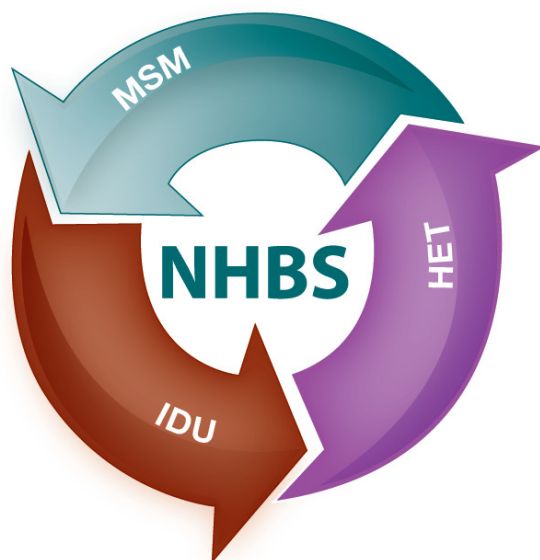


**National HIV Behavioral Surveillance – Round 4:
Injection Drug Use (NHBS-IDU4) and
Heterosexuals at Increased Risk for HIV (NHBS-HET4)**

FORMATIVE ASSESSMENT MANUAL



NATIONAL HIV BEHAVIORAL SURVEILLANCE SYSTEM

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

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1.1 Overview

Formative assessment is the process by which researchers or public health practitioners define a community of interest, determine how to access that community, and describe the attributes of the community that are relevant to a specific public health issue. For the National HIV Behavioral Surveillance system on injection drug use (NHBS-IDU) and among heterosexuals at increased risk for HIV (NHBS-HET), formative assessment lays the foundation needed for collecting behavioral surveillance and HIV prevalence data in these populations. The information gathered during formative assessment will enable project sites to tailor field operations to their local settings and to identify and address any barriers to operations. These efforts will help project sites obtain a sample that reflects the diversity of the local populations at high-risk for HIV and meets the target number of eligible participants. Throughout this manual, the population of interest for an NHBS cycle (i.e., persons who inject drugs in NHBS-IDU and heterosexuals at increased risk for HIV in NHBS-HET) is referred to as the “target population.”

The key to successfully conducting both formative assessment and field operations is establishing and maintaining strong relationships with both the local communities in which the target populations reside and those who provide health, prevention, and social services to the community. Accordingly, formative assessment should not focus solely on data collection; it should focus on community outreach as well.

1.2 Formative Assessment Goals

The principal goals of NHBS-IDU and NHBS-HET formative assessment are to:

- Garner the support of the community and its stakeholders.
- Describe the social, demographic, and peer network characteristics of the target populations.
- Identify potential “seeds,” or initial recruits, for respondent-driven sampling (RDS).
- **NHBS-HET only:** Identify high-risk areas (HRAs).
- Obtain information needed for conducting field operations (e.g., accessible field site location(s), ideal hours of operation, and appropriate staff).
- Identify potential barriers to recruitment and participation, and develop solutions to address them.

- Develop questions of local interest for HIV prevention.
- Monitor field operations and participant enrollment.

1.3 Institutional Review Board Procedures

The Centers for Disease Control and Prevention (CDC) has conducted an administrative review of the NHBS protocol, including an assessment of its human subjects protections, and has determined that NHBS is surveillance and not research. Because of this non-research determination, review and approval of the NHBS protocol by the CDC Institutional Review Board (IRB) is not required. Project sites should note, however, that CDC’s non-research determination for NHBS does *not* supersede local policies and procedures for human subjects protection. These policies may require sites to submit the NHBS protocol to their local IRB(s) for an expedited or full review. Even if local IRB(s) determine that NHBS is not research, sites may still want to submit the NHBS protocol for local IRB review and approval since many scientific journals will not publish findings from projects that have not been reviewed by an IRB.

Because formative assessment interviews involve engagement with human subjects, project sites should obtain informed consent from individuals participating in these activities. **Appendices A, B, and C** of the *NHBS Round 4 Model Surveillance Protocol* contain model formative assessment consent forms that sites can customize for local use. As with all NHBS data, formative assessment data must be collected anonymously. Therefore, interviews should never be video- or audio-taped. To further protect the anonymity of those interviewed, sites that are required to submit the NHBS protocol to their local IRB(s) should request a waiver of documentation of informed consent from their IRB(s) so that consent can be obtained verbally. **Appendix N** of the *NHBS Round 4 Model Surveillance Protocol* contains a model waiver of documentation form that can be modified for local use.



