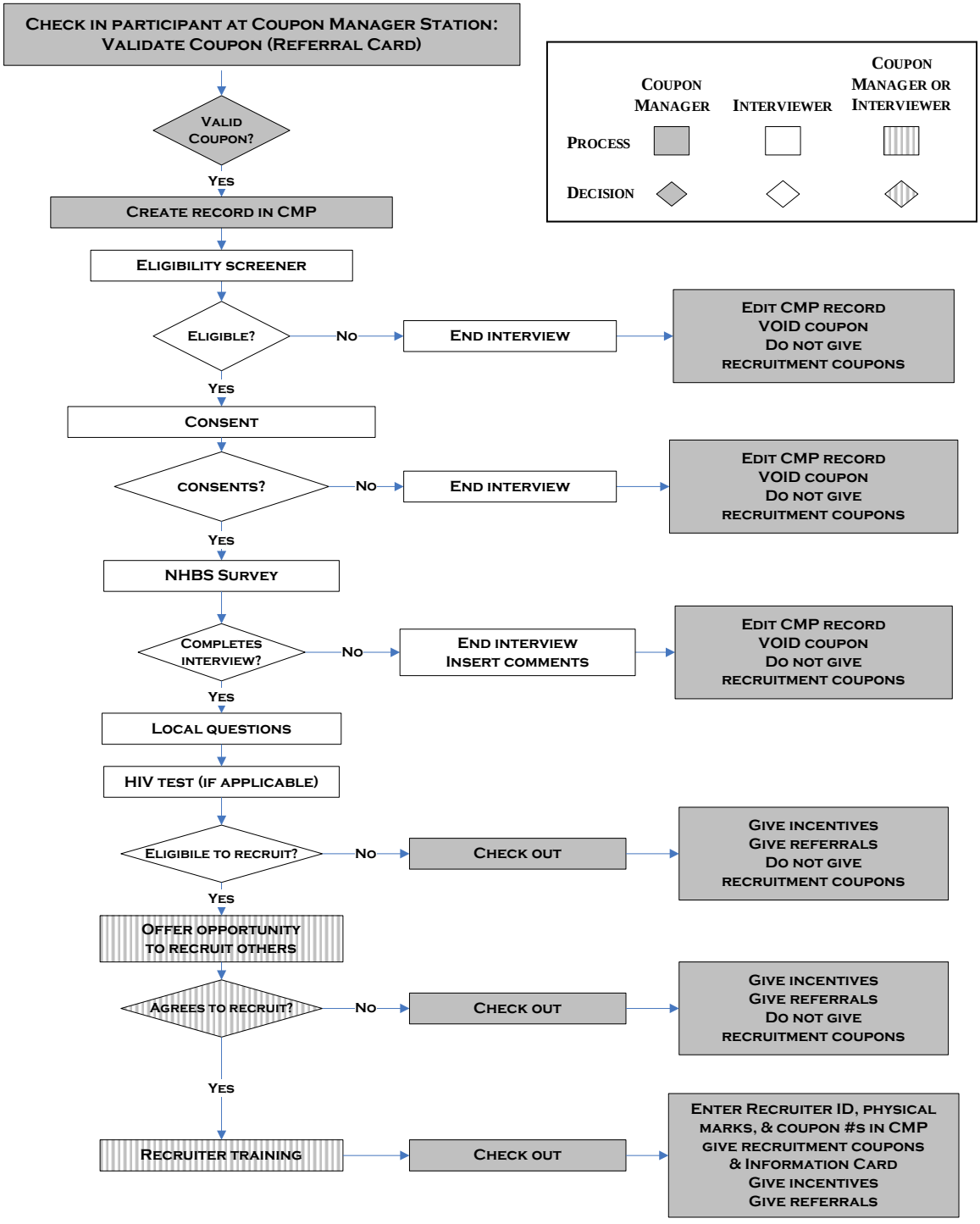
1) **Link recruiters with their recruits:** Each participant's data are linked to that of their recruits by their coupon numbers. This link is necessary to monitor the growth of recruitment chains and to conduct RDS analysis.

2) **Manage recruiter rewards:** The CMP tracks the rewards owed to participants for successfully recruiting others and ensures that participants are not paid for recruiting those who are not eligible or do not complete the interview.

3) **Collect responses to the *Recruiter Questions*:** The *Recruiter Questions* are used to measure non-response bias by asking about the demographic characteristics of individuals who refused to take coupons from the participant and the reasons why they refused. The CMP displays these questions when a participant returns to claim their rewards for recruiting others. The *Recruiter Questions* will be discussed further in **Section 8.3** of this manual.

Detailed instructions on using the CMP can be found in the *Coupon Manager Training Manual* on the NHBS Data Coordinating Center (DCC) data portal. The CMP should be installed on a laptop or desktop computer and kept at the "coupon manager station," an area of the field site designated for checking in and checking out.

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



participants. A staff member should be assigned to operate the CMP and manage all operational activities at the coupon manager station; this person is referred to as the "coupon manager." The coupon manager station should be stocked with all supplies

needed for check-in and check-out activities, including an appointment book (if used), a CMP Log (see below), coupons (see Chapter 6), and incentives (if given by the coupon manager).

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

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

Since all data collection software can experience errors and data loss, project areas should keep a CMP log, which is a hard copy of pertinent information entered into the CMP, such as the date of the interview, the participant's coupon (or referral card) number, the interviewer ID, and the numbers on the recruitment coupons given to the participant. Please see **Appendix J** for a model CMP Log. Furthermore, at the end of each day of field site operations, project areas should back up their CMP database to a secure location, like an external drive or network.

7.2b Participant Tracking Form

Project staff should use the Participant Tracking Form to document and track the operational activities completed by each participant. The form should also be used to record HIV testing information and data edits for subsequent entry into the HIV Test Results Log and the Data Error Log on the DCC data portal. If the coupon manager collects this information during check-in, it can be recorded on the Participant Tracking Form for later entry by the interviewer.

The Participant Tracking Form is helpful because it provides a hard copy of completed activities in the event of data loss, facilitates communication among project staff, and assists with data management. To tailor the form for local operations, project areas may add any additional fields they consider necessary.

7.3 Check-in

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

7.3a Validate coupon or referral card

The coupon manager should first greet the potential participant and ask them for their coupon (or referral card). 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 them to return after the activation date or on a scheduled appointment date.

- ***If the coupon has expired***, the coupon manager should not return the coupon to the person. Instead, the coupon manager should search the CMP for the coupon number and once located, change the status of the coupon to "Expired" if the CMP has not already changed the status automatically. The coupon manager should then mark the coupon *"EXPIRED"* and file it in the weekly folder or envelope. The coupon manager should explain to the person that their coupon has expired:

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

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

- ***If a participant comes in with a photo coupon that has already been used***, advise them to follow up with their recruiter to see if they have any unused coupons left they can share with them.

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***, they cannot be interviewed under any circumstances. The coupon manager should make this clear to the person:

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

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

  > *"I'm sorry, we won't be able to see you today. Can we reschedule your appointment for another day?"*

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

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

7.3b Create record in the CMP

After validating the potential participant's coupon (or referral card), the coupon manager should create a record in the CMP for that person. To create the record, the coupon manager should first change the coupon status in the CMP from "Outstanding" to "Submitted." The coupon manager should then enter the following information in the CMP:

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

- **'Photo' or 'Paper' coupon:** Indicate whether the potential participant's coupon is a 'photo' or 'paper' coupon in the CMP.