Because discussions with health department staff are not considered engagement with human subjects, project sites can gather formative information from these staff without IRB approval. For example, sites could meet with health department staff to identify potential field site locations, to plan field operations, to identify key informants for interview, and to develop local survey questions.

1.4 Formative Assessment Process

During formative assessment, project sites will gather information through secondary data review and primary data collection. To maximize the effectiveness of these formative assessment activities, sites should employ an iterative process (**Figure 1**); information obtained from the secondary data review should inform primary data

collection, which should then validate or provide further insight into the findings from the secondary data review. Using this iterative process, sites will be able to realize the formative assessment goals outlined in **Section 1.2**. Of particular importance, formative assessment will enable sites to identify potential obstacles to field operations, such as participation barriers, and develop solutions to minimize or eliminate these obstacles.

Figure 2 illustrates the suggested work flow for conducting formative assessment activities. The figure also shows possible sources of information for primary data collection and indicates how the information gathered from each can inform the collection of subsequent information. In brief, the formative assessment process starts with a review of published and unpublished secondary data which is used to describe the target populations and develop a plan for primary data collection. This plan serves as a blueprint for obtaining information from primary sources. The initial source of primary data is usually health department staff. Interviews with these staff can provide a general overview of the target population and the HIV epidemic in this population, as well as provide the names of additional sources of information. Primary data collection then continues with interviews with these other sources in a feedback loop – the information gathered from one source informs the collection of subsequent information and identifies additional sources of information. The process ends when sufficient data have been collected to address all relevant gaps in information.

Since multiple objectives can be achieved in a single meeting, it is helpful to keep all the NHBS formative assessment goals in mind when meeting with individuals or groups. Formative assessment staff should always be prepared to:

- Garner support for NHBS activities.
- Learn about the target population and community.
- Ask for referrals to others who can be interviewed about the target population and community.
- Ask for referrals for potential “seeds” (initial recruits).
- Learn about accessible field site locations and ideal hours of operation.
- Request available data.
- Request input for local questions.

1.5 Formative Assessment Timeline and Documents

Project sites will conduct formative assessment over a period of approximately 4 months preceding the start of field operations. To help plan and manage their formative assessment activities, sites will be required to develop an Implementation Timeline for completing the various activities. The end products of the formative assessment process

are the Secondary Data Report, the Primary Data Report, and for *NHBS-HET only*, the HRAs and Maps Report. These documents, along with the Implementation Timeline, are described in **Chapter 8** of this manual.

Figure 1. The iterative process of formative assessment

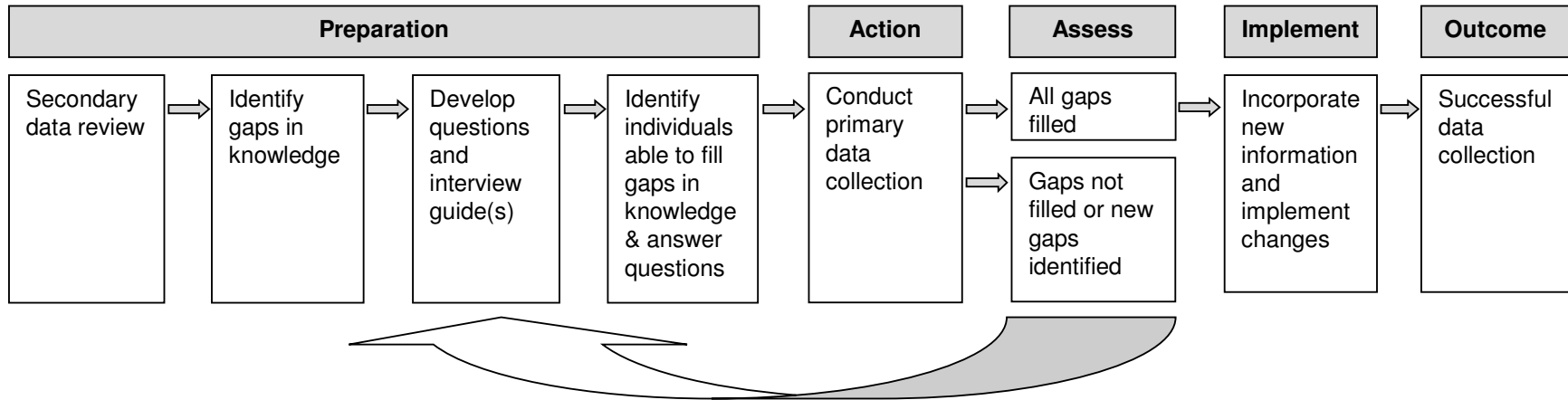
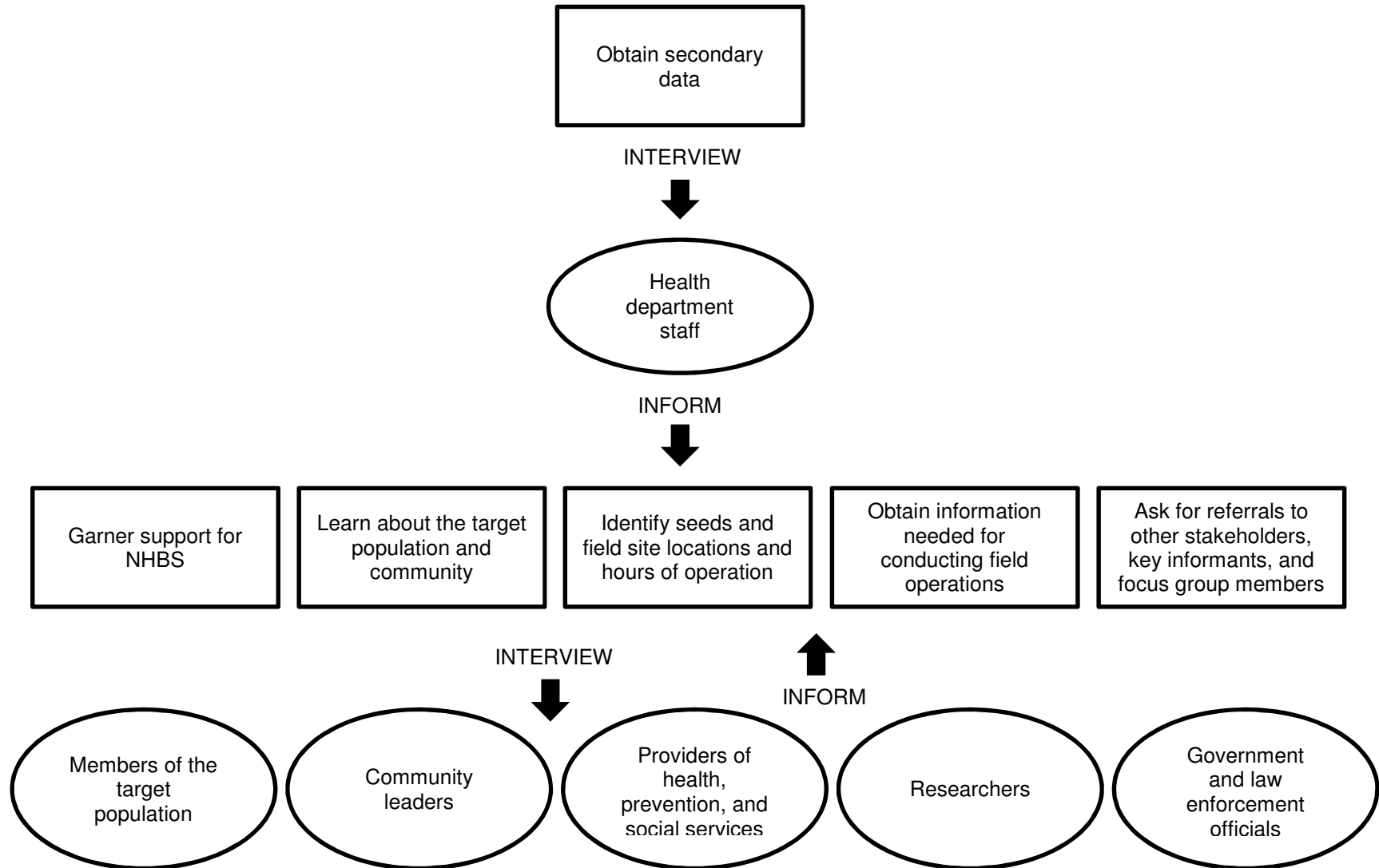


Figure 2. Suggested work flow for formative assessment activities



2.1 Overview

Ideally, project staff conducting formative assessment should include an ethnographer or a researcher with close knowledge of ethnographic methods and the NHBS target population, the project coordinator, and at least two additional staff members. During the HET cycle, at least one staff member should have experience using Geographic Information Systems (GIS) software, which is necessary to identify high-risk areas (HRAs) for infection.