- **Survey ID:** The potential participant's survey ID will be the same as their 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 Fill out Participant Tracking Form

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

- Interviewer ID
- Date
- Survey ID
- Whether or not the participant is a seed
- Field Site ID

7.3d Escort participant to interviewer

Once the coupon manager has checked in the participant, they should introduce the participant to the assigned interviewer. They should also give the Participant Tracking Form and coupon (or referral card) to the interviewer. If the interviewer knows the person, the coupon manager should assign a different interviewer. In rare cases when this is not possible, staff should schedule the interview for a later time/date with another interviewer.

7.4 NHBS Interview

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

The NHBS interview is composed of three main sections: the eligibility screener, the consent, and the survey. The interview is conducted using a portable computer and the entire process takes approximately 1 hour to complete. All interviews must be conducted in 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 and Trans cycle-specific eligibility criteria. The portable computer will automatically determine whether someone is eligible to participate based on the following criteria:

General NHBS eligibility:

- Is 18 years of age or older
- Has not previously participated in the current project cycle
- Lives in the participating MSA or Division
- Is able to complete the interview in English or Spanish
- Is able to provide informed consent

Trans cycle-specific eligibility:

- Presents a valid NHBS-Trans coupon
- Assigned "male" or "intersex" at birth:
    - For those assigned male-at-birth: gender identity of "woman," "trans woman," or "a gender not listed" (other gender identity)
    - For those assigned intersex-at-birth: gender identity of "trans woman"

Individuals who do not meet one or more of the eligibility criteria will be told "the computer has not selected you to participate in the health survey." If someone is ineligible, the interviewer should end the interview and thank the person for their time. After the person leaves the field site, the interviewer should tell the coupon manager that the person was ineligible and give them the person's coupon. The coupon manager should indicate in the person's CMP record that their recruiter is not owed a reward, mark the coupon *"USED,"* and file the coupon in the weekly folder or envelope.

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

Previous participants

The coupon manager can prohibit previous participants from enrolling again if they recognize 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 indicate that they are a known previous participant during eligibility screening. The portable computer will then automatically make the person ineligible.

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

Intoxicated participants

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

Participants outside the eligible age range

If project staff suspect that a potential participant is outside the eligible age range (i.e., the participant is less than 18 years old), they should alert the field supervisor of their concerns. The field supervisor and the project staff should then discuss whether or not the person appears to be too young to participate in NHBS. If the field supervisor and the project staff agree that the person appears to be less than 18 years old, the field supervisor should tell the person's interviewer to indicate that they are "thought to be too young" during eligibility screening. The portable computer will then automatically make the person ineligible.

Only the field supervisor, in consultation with project staff, can make the final determination that a person is outside the eligible age range; project staff should not decide this on their own. If a participant is determined ineligible for the survey because they are outside the eligible age range, staff can still offer to connect them with services for trans women as applicable.

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

7.4b Consent

The interviewer should read the consent form to each eligible participant and answer any questions the participant may have. Depending on local Institutional Review Board (IRB) requirements, project areas may choose to have the interviewer paraphrase the information in the consent form instead of reading it verbatim. If the local IRB requires informed consent to be obtained before a potential participant is screened for eligibility, project areas 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 areas to maintain written documentation of consent). Participants can consent to participate in either: 1) the NHBS survey, 2) the NHBS survey and an HIV test, 3) the NHBS survey and STI testing (if applicable), or 4) the NHBS survey, HIV test, and STI testing (if

applicable). If applicable, participants can also consent to other laboratory tests offered locally or to have their blood stored locally for HIV incidence testing and other tests. Further details of the consent process are provided in the *NHBS-Trans 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 a person chooses ***not*** to participate in the survey, the interviewer should end the interview and thank the person for their 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 indicate in the person's CMP record that their recruiter is not owed a reward, mark the coupon *"USED,"* and file the coupon in the weekly folder or envelope.

Participants who change their mind about HIV testing

Participants who initially decline HIV testing will have another opportunity to consent to testing at the end of the core questionnaire. This will give the participant a second chance to consent to HIV testing if they initially declined testing but then changed their mind during the survey.

7.4c NHBS survey

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

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

Network questions

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

- **Participants know one another as members of the target population:** The first *Network Question* asks the participant to classify their relationship to the person who gave them their recruitment coupon to determine whether the participant and the recruiter know one another or are "strangers." Recruitment by a stranger violates the RDS assumption that "participants know one another."

- **Participants can accurately report their personal network size:** The second *Network Question* asks the participant to estimate the number of transgender women they know and have interacted with in the past 30 days. During RDS analysis, participants with smaller networks are given more weight than participants with larger networks to compensate for their having a lower probability of being recruited (participants with smaller networks know fewer people who could potentially recruit them).

Core questionnaire

The core questionnaire consists of several sections: demographics, healthcare access, gender identity, medical gender affirmation, other injections, sexual behavior, alcohol and drug use, drug treatment, HIV testing experiences, mental health, discrimination, abuse and harassment, incarceration, and assessment of prevention activities. At the end of the core questionnaire (and before the start of the local questions), the interviewer will be instructed to record their confidence in the validity of the participant's responses using the following scale: "confident," "some doubts," or "not confident at all." Validity refers to whether the participant understood the questions and answered them truthfully and accurately. If an interviewer records that they are "not confident at all" in a participant's responses, then that participant's interview data will not be included in the national NHBS dataset and the participant will not be eligible to recruit others.

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

Ending an interview early

If a participant does not want to continue the survey, is too intoxicated to continue, or is behaving inappropriately, the interviewer should end the interview and record the reason for stopping the interview in the notes section of the Participant Tracking Form. The interviewer should then escort the participant to the coupon manager station and return the participant's coupon to the coupon manager. The coupon manager should indicate in the participant's CMP record that their recruiter is not owed a reward, mark the coupon *"USED,"* and file the coupon in the weekly folder or envelope. A project area's IRB may require that the recruiter receive a reward if the participant was eligible and started the interview, but did not complete it. In this case, the coupon manager should indicate in the participant's CMP record that their recruiter is owed a reward. The participant should not be paid an interview incentive and they should not be given coupons to recruit

others. Project areas that are required to provide an interview incentive by their local IRB may do so, but they ***cannot*** distribute recruiter coupons to the participant.

7.5 Data Error Log

The Data Error Log on the DCC data portal provides documentation of any corrections that need to be made to the data (see the *NHBS-IDU5 Data Management Training Manual*). If mistakes are made or problems occur during an interview, the interviewer should use the data edits section of the Participant Tracking Form to record the name of the problematic variable, the incorrect value (old value) for the variable, and the correct value (new value) for the variable. At the end of each day, the field supervisor should collect all the Participant Tracking Forms, review the data edits with the interviewers, and make sure the information on the forms is complete. If the same errors are made repeatedly, additional training should be provided to the interviewers to help them avoid future occurrences.

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

7.6 HIV Testing and Referrals

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

7.6a Counseling and testing

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

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

7.6b Referrals to HIV care and services

All participants who test positive for HIV should be referred to appropriate medical care and HIV case management services at the time they receive their test results (see **Section 9.8** of this manual). Project areas should focus referrals on providers and agencies who are well-received by members of the trans communities in their local areas, as identified during formative assessment.

7.6c Referrals to other services

Based on their formative assessment, project areas should identify other health care and social service providers appropriate for trans women in the community. Project areas should maintain a list of the names of these providers and their contact information so they can readily make referrals.