2.2 Ethnographer

Project sites may wish to hire an ethnographer to lead their formative assessment activities. An ethnographer is a researcher who has been trained to collect data in their natural environment, placing an emphasis on the context in which particular social phenomena occur. Another strength of an ethnographer's approach to data collection is the use of multiple data sources and methods to confirm the information gathered. If an ethnographer is hired, the principal investigator is responsible for making sure that the ethnographer's work remains focused on the NHBS formative assessment goals (**Section 1.2**). The ethnographer must understand that the purpose of the formative assessment process is to inform and guide the successful collection of NHBS data.

The ideal ethnographer has either masters- or doctoral-level training in anthropology or sociology with experience working with a range of ethnographic methods, such as observations, key informant interviews, focus groups, and street intercept surveys. To be most effective, the ethnographer should also be familiar with the local target population and its various sub-populations. Ethnographers can be found through the anthropology or sociology departments of local universities and colleges, at community-based research institutes, or in the local health department.

Even if an outside researcher is hired as the ethnographer, the project staff should still remain actively involved in formative assessment activities. The ethnographer should train the project staff in the formative assessment process and its methods of data collection, and they should oversee the staff's work. The ethnographer should also provide the principal investigator and project coordinator with periodic updates on the progress of formative assessment and the findings. To ensure that formative assessment activities are completed successfully and in a timely manner, the principal investigator or project coordinator should meet with the ethnographer at the beginning of the project cycle to develop a set of deliverables and a timeline for achieving them.

2.3 Project Coordinator

The project coordinator is responsible for conducting the secondary data review, assisting the ethnographer, and monitoring the formative assessment activities. The project coordinator should help the ethnographer by providing them with background information on the project area, the RDS methodology, and the HIV epidemic among the local target population. The project coordinator should also help the ethnographer identify and contact community stakeholders and key informants for interview. Lastly, and of foremost importance, the project coordinator is responsible for incorporating the formative assessment findings into staff trainings and plans for field operations.



If a project site does not hire an ethnographer or other outside researcher to lead its formative assessment activities, the project coordinator should assume the duties outlined for the ethnographer in **Section 2.2**.

2.4 Project Staff

At least two project staff should assist the ethnographer with formative assessment activities. Their responsibilities could include the following:

- Garnering community support.
- Collecting information for the secondary data review.
- Identifying and contacting community members, stakeholders, and key informants to participate in interviews or focus groups.
- Helping with interviews and focus groups.
- Conducting street intercept surveys.
- Identifying potential field site locations.
- Identifying and interviewing potential seeds.

3.1 Overview

Secondary data are data that have been previously collected by other researchers, surveillance systems, or registries. As background information, secondary data form the basis of a project site's formative assessment activities. They can be used to describe the demographic characteristics of the local target populations, assess the scope of the HIV epidemic among these populations, and determine which sub-populations are most affected by the epidemic.

Secondary data are a critical component of formative assessment because they lay the foundation for the next steps in the process. Gaps in information in the secondary data will help project sites develop primary data collection plans and determine where to focus their primary data collection efforts. Sites can also use the secondary data to identify potential collaborators and key informants within the health department and target population, as well as to identify possible focus group participants. After formative assessment activities have been completed and field operations have begun, the secondary data can serve as a reference for monitoring how well participants reflect the local target population and the sub-populations at greatest risk for HIV infection.

3.2 Sources of Data

Project sites should use both internal and external sources of secondary data. Internal sources of data are research projects, surveillance systems, and registries within the health department, whereas external sources are those outside the health department.

3.2a Internal sources of data

Multiple sources of data on the local target populations and HIV epidemic will be available through the health department. Data from two of these sources, NHBS and the HIV Surveillance System, must be examined as part of formative assessment. Data from other health department sources should be assessed as needed.