These services can include:

- STI testing and treatment
- Agencies that offer free HIV tests
- Trans-friendly health clinics
- Mental health services
- Housing services/shelters
- Syringe exchange (if available)
- Substance abuse services
- Domestic violence shelters and programs
- Rape/sexual assault crisis lines
- Skills training/job seeking
- Services for trans women (if available)
- Legal services
- Assistance with accessing ID cards and health insurance
- Other social service organizations that provide financial assistance or assistance with food, clothing, utilities, or employment

If HIV testing and counseling is done by a different staff member than the interviewer, the interviewer should discuss referrals to services at the end of the interview. This is because the participant may have disclosed information in the interview that indicates need for referrals, and thus the interviewer is best placed to discuss those referrals. Referrals offered, however, should not be limited to information disclosed during the interview. The HIV tester and coupon manager should also be prepared to discuss referrals if additional information is disclosed during HIV test counseling or check-out.

We recommend that staff provide all participants with a list of referrals, but are also proactive in helping participants use the referrals. Staff should also provide participants a private room to make phone calls to service providers**. Any phone call to a service that requires the participant to provide personally identifiable information (PII) to the service provider must be placed after all NHBS operations have ended, including checkout and payment.** To ensure that any referrals discussed with and agreed to by the participant at the end of the interview or during HIV testing and counseling are made, we recommend that staff discreetly write this information on the Participant Tracking Form.

Project areas can also provide participants with prevention materials such as condoms, lubricants, and hygiene kits- in adequate quantities to meet participants' needs. Staff can also emphasize that while the participant may not need services, they may know of others who do.

7.7 Recruiter Training

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

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. The interviewer should record this information on the Participant Tracking Form. 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").

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.

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

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

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

7.7c Conducting recruiter training

During recruiter training, project areas should explain to participants how to properly recruit other trans women for the project and how to obtain their recruiter rewards. To motivate recruiters and promote community buy-in, project areas should also underscore the benefits of the project to participants and the community. Recruiter training is key to the success of RDS. If training is incomplete or unclear, recruiters will be less effective and recruitment chains may not grow. A model recruiter training script is included in **Appendix R**, but project areas may prefer to use talking points instead (see **Appendix S**). 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 people they know and ***not*** strangers. One of the assumptions of RDS is that participants know one another as members of the target population.

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

7.8 Check-out

With RDS, 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 them to the coupon manager station, and the staff member should relay the following information to the coupon manager through the Participant Tracking Form:

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

7.8b Coupon manager duties

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

Editing the CMP record

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

- ***If the participant was not eligible, did not consent to the survey, or did not complete the survey***, the coupon manager should indicate in the participant's CMP record that their recruiter is not owed a reward, mark the coupon

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

- ***If the participant completed the survey but did not agree to recruit others***, the coupon manager should indicate in the participant's CMP record that their recruiter is owed a reward, mark the participant's coupon "*USED,*" and file the coupon in the weekly folder or envelope.

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

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

  Step 2) The coupon manager should create a recruiter ID for the participant based on the questions in **Table 7.1** and enter the ID in the participant's CMP record. Since the smallest data entry error can make participant identification difficult or impossible, the coupon manager should be extremely careful entering recruiter IDs in the CMP and 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 any distinguishing "physical marks," like tattoos or birthmarks, that could be used for future identification (see **Table 7.2** for instructions on collecting and recording physical marks). The coupon manager 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 of the assigned coupons in the participant's CMP record.

Step 5) If necessary, the coupon manager can add comments to the participant's CMP record that could help with participant identification or project management.

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

Table 7.1 – Recruiter ID questions

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

Project areas familiar with core RDS cycles of NHBS (IDU and HET) may notice one less question used to create the Recruiter ID. A gender marker question is not included in the Recruiter ID for NHBS-Trans. Gender marker is not included due to the fluid nature of gender identity and the possibility that participants may have multiple gender identities. However, the CMP requires a 10 character Recruiter ID. For NHBS-Trans participants, CMP will automatically insert a "T" between the characters for questions 5 and 6. This is not intended to suggest that all NHBS-Trans participants have a transgender gender identity. This is simply a back-end solution to a software issue that was identified in the development of CMP. Participants do not need to provide a gender identity when creating a Recruiter ID.

Distributing coupons

If the participant agrees to recruit others, the coupon manager should give them coupons and reiterate that they will only receive rewards for the people they recruit who are selected and complete the survey. The coupon manager should also give the participant an information card with the hours, location(s), and phone number of the field site(s). Participants can call the field site to see if they are owed any recruiter rewards (the coupon manager can use the participant's survey ID or recruiter ID to locate their CMP record).

Table 7.2 – Collecting and recording physical marks

The coupon manger should explain to the participant why it is important to collect their physical marks:

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

Project areas should develop a protocol for collecting physical marks in a systematic manner. For example, the coupon manager could start with the face, then check the neck, the right arm, and the left arm. The coupon manager should also ask if the participant has any physical marks in other areas of their body that are not readily visible. However, the coupon manager should only examine and note physical marks that are in areas of the body that are not considered "private." For example, it would be appropriate to view a tattoo on a participant's ankle, but not on their 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 CMP, the coupon manager should describe the physical mark in as much detail as possible, noting its color(s), shape, and location on the body. For example, "Red 'I ♥ Terri Lou' tattoo on inner left forearm."

Please see **Appendix Q** for a model information card and **Appendix T** for instructions on how to create the cards. Project areas should also keep track of the coupons given out using the CMP Log (**Appendix J**).

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

Reinforcing recruiter training

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

> *"Can you explain to me what you need to do with these coupons?"*
>
> *"Can you tell me who you need to give these coupons to?"*

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

Giving out incentives

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

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

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

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

Local project areas are free to determine incentives based on standards in their local communities. Furthermore, if project areas are prohibited from providing cash incentives to participants, they may provide an alternative form of remuneration like a gift card or a gift check. Any alternative form of remuneration must protect participant anonymity (e.g., participant names cannot be collected or recorded) and it must have an intrinsic value to members of the community (e.g., gift cards should only be from stores that are locally accessible and well-regarded within the community). If your project area is unable to provide cash incentives, you must demonstrate the following (in **Appendix A** – Operations Checklist) and obtain project officer approval for any non-cash incentives:

1) Cash incentives are not allowed in your project area.
2) The incentive provided is desirable to trans women.
3) The incentive will not bias the sample. For example, it is not more desirable to certain racial/ethnic or age groups of trans women than others.

When a prospective participant is found to be ineligible, project areas may wish to provide a small thank you gift, such as bus or subway fare. In addition, project areas that have local funds available (i.e., funds that do not come from the NHBS cooperative agreement) may compensate participants who return for their final HIV or STI test results. Project areas should specify the amount of compensation in their consent form and they must obtain approval from their CDC project officer.

Providing prevention materials and offering referrals

The coupon manager should review the Participant Tracking Form for any referrals that may have come up during the interview and need to be made after NHBS operations have ended. These include referrals to services that require the participant to provide PII.

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

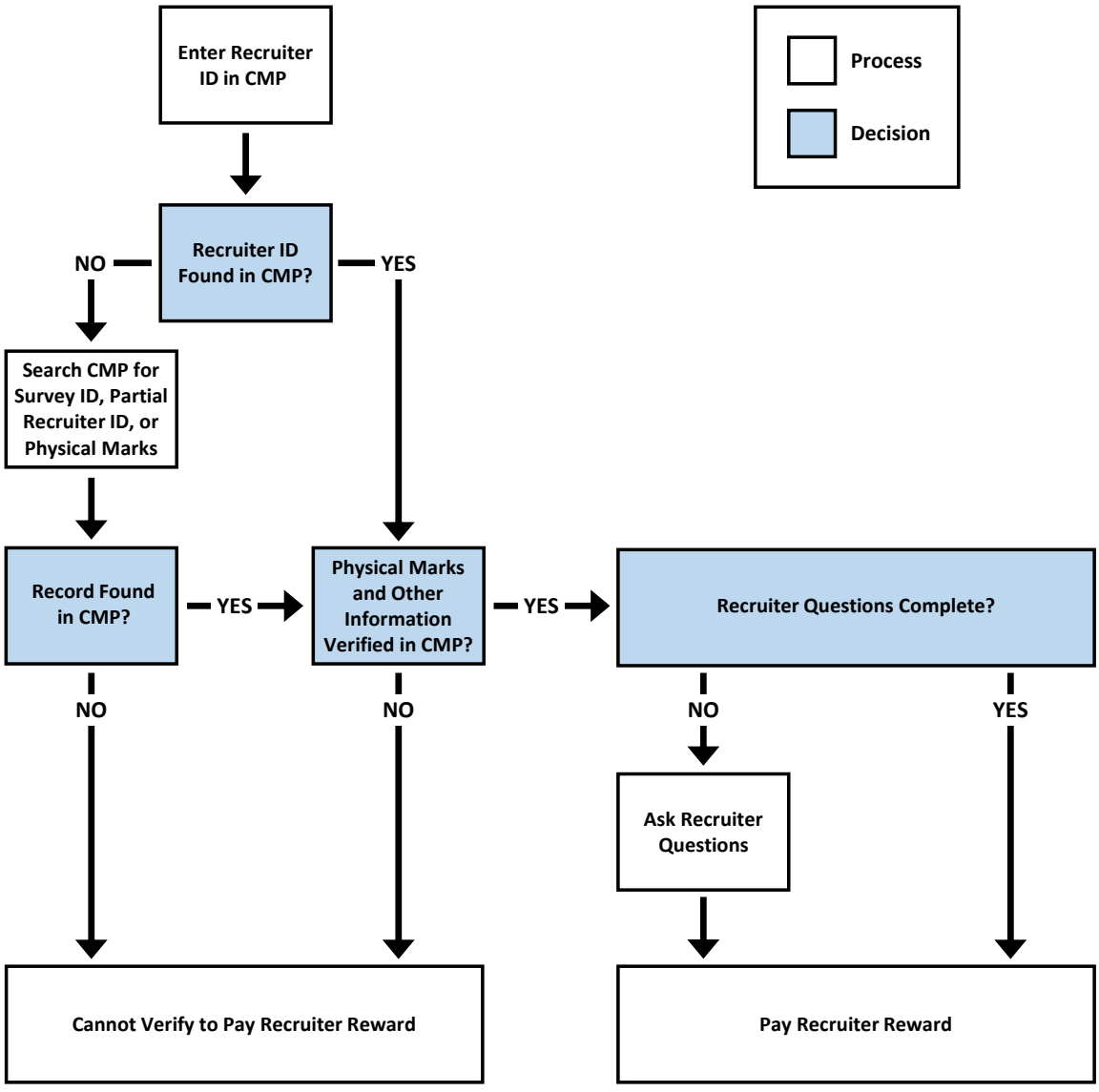
Participants in need of health care or social services should be offered referrals to the appropriate providers in the community. Based on their formative assessment, project areas should identify those health care and social service providers most commonly used by trans women in their community. Project areas should maintain a list of the names of these providers and their contact information so that they can readily make any necessary referrals.

8 Recruiter Reward Process

8.1 Overview

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

Figure 8.1 – *Recruiter Questions* and recruiter reward process



8.2 Verify Participant's Identity

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

8.2a Unable to locate recruiter ID in the CMP

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

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

When a recruiter ID cannot be found in the CMP, the coupon manager should first try to re-create the recruiter ID by asking the questions again. Showing the participant a list of the questions can improve accuracy and is often helpful. If the record still cannot be located, the coupon manager should search the CMP for the participant's survey ID (coupon number) or a partial recruiter ID that contains information the participant is most likely to remember, such as their month of birth, year of birth, and race/ethnicity. For example, instead of using the full recruiter ID "JOMJ1075TW" to search for the participant's record, the coupon manager could just use "1075TW." 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 their date of interview, month and year of birth, race/ethnicity, and physical marks. In addition, if the recruiter ID was initially entered in the CMP incorrectly, the coupon manager should correct it.

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

8.3 Ask Recruiter Questions

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

Table 8.1 – *Recruiter Questions*

How many of the coupons did you give out?
Has anyone refused the coupons?
How many people refused the coupons?
How many of those who refused coupons were Hispanic or Latino?
What is the race of those who refused coupons? That is, how many were American Indian or Alaska Native, Asian, Black or African-American, Native Hawaiian or Pacific Islander, or White?
Which of the following are reasons that people who refused gave you about why they did not take a coupon? *(Read each one, check all that apply)* • They already participated in the survey • They didn't have time • They didn't live in the area • They didn't trust you (recruiter) • They don't like research/surveys • They didn't want to be identified as Trans • Some other reason (please specify): _____

As long as the status of the *Recruiter Questions* remains "Incomplete," the questions should be asked and the responses confirmed ***every*** time a participant returns to the field site to collect their recruiter rewards or calls the field site to see if they are owed any rewards. When asking the *Recruiter Questions* a subsequent time, the coupon manager should explain that they may be repeating questions they asked before. The coupon manager can help the participant remember their previous responses by telling them what has already been recorded in the CMP. For example, the first time a participant answers the *Recruiter Questions*, they state that they gave out 2 coupons and 1 person refused a coupon. When they return for a second time, the coupon manager could say:

> *"The last time you were here, you said you gave out 2 coupons. Have you given out any more coupons since that time?"*
>
> *"You also said 1 person refused a coupon. Has anyone else refused a coupon?"*

If additional people have refused coupons, the coupon manager should then ask the remainder of the *Recruiter Questions*. Any inconsistencies in the participant's responses should also be clarified. Once the participant has given out all their coupons and answered the *Recruiter Questions*, the status of the *Recruiter Questions* will change to "Complete" and the questions do not need to be asked again.

8.4 Verify and Pay Reward

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

Project areas should consider the following when paying recruiter rewards:

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

9 HIV and Other Testing

9.1 Overview

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

9.2 Testing

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

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

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

Project staff are not able to change the consent variable in the Data Error Log on the NHBS Data Coordinating Center (DCC) data portal. Consent for HIV and other testing can only be recorded in the portable computer.

Project areas 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 areas should also contact their laboratory to find out what types and trade names of tests will be performed on each type of specimen and document this information in the Operations Checklist. Project areas will need this information for entering HIV test results into the HIV Test Results Log on the DCC data portal.

9.2a HIV testing

The purpose of HIV testing is to determine the prevalence of HIV infection among NHBS participants and to describe behavioral risk factors associated with infection. Even participants who 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 areas can choose from a number of HIV testing options, but they must select their testing method, including the test(s) and specimen type(s), before data collection begins. Since data from previous NHBS cycles suggest that blood-based HIV tests have greater sensitivity than oral tests, blood specimens should be used for HIV testing in NHBS 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) are only labeled for use on blood specimens.

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

Rapid HIV testing

Project areas 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 9.8** below). In addition, receipt of a preliminary positive test result may increase a person's likelihood of seeking additional testing or care.