National HIV Behavioral Surveillance

Project sites should begin the secondary data collection process by reviewing their NHBS data from previous IDU and HET cycles, including their formative assessment reports, recruitment monitoring reports, and survey and HIV testing data. Because NHBS data can provide such a broad range of information, they can help with many aspects of formative assessment. They are particularly useful for identifying operational problems that have occurred during previous cycles. For example, by comparing the racial/ethnic or age characteristics of previous NHBS-IDU or NHBS-HET participants to the

description of the local populations in the formative assessment reports, project sites can determine how well participants have represented the diversity of the local populations, especially those sub-populations at greatest risk for HIV infection. The underrepresentation of a sub-population among participants may indicate that a barrier to participation existed for that sub-population. Once identified, operational problems can then be further examined through the formative assessment process and possible solutions can be developed.

Affiliation Matrices: Sites with the capacity to analyze data using the RDS Analysis Tool (RDSAT) should examine the affiliation matrices from previous NHBS cycles to determine which sub-populations are more likely to form network (social) ties with one another, and therefore, are more likely to recruit one another (see the *RDSAT User Manual* available at <http://www.respondentdrivensampling.org> for instructions on conducting analyses with RDSAT). An affiliation matrix measures the extent to which individuals with a given characteristic form network ties with those with the same characteristic (homophily) or form ties with those with a different characteristic (heterophily). A value in the affiliation matrix is called an “affiliation index” and ranges from -1.0 to +1.0. Each value indicates the proportion of network ties that individuals from one sub-population **preferentially** form with those from the same sub-population or **preferentially** form with those from another sub-population. Positive values represent a preference to form network ties and negative values represent a preference to **not** form ties. For example, an affiliation index of +1.0 between two different sub-populations indicates that individuals from the first sub-population **preferentially** form network ties with those from the second sub-population 100% of the time, whereas an affiliation index of -1.0 indicates that individuals from the first sub-population **preferentially do not** form network ties with those from the second sub-population 100% of the time (i.e., they do not form any network ties with the second sub-population). An affiliation index of 0 indicates that network ties are not formed preferentially; they are instead formed **randomly**. When the affiliation index is 0, the proportion of the first sub-population’s network ties that are formed with the second sub-population is the same as the proportion of individuals in the overall population who are from the second sub-population (e.g., if 30% of the individuals in the overall population are from the second sub-population, then 30% of the first sub-population’s network ties will be formed with individuals from the second sub-population).

Affiliation indices between 0 and ± 1.0 represent both the preferential and random formation of network ties. For example, an affiliation index of +0.40 between two different sub-populations indicates that individuals from the first sub-population **preferentially** form network ties with those from the second sub-population 40% of the time and **randomly** form network ties the remaining 60% of the time. If 30% of the individuals in the overall population are from the second sub-population, then 58% of the first sub-population’s network ties would be formed with individuals from the second sub-population ($[40\% \times 100\%] + [60\% \times 30\%] = 58\%$). On the other hand, an affiliation index of -0.40 between two different sub-populations indicates that individuals from the first sub-population **preferentially do not** form network ties with those from the second

sub-population 40% of the time but *randomly* form network ties the remaining 60% of the time. If 30% of the individuals in the overall population are from the second sub-population, then 18% of the first sub-population’s network ties would be formed with individuals from the second sub-population ($[40\% \times 0\%] + [60\% \times 30\%]= 18\%$).

By providing insight into network ties, affiliation matrices can help project sites predict recruitment patterns among sub-populations, which is extremely useful for determining field site locations and selecting seeds. Sites should produce affiliation matrices for important demographic characteristics, such as race/ethnicity, age, and any other characteristics which may divide the target population into separate networks (e.g., drug of choice in NHBS-IDU and geography in NHBS-HET). CDC project officers can provide sites with assistance interpreting their affiliation matrices.

Affiliation matrices can help project sites identify the need for multiple field sites. If an important sub-population is geographically concentrated in one area and does not have network ties to the other sub-populations, it may be necessary to have an additional field site in a location that is readily accessible to the important sub-population. Affiliation matrices can also help project sites determine which demographic characteristics are required among seeds. Several examples of affiliation matrices are included below to show how they can be used to select seeds. The rows in the affiliation matrices represent the sub-populations who formed the network ties and the columns represent the sub-populations with whom the ties were formed. Homophily (the preference to form or not form network ties with those from the same sub-population) is indicated by the affiliation indices along the diagonal.