To perform rapid testing, a project area must first obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver (http://www.cms.gov/CLIA/downloads/HowObtainCertificateofWaiver.pdf). Alternatively, project areas may operate under an existing waiver already held by their organization. There are seven rapid tests that are currently CLIA-waived for use in field settings by non-laboratory staff: Alere Determine, Chembio DPP, Chembio SURE CHECK (formerly Clearview COMPLETE), Chembio STAT-PAK (formerly Clearview STAT-PAK), INSTI, OraQuick, and Uni-Gold. The package insert for each of the 7 rapid tests contains specific instructions for conducting that test, as well as instructions for running test controls. The insert lists the materials included in the test kit, required materials that are not included in the kit, specimen collection procedures, and testing requirements. Prior to the start of HIV testing, project staff who are administering tests or overseeing testing activities must carefully read and understand the package insert. They should also have a copy of the insert readily available at each field site for reference. Rapid testing must be conducted in an appropriate environment with respect to temperature and lighting. These requirements can be found in the package insert and should be adhered to at all times. Rapid testing should also be conducted in an area with adequate work space.

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

Before specimen collection begins, the participant's survey ID number should be recorded on the rapid test device. For project areas conducting rapid testing on whole blood specimens collected by fingerstick, some helpful hints for fingerstick blood collection can be found in **Section 9.4b** (below).

During rapid test development, the face of the test device should not be visible to the participant; the test face should be turned away from the participant or it should be covered. Ideally, project areas should conduct rapid testing in an area that is separate from the interview space. This will be less disruptive to the interview and will allow for more accurate reading of the test results. Nevertheless, if project areas must conduct testing in the same space as the interview, they ***cannot*** collect the test specimen before the core questionnaire is completed (they can collect the specimen either between the core and local questionnaires or after both the core and local questionnaires). Furthermore, because counseling cannot be provided before the core questionnaire is completed, test results cannot be disclosed to participants until the end of that section of the survey.

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

example, operations could be set up so that all participants receive incentives and confirmatory testing in the same private area.

Rapid-rapid algorithm

Project sites have the option of conducting a 2-test rapid HIV testing algorithm (rapid-rapid algorithm) which does not require the collection of a confirmatory specimen for laboratory-based testing. With the rapid-rapid algorithm, project areas would screen participants with one rapid test and then confirm reactive test results with a second rapid test. If the first rapid test for participants who self-report being HIV-positive is reactive, the second rapid test does not need to be performed; however, the second rapid test would be performed if the first was non-reactive. All participants with at least 1 reactive rapid test should be referred to care (see **Section 9.8**). As described below, counseling messages for participants who have 2 reactive rapid tests would differ slightly from messages for those who have 2 discordant test results (i.e., the first test is reactive and the second test is non-reactive).

Counseling message for participants with 2 reactive rapid tests:

> *"The result of your second test was also positive, which means you have HIV infection. I'd like to refer you to a health care provider who can do some additional testing and get you enrolled in medical care."*

Counseling message for participants with 2 discordant rapid tests:

> *"The result of your first test was positive, but the result of your second test was negative. Since these 2 tests gave us different results, we can't be sure whether you have HIV infection. I'd like to refer you to a health care provider who can do some additional testing to determine if you have HIV infection and can get you enrolled in medical care if you do."*

Project areas are required to send DBS to the CDC laboratory for all HIV-positive participants who consent to blood storage. This includes participants with at least one reactive rapid test result or all participants who self-report being HIV-positive regardless of their rapid test result.

Project areas using the rapid-rapid algorithm may use any 2 rapid tests that are different, meaning the tests are from different manufacturers or from the same manufacturer but rely on different analytes or methods of detection. The only two tests that have not been determined to be different for the algorithm are the Chembio SURE CHECK and Chembio STAT-PAK. Ideally, a rapid algorithm should start with the most sensitive test, meaning the first test should be one that could detect infection early. That being said, it may be most efficient to choose a rapid test with a shorter run time for the second test to minimize how long the participant has to wait for their test results (**Table 9.1** lists the run times for the current CLIA-waved rapid tests). When deciding which rapid tests to use, project areas should also consider how the methods of the various tests will impact field

operations. Project areas should discuss these logistical considerations with their CDC project officer before choosing which rapid tests to use in the algorithm.

Table 9.1 – Run times for CLIA-waved rapid tests

Trade Name	Time to Test Result
BioLytical INSTI HIV-1/HIV-2 Antibody Test	< 2 minutes
Trinity Biotech Uni-Gold Recombigen HIV-1/2	10 minutes
Chembio SURE CHECK HIV 1/2 Assay *(formerly Clearview COMPLETE)*	15 minutes
Chembio Clearview HIV 1/2 STAT-PAK	15 minutes
Alere Determine HIV-1/2 Ag/Ab Combo Test	20 minutes
Orasure OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	20 minutes
Chembio DPP HIV 1/2	10-25 minutes

Quality assurance for rapid HIV testing

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

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

2) Scheduled supervisor observed counseling and testing sessions to ensure that the HIV test counselor conducts the entire testing process correctly according to protocol instructions. The HIV Counseling and Testing Evaluation Form (**Appendix F**) can be used to document staff performance.

3) External test control results recorded with each new test kit lot or other additional intervals determined by local protocols and the test package insert. It is important

to note that external rapid test controls should be run in the environment in which testing will occur to ensure the tests are working and conditions are appropriate (e.g., overhead lighting). For example, if a project area is doing all the testing in a van, the external controls should be run in the van. A model Rapid Testing Quality Control Log can be found in **Appendix K**.

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

Rapid test results must be read within the timeframe indicated in the package insert for the specific test being used. In addition to monitoring the activities listed above, project areas should develop a system for recording the time the test was started and the time the test result was read. For example, these times could be recorded on the HIV Testing Log or the Participant Tracking Form (**Appendix I**).

A reference guide for Rapid Testing Quality Assurance can be found at http://www.cdc.gov/hiv/pdf/testing_QA_Guidlines.pdf and additional guidance for HIV testing in non-clinical settings can be found at https://www.cdc.gov/hiv/testing/nonclinical/index.html.

9.2b Hepatitis testing

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

Project areas planning on conducting hepatitis testing must discuss their proposed testing method with their CDC project officer and receive approval before specimen collection can begin. **Appendix U** provides additional guidance on testing for HBV and HCV, as well as information on interpreting test results.

9.2c STI testing

Project areas should offer testing for gonorrhea and chlamydia in accordance with the guidance outlined in the *NHBS-Trans Operations Manual – STI Testing Supplement*. Project areas may only opt out of these activities with approval from their CDC project officer and appropriate justification (e.g. local regulations prohibit anonymous STI screening). Because project areas will be sending specimens to a laboratory for testing, no CLIA certificate is needed for the STI component.

Project areas that would like to offer additional, locally funded STI testing must discuss their proposed plans for testing and referral to care with their CDC project officer and they must receive approval before specimen collection can begin.

9.2d Future testing

Project areas should offer to store blood and any other collected specimens at CDC or, if applicable, locally for future testing. Test results will not be returned to participants for any future testing conducted. Project sites should notify their laboratory whenever specimens are to be stored locally for future testing. Participants will be asked to consent to storage of either their blood specimen, their STI test specimen, or both their blood and STI test specimens based on whether they consented to HIV testing, STI testing, or both HIV and STI testing.

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

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

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

9.3 Staffing and Training

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

Project areas that choose to collect blood by venipuncture are required to have a phlebotomist on staff since any person who collects blood via venipuncture must be certified in phlebotomy. Project areas should check their local policies to determine how many hours of phlebotomy training are required for certification. Most states do not have specific phlebotomy regulations. Instead, regulations are developed by the organization

overseeing the blood collection (e.g., health department, clinic, or hospital). Project areas are responsible for ensuring that their staff members' phlebotomy training is current.

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

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

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

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

9.4 Specimen Collection

Specimens for HIV tests can be collected with venipuncture or dried blood spots (DBS).

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

9.4a 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 areas should check with their local laboratory to determine which collection tubes are indicated for the types of tests they will offer. For example, serum "red top" tubes or EDTA "purple top" tubes are commonly used for HIV testing. To ensure an adequate specimen volume for testing, blood collection tubes should be filled completely. If additional tests other than HIV are offered, it may be necessary to collect extra tubes or different types of tubes. It may also be necessary to collect extra tubes if specimens have to be sent to different laboratories.

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

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

To enable the CDC laboratory to distinguish between the same survey ID numbers from different project areas, a 3-letter code indicating the project area must be added to the beginning of the survey ID. The 3-letter codes have been assigned as follows:

Atlanta	**TAT**	New York City	**TNY**
Dallas	**TTX**	Philadelphia	**TPH**
Los Angeles	**TLA**	San Francisco	**TSF**
New Orleans	**TNO**	Seattle	**TSE**

For example, survey ID "2475" from Los Angeles would be labeled as "TLA2475" on the DBS card.

DBS from fingerstick

DBS should be collected with 903 filter paper cards and, to obtain a sufficient quantity of blood, the lancets used for fingersticks should be blades rather than needles (see **Appendix V** for recommended cards and lancets). 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 circulation if possible (an instant hand warmer can be used). To further increase blood circulation, it sometimes helps to massage the whole hand and finger to be stuck, not just the fingertip. While the tester is organizing the specimen collection materials, they can also have the participant open and close ("pump") their hand or squeeze and release a stress ball several times to increase blood circulation. Having the participant hold their hand below the level of their heart before performing the stick increases blood circulation as well.
- 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. The participant's hand should be laid 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 blood collection card.
- Hold the finger downward, below the heart. If necessary, the finger can be massaged at the base or pressure can be applied next to the puncture point to increase blood flow. When massaging the base of the finger, provide intermittent pressure rather than constant pressure; apply pressure in a "squeeze, release, squeeze, release" pattern. Massaging the whole hand is also effective for increasing blood flow.
- A reference guide for fingerstick blood collection can be found in **Appendix W**.

After making the fingerstick, place the blood collection card close to the puncture site but ***DO NOT*** touch it to the puncture site at any time during the collection process.

Approach the first circle and allow a large drop of blood to form on the tip of the finger. Without touching the tip of the finger to the card, allow the large drop of blood to barely touch the card inside the first circle; the filter paper will wick the drop of blood away from the finger. Allow the blood to completely fill the circle before moving on to the next circle. Moving from 1 circle to the next, fill the remaining circles in the same way. Project areas should try to fill all the circles on the cards that will be sent to the CDC laboratory. Those project areas using DBS for laboratory-based HIV testing should check with their local laboratory to find out how many full circles the laboratory will need on its cards. When finished, apply cotton to the puncture site until bleeding stops.

It is very important that a circle be filled completely before moving onto the next circle. If the participant does not bleed for very long and there is only enough blood to fill 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 with the 903 filter paper flap folded back to expose the spots. Nevertheless, since the DBS must be dry before packaging, overnight drying is sometimes required; but the drying time should not exceed 24 hours. The cards can be clipped to test tube racks for drying. If necessary, the racks can be placed in a cardboard box to transport the cards from the field site to the project office for drying and eventual packaging. The cards should remain on the racks until they are dry and ready to be packaged.

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

DBS from blood tubes

Project areas 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 the needed circles on the card have been filled, the card should be dried as described above in the "DBS from fingerstick" section. Project areas should try to fill all

circles on the cards that will be sent to the CDC laboratory. Those project areas using DBS for laboratory-based HIV testing should check with their local laboratory to find out how many full circles the laboratory will need on its cards.

9.4c STI specimens

For project areas participating in STI testing, specific instructions on collecting STI specimens are described in *NHBS-Trans Operations Manual – STI Testing Supplement*.

9.5 Specimen Storage and Processing

9.5a Venipuncture

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 (< 86º 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

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

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

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

humidity indicator cards in the bags on a ***daily*** basis and to replace the desiccant packs if the indicator cards change from blue to pink. The used desiccant packs and indicator card should be discarded, and a new indicator card should be added to the bag along with new desiccants.

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

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

9.6 Specimen Transport and Shipping

9.6a Local transport of venipuncture specimens

As mentioned previously, blood specimen collection and transport should be timed so that specimens arrive at the laboratory and are processed within 24 to 48 hours of specimen collection. Project areas should develop transport procedures in conjunction with their local laboratory. When developing these procedures, they should consider transport time to the laboratory, the days and hours of laboratory operation, specimen intake procedures, and the days and hours of field operations. A Specimen Transport/Shipping Log should be included with the batches of specimens sent to the laboratory. **Appendix O** contains a model log that project areas can modify for their local needs.

9.6b Shipping DBS

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

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

Shipping DBS to CDC

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

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

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

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

9.6c Shipping STI specimens

STI specimens are stable at room temperature (2-30°C/36-86°F) and must be shipped to the CDC laboratory weekly. They should be packaged and shipped according to the shipping guidance as described in the *NHBS-Trans Operations Manual – STI Testing Supplement*.

STI and DBS specimens must be packaged and shipped separately since they are going to two different laboratories at CDC.

9.7 Returning Test Results

Project areas must make final HIV test results available to participants, and they should keep track of the provision of results. After the NHBS survey is completed, project areas offering rapid testing should provide counseling and return negative and preliminary positive test results to participants. Each box of rapid HIV tests comes with a set of "subject information" pamphlets that should be given to the participants when they receive their rapid test results. The pamphlets provide an explanation of the rapid test and test results. For those participants with preliminary positive test results, project areas should also collect specimens for confirmatory testing. Although participants have the right to refuse receipt of their rapid test results, it is still very important to collect a confirmatory specimen from participants with preliminary positive test results since only the final test result will be included in the NHBS dataset. Depending on whether project areas are using the rapid-rapid algorithm or laboratory-based confirmatory testing, they should follow the guidance outlined below:

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

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

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

Appointments for returning test results should be made with the Appointment Cards in **Appendix M.**

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

As discussed in Chapter 5 of the *NHBS Trans Model Surveillance Protocol,* test counselors should target prevention messages to specific risks identified during the survey. Project areas that have separate interviewers and testing staff should develop procedures for communicating risk information between staff. For example, test counselors could administer a separate risk assessment or the interviewer could confidentially pass risk information to the test counselor. The collection of any risk information for test counseling must comply with the Assurance of Confidentiality for HIV/AIDS Surveillance Data (see Appendix M of the *NHBS Trans Model Surveillance Protocol).* Project areas 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, and project areas conducting STI testing can find general information on transgender health at https://www.cdc.gov/lgbthealth/transgender.htm.

9.8 Referrals to Care and Services

All referrals to care, support services, case management, or partner notification services must be made anonymously. Project areas 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 as well as social services such as counseling, housing, etc.

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

Project areas can strengthen their referral process by collaborating with local entities such as community-based organizations (CBOs) or HIV clinics. An anonymous referral to care or services should involve more than simply telling a participant where to go to

receive care or services. Project areas should make an effort to actually link the participant to the needed care or services. For example, project staff could offer a phone to call an agency to schedule a medical appointment. Referral to organizations that can make the appropriate linkage to care and follow-up are also acceptable.

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

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

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

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

9.9 Data Management

9.9a HIV testing

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

Data from the hard copy of the HIV Testing Log should be entered into the online HIV Test Results Log on the DCC data portal on a ***daily basis***. It is important for project areas to enter these data daily so that the process monitoring reports generated by the DCC are up-to-date and reflect each project area's latest data. Project areas should refer to the *NHBS-IDU5 Data Management Training Manual* for specific instructions on data entry and a listing of required variables. To aid in understanding data entry for laboratory-based testing, a categorical list of the trade names of HIV tests is included in **Appendix X**.