Example 1:

Affiliation Matrix:

	Group 1	Group 2	Group 3
Group 1	0.309	-0.416	-0.444
Group 2	-0.322	0.433	-0.482
Group 3	-0.283	-0.425	0.375

Members of each of the three groups preferentially formed network ties with members of their own group (shown by the positive indices along the diagonal [positive homophily]) and preferentially *did not* form network ties with members of the other two groups (shown by the negative indices). Since these groups preferred not to form network ties with one another, there would probably be very little cross recruitment between them. Therefore, seeds should be selected from each of the groups to expedite the recruitment of members of all the groups.

Example 2:

Affiliation Matrix:

	Group 1	Group 2	Group 3
Group 1	0.002	0.012	0.034
Group 2	0.096	0.122	-0.049
Group 3	-0.012	-0.111	0.104

In the second example, all the affiliation indices are very close to zero. Because the groups did not have any meaningful preference to *not* form ties with one another (they primarily formed network ties randomly), there would likely be cross recruitment between all the groups. As a result, group membership would not have to be considered when selecting seeds.

Example 3:

Affiliation Matrix:

	Group 1	Group 2	Group 3
Group 1	0.309	0.012	0.031
Group 2	0.021	0.433	0.005
Group 3	0.044	0.002	0.375

In the third example, members of each of the three groups preferentially formed network ties with members of their own group (shown by the positive indices along the diagonal [positive homophily]), but they did not exhibit any preference for or against the formation of network ties with members of the other two groups (shown by the indices very close to zero). Although members of each group preferentially formed ties with members of their own group, cross recruitment between groups would still likely occur. It therefore would not be essential to consider group membership when selecting seeds. Nevertheless, to reach equilibrium more quickly (see **Chapter 4** of the *NHBS Round 4 Model Surveillance Protocol*), it could be useful to select seeds from each of the groups (or from as many groups as possible). In addition, if members of one of the groups have been greatly underrepresented among participants in previous NHBS cycles, selecting all or most seeds from the underrepresented group could improve representation of that group during the current NHBS cycle.

Example 4:

Affiliation Matrix:

	Group 1	Group 2	Group 3
Group 1	0.309	0.311	-0.332
Group 2	0.412	0.433	-0.478
Group 3	-0.412	-0.366	0.375

In the last example, members of each of the three groups preferentially formed network ties with members of their own group (shown by the positive indices along the diagonal [positive homophily]). However, members of Groups 1 and 2 also preferentially formed

ties with one another (shown by the positive indices 0.311 and 0.412), but they preferentially *did not* form ties with members of Group 3 (shown by the negative indices -0.332 and -0.478). Analogously, members of Group 3 preferentially *did not* form ties with members of Groups 1 or 2 (shown by the negative indices -0.412 and -0.366). While there probably would be cross recruitment between Groups 1 and 2, there likely would be little cross recruitment with Group 3. Accordingly, it would be essential to select seeds from Group 3, along with seeds from either Group 1 or Group 2.

HIV Surveillance System

To characterize the local HIV epidemic, project sites should analyze HIV and AIDS case data from their HIV Surveillance System. For the ***NHBS-IDU cycle***, the data should be restricted to those HIV and AIDS cases that were *reported* through December 2014 and were newly *diagnosed* with HIV between January 2009 and December 2013. For the ***NHBS-HET cycle***, the data should be restricted to those HIV and AIDS cases that were *reported* through December 2015 and were newly *diagnosed* with HIV between January 2010 and December 2014. (*Note: AIDS cases should be selected by the date of HIV diagnosis; not the date of AIDS diagnosis.*) If possible, cases should be adjusted for reporting delays and cases that do not have a known HIV transmission category should be adjusted using the multiple imputation (MI) method developed by CDC's HIV Incidence and Case Surveillance Branch (HICSB) or a redistribution method developed by the local health department. Questions regarding the HICSB MI method should be directed to the CDC Division of HIV/AIDS Prevention (DHAP) Informatics Customer Support at 1-877-659-7725 or DHAPSupport@cdc.gov.

Other internal sources

Other sources of data within the health department are HIV counseling, testing, and referral databases and sexually transmitted disease (STD) and hepatitis surveillance systems. The health department's HIV epi profile and prevention plan can provide further information on local target populations, their HIV-risk behaviors, and their HIV prevention and treatment needs. Published journal articles and reports could also provide information on these topics.