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

9.9b Hepatitis testing

Project areas that conduct hepatitis testing without CDC funding may enter hepatitis test results into the DCC data portal if they wish. At data closeout, the DCC will then be able to include the project area's hepatitis test results in the project area's final NHBS dataset. Data management requirements for hepatitis testing are similar to those for HIV testing. While in the field, staff should record hepatitis test results on a hard copy of the Hepatitis Testing Log (see Appendix J of the *NHBS Trans Model Surveillance Protocol*). The hard copy of the Hepatitis Testing Log, as well as any other hepatitis testing forms or logs, must be secure and in the possession of project staff at all times when in use in the field; otherwise, the forms and logs should be kept locked in a file cabinet or file box.

If project areas choose to send their hepatitis test results to the DCC for processing, they should enter the data from the hard copy of the Hepatitis Testing Log into the online Hepatitis Test Results Log on the DCC data portal on a ***daily basis.*** It is important for

project areas to enter these data daily so that the process monitoring reports generated by the DCC are up-to-date and reflect each project area's latest data.

9.9c STI testing

Project areas that will conduct gonorrhea and chlamydia testing must follow the data management guidance outlined in the *NHBS-Trans Operations Manual – STI Testing Supplement*. The CDC Division of STD Prevention will enter STI test results into the DCC data portal for these project areas. The project areas, in turn, will be responsible for tracking whether STI results are returned to participants and for collecting additional data on the provision of results throughout the data collection period. Project areas should work with project officers to send these additional data via the secure file transfer program on the DCC data portal at the end of data collection**.** At data closeout, the DCC will include each project area's STI test results in the project area's final NHBS dataset. Data management requirements for STI testing are similar to those for HIV testing. Any hard copy STI testing logs or forms must be secure and in the possession of project staff at all times when in use in the field; otherwise, the logs and forms should be kept locked in a file cabinet or file box.

Because CDC will enter STI test results into the DCC data portal rather than the project areas, those that are using local labs to conduct STI testing will not be able to enter their results into the portal.

10 Process Monitoring and Ongoing Formative Assessment

10.1 Overview

Process monitoring and ongoing formative assessment enable project areas to maintain the highest standards for data collection and will help them achieve the overall project objective of enrolling a sample of 200 trans women. The information project areas obtain through these assessment methods will complement the information they gathered during the formative assessment conducted at the start of the project cycle.

10.2 Process Goals

The NHBS process goals help project areas 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 for the interview.
- 90% of those who complete an interview consent to an HIV test.
- A minimum of 200 interviews are completed by participants who meet the eligibility criteria to receive recruitment coupons.

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

10.3 Process Monitoring Reports

The NHBS Data Coordinating Center (DCC) will produce the process monitoring reports for project areas to assess recruitment and enrollment, coupon distribution, eligibility, sample characteristics, HIV, STI, and hepatitis testing, seeds, RDS methods, previous participants, and interviewer skills. The reports will be posted on the DCC data portal and should be reviewed by project areas weekly. Project areas 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 project area's CDC project officer may

recommend that the project area address the problem by adjusting operations or by providing additional staff training. The CDC project officer may also recommend that the project area further evaluate the problem by conducting ongoing formative assessment. In addition, if project areas wish, they may create their own reports to monitor any issues of local interest.

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

10.3a Recruitment Monitoring Report

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

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

10.3b Coupon Manager Program Report

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

- Coupon Tracking
- Number of Coupons Distributed to Recruiters
- Number Who Reported Coupon Refusals
- Race/ethnicity of Coupon Refusals
- Reasons for Coupon Refusals

Project areas should use this report to monitor recruitment, manage coupon distribution, and evaluate participation barriers.

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

The Number of Coupons Distributed to Recruiters table can also help project areas track and manage coupon distribution. It lists the number of coupons given to each recruiter by recruiter type and the date any changes were made to this number. This is especially important if areas are using differential coupon distribution (see **Section 6.3a** of this manual).

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

The Race/ethnicity of Coupon Refusals table displays the race group and Hispanic ethnicity of people who refused to accept the coupons offered by participants. Project areas can use this information to determine whether a particular race group or Hispanic ethnicity 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 two "coupon refusals" tables will enable project areas 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* (**Appendix Y.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:

- Questionnaire Version
- Eligible
- Age
- Sex Listed at Birth
- Gender Identity
- Race/ethnicity
- MSA Resident
- Known Previous Participant
- Able to Participate (i.e., able to complete the survey in English or Spanish)
- Too Young to Participate

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

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

- Age
- Sex Listed at Birth
- Gender Identity
- Race/ethnicity
- Education
- Homeless in Past 12 Months
- Income
- Zip Code

Project areas should review the tables in this report to monitor the demographic characteristics of participants who successfully completed the interview. The demographic characteristics of these participants should reflect those of local trans women, as described in the project area's formative assessment reports.

10.3e Test Results Report

The *Test Results Report* (**Appendix Y.5** of this manual) consists of three tables:

- HIV Rapid Test Result
- HIV Self-reported Test Result
- Specimen sent to CDC Lab

Using this report, project areas can monitor their HIV test results. The HIV Rapid Test Result table compares the result of the first rapid test in the rapid-rapid algorithm with the result of the second rapid test, and the HIV Self-reported Test Result table shows whether or not the participant self-reported being HIV-positive compared to his final test result. A lack of concordance between the first and second rapid tests in the HIV Rapid Test Result table may indicate improper specimen collection or the over-reading of rapid test results, necessitating additional staff training. The HIV Self-reported Test Result table can be used to track HIV prevalence among participants. Other important information provided by this table is the proportion of participants who are unaware that they are infected with HIV or who are unwilling to disclose that they are infected with HIV (i.e., did not report being HIV-positive, but had a final HIV test result that was positive) and the proportion of possible false-negative HIV test results (i.e., did report being HIV-positive, but had a final HIV test result that was negative or indeterminate). Project areas can use the Specimen Sent to CDC Lab Report to determine whether the proper specimens are being sent to the CDC lab. Depending on circumstances, project areas may need to send all specimens to the CDC lab or they may only need to send specimens from participants who do not test HIV-negative.

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

10.3f Seed Report

The *Seed Report* (**Appendix Y.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 areas assess the success of seed enrollment. The Seed Characteristics table indicates the sex at birth, gender identity, race/ethnicity, age, and zip code for each seed, as well as whether or not the seed was eligible to recruit. If the *Sample Characteristics – Interviewed Report* shows underrepresentation of any sub-populations, project areas should review the Seed Characteristics table to determine whether this lack of sample diversity could be due to a lack of seed diversity.

10.3g Respondent-Driven Sampling Report

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

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

Project areas should review the Recruitment by Stranger table report to determine whether recruitment is occurring outside of personal networks (i.e., participants are being recruited by strangers). If participants are being recruited by strangers, project areas may need to improve their recruiter training so that participants only recruit individuals they know personally, or they may need to provide additional interviewer training so that interviewers accurately follow-up when a participant responds that they were recruited by a stranger. Interviewers should be able to help participants differentiate between recruitment by a stranger and recruitment by an acquaintance. A high level of recruitment by strangers may also indicate that a "recruitment scheme," like selling coupons or receiving kick-backs from recruits, is occurring in the community. Project areas that suspect a scheme should discuss the situation with their project officer to identify an appropriate course of action.

The Field Site Enrollment table will show enrollment by field site for each day of the week. This table will not only allow project areas to track the pace of enrollment by field site and day of operation, but it will also help them identify incorrect field site IDs. 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 area would have to investigate the discrepancy to determine whether the interviewer recorded the wrong field site ID or whether they programmed the wrong date in the portable computer. Correct field site IDs are essential for ensuring the accuracy of the Cross Recruitment table.

One of the assumptions of RDS is that participants are linked together in a single social network, although this assumption may be difficult or impossible to meet if the participants are geographically dispersed. The Cross Recruitment table helps project areas examine this assumption by cross tabulating a participant's field site with their recruiter's field site. Cross recruitment among field sites occurs when a participant is 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 NHBS results. In some cases, however, the absence of cross recruitment among field sites may be necessary to ensure adequate representation of all the major sub-populations of trans women.

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

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

10.3h Possible Previous Participant Report

To help project areas identify participants who may have taken or tried to take the survey more than once, the *Possible Previous Participant Report* (**Section Y.8** of this manual) contains a table listing participants who have the same date of birth and race/ethnicity. The table shows all participants with matching data and complete interviews.

To further assess whether participants with the same date of birth and race/ethnicity are the same person, project areas should check the participants' physical marks and recruiter IDs in the Coupon Manager Program (CMP). The participants' date of birth and race/ethnicity listed in the *Possible Previous Participant Report* may help with this assessment. In addition to the variables in the report, project areas may want to examine other variables that should not change over time (e.g., country of birth) or variables that are not likely to change during the data collection period to help them determine whether two participants are the same person. When project areas identify two participants with valid, completed interviews who have the same or similar information, they should discuss their findings with their CDC project officer and decide whether the second record should be treated as that of a previous participant and removed from the analysis dataset by updating the eligibility status.

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

10.3i Interviewer Report

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

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

Project areas should review the tables in this report to identify possible interviewer deficiencies or areas for improvement. Whenever interviewers perform below acceptable standards, project areas should provide them with any additional training needed and closely monitor their progress. If the interviewers fail to show improvement, project areas should remove them from their positions until they can demonstrate a sufficient level of competence.

The Interview Length table shows the number of interviews completed by each interviewer and the amount of time each spent on eligibility screening, the consent process, and the core survey. Project areas 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 Interviewer Confidence in Responses table lists the interviewers' responses to the validity question ("How confident are you of the validity of the respondent's answers?"). Project areas should monitor how often each interviewer selects the response options "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.

The Testing Consent table shows the number and proportion of participants who completed an interview who consented to HIV, STI, or hepatitis testing, and specimen storage. This information is stratified by interviewer so project areas can determine whether certain interviewers are less successful than others at obtaining consent for testing or blood storage. If lower consent rates are found among some interviewers,

additional training may be necessary to help these interviewers improve their testing messages and communication skills.

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 areas 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 areas 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 DCC data portal. They should also provide their interviewers with 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. Further information on coding insurance plans is included in the *NHBS-Trans Interviewer Guide*.

10.4 Ongoing Formative Assessment

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

When conducting ongoing formative assessment, project areas should begin with the least labor-intensive and time-consuming methods (e.g., the review of existing data, observations, and informal conversations) and then, if simpler methods do not yield results, they should proceed to more labor-intensive and time-consuming methods (e.g., key informant interviews and focus groups). Project areas 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 areas should only use ongoing formative assessment to investigate operational problems that have been identified. They should not use it to conduct sub-studies or to evaluate new research questions. Whenever project areas identify an operational or enrollment problem using ongoing formative assessment, they should discuss the

problem with their CDC project officer and develop a plan to resolve it. Plans to address operational and enrollment problems can also be shared with the Community Advisory Board for additional feedback.

Table 10.1 – Operational problems and potential evaluation methods

Operational Problem	Potential Evaluation Methods
Low or declining enrollment	***Quantitative:*** Project areas should review the Coupon Tracking table in the *Coupon Manager Program Report* to determine how many coupons have been distributed and the number and proportion of coupons returned. The number of coupons distributed less the number returned equals the number of coupons currently in circulation, a measure of how many potential participants there are in the community. A low proportion of coupons returned indicates a barrier to recruitment or participation, which should be further assessed using the "coupon refusals" tables in the *Coupon Manager Program Report*. The Recruitment Chains table in the *Respondent-Driven Sampling Report* will also help project areas monitor the progress of recruitment and enrollment. ***Qualitative:*** Project areas should use observations, informal conversations with participants or street intercept surveys to determine whether enrollment is being hindered by such factors as the field site location or hours of operation, the incentive amount or type, a poor reputation for the project, safety or confidentiality concerns, or the time commitment required.
A large proportion of ineligible participants	***Quantitative*** Project areas should review the *Sample Characteristics – Screened Report* to determine if there are any particular eligibility criteria that potential participants are failing or if certain demographic sub-populations are more likely to be ineligible. ***Qualitative*** If the proportion of participants who are within the eligible age range, who meet gender identity criteria, or who are MSA residents is low, project areas should observe the recruiter training provided by project staff and conduct exit interviews with participants to see if they know that they should only recruit people who are at least 18 years of age, identify as a woman or trans woman, and live in the project area.

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

Operational Problem	Potential Evaluation Methods
A large proportion of ineligible participants *(continued)*	If a high proportion of participants are thought to be too young, project areas should conduct observations, informal conversations with participants, street intercept surveys, or key informant interviews to find out if people in the community are misrepresenting their age so that they can participate in the survey.
Demographic characteristics of participants do not match those of local trans women	***Quantitative*** Project areas should review the *Sample Characteristics – Screened Report* to determine whether members of the underrepresented sub-population are more likely to be ineligible, and they should check the "coupon refusals" tables in the *Coupon Manager Program Report* to find out if members of the underrepresented sub-population are more likely to refuse coupons. They should also review the Seed Characteristics table in the *Seed Report* to assess whether a lack of sample diversity could be due to a lack of seed diversity. Project areas should use RDSAT to examine any variables relevant to the underrepresented sub-population (e.g., examine "age" if young people are underrepresented). They should check the affiliation matrix in the RDSAT output to see if members of the underrepresented sub-population are substantially less likely to be recruited by members of other sub-populations and they should check the recruitment count in the output to see if members of the underrepresented sub-population are less effective recruiters (i.e., are less likely to recruit other participants). ***Qualitative*** If members of the underrepresented sub-population are more likely to be ineligible, project areas 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 areas should also use street intercept or key informant surveys to determine whether there are misperceptions in the community regarding the eligibility criteria.

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

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

11 Data Submission and Management

11.1 Overview

The purpose of this chapter is to briefly describe NHBS data submission and management procedures. Project areas will submit their data to the NHBS Data Coordinating Center (DCC), which is managed by ICF International. Specific instructions on how to submit data to the DCC are described in the *NHBS-IDU5 Data Management Training Manual*. The DCC will also provide training via videos posted to the DCC Data Portal that the data manager from each project area is required to attend. Project areas are also encouraged to contact their TAC at the DCC for additional support.

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 areas are responsible for entering or submitting the following data via the DCC data portal:

- Coupon Manager Program (CMP) data
- QDS™ Warehouse containing the NHBS core interview files
- HIV test results
- STI results returned (if applicable)
- Hepatitis test results (if applicable, optional for locally funded hepatitis testing)
- Data corrections

Project areas should observe the schedule in **Table 11.1** for entering or submitting their data through the DCC data portal, and they should refer to the *NHBS-IDU5 Data Management Training Manual* for specific guidance on using the portal.

11.3 Data Management

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

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

Table 11.1 – Data entry and submission schedule

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

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