3.2b External sources of data

External sources of data are just as important as internal ones. Project sites must examine data from the Census Bureau as part of formative assessment, and it is very likely that they will need to rely on a variety of external sources of data.

Census Bureau

Census data should be used to describe the demographic and socioeconomic characteristics of the general population that lives in the local project area.

Other external sources

Other sources of data outside the health department are published journal articles and reports from public and private researchers and organizations. These publications can be found through literature searches (e.g., <http://www.ncbi.nlm.nih.gov/pubmed>) and internet searches (e.g., <http://scholar.google.com/>). Moreover, the authors of these publications could serve as project collaborators or key informants. Project sites can also find local community resources for the target population on-line.

NHBS-IDU only: Additional data sources useful in characterizing the local population of persons who inject drugs and specific sub-populations at greatest risk for HIV infection (e.g., young persons who inject drugs) include syringe exchange programs, substance abuse treatment programs, the city/county medical examiner's office, and local law enforcement. If possible, project sites should request these data by key characteristics that may inform NHBS implementation, such as age, race/ethnicity, and residence (e.g., county or neighborhood). **Table 1** describes other external sources that may provide local data on persons who inject drugs.

Table 1. External sources of data on persons who inject drugs

DATA SOURCES	DESCRIPTION	DATA CONTENTS	WEB LINK
<i>National Institute of Drug Abuse (NIDA)</i>			
<p><i>From 1976-2014:</i> Community Epidemiology Work Group (CEWG) Reports</p> <p><i>From 2015 onward:</i> National Drug Early Warning System (NDEWS) Reports</p>	A synthesis of available data describing the epidemiology of drug abuse for both the country and participating metropolitan areas.	Drug abuse indicator data, findings from surveys, and other quantitative information compiled from local, state, and federal sources. Data are enhanced with qualitative information obtained from ethnographic research, focus groups, and other community-based sources. Local contacts with expertise on drug abuse could be obtained from the list of epidemiologists from the sentinel sites.	<p><i>From 1976-2014:</i> http://www.drugabuse.gov/about/organization/CEWG/CEWGHome.html</p> <p><i>From 2015 onward:</i> http://www.ndews.org</p>
<i>Substance Abuse and Mental Health Services Administration (SAMHSA)</i>			
National Survey on Drug Use and Health (NSDUH)	Annual survey of prevalence, patterns, and consequences of drug and alcohol use and abuse in the general, non-institutionalized civilian population ages 12 years and over in the U.S.	Demographic and drug use data among individuals.	http://www.samhsa.gov/data/population-data-nsduh
Treatment Episode Data Set (TEDS)	Information collected by states from local alcohol and drug abuse treatment facilities characterizing admissions to alcohol and drug treatment.	Demographic and drug history information about individuals admitted to treatment; changes in treatment admissions.	http://www.samhsa.gov/data/client-level-data-teds
Behavioral Health Treatment Services locator	Searchable database of treatment facilities in the U.S. for substance abuse/addiction and/or mental health problems.	Location of the programs in a map of the city as well as general information about each program.	https://findtreatment.samhsa.gov/locator/home
<i>Centers for Disease Control and Prevention (CDC)</i>			
Youth Risk Behavior Surveillance System (YRBSS)	National school-based survey conducted by CDC and state, territorial, and tribal governments, along with local education and health agencies. National and select state, district, territorial, and tribal results are available.	Data on health seeking and risk behaviors, including injection drug use.	http://www.cdc.gov/healthyouth/data/yrebs/

4 ***NHBS-HET only:* High Risk Areas and Maps**

4.1 Overview

High risk areas (HRAs) are low-income areas within an MSA or MSA Division where heterosexuals are expected to be at greatest risk of HIV infection compared to other areas of the MSA. For NHBS-HET, HRAs are defined as the 25% of census tracts in the MSA or MSA Division that have the highest proportion of residents who live below the Census Bureau's poverty threshold. HRAs are used to determine the best locations for field sites, as well as to identify neighborhoods where seeds can be recruited. To effectively accomplish these tasks, project sites should identify and map their HRAs, including any relevant information, such as the race and ethnicity of HRA residents. HRA maps and race/ethnicity maps are required components of the HRAs and Maps Report (see **Section 8.4** of this manual).

4.2 HRA Maps (Required)

Project sites should identify and map their HRAs using a geographic information system (GIS) mapping software, such as ArcGIS. Most health departments provide GIS services, but if these services are not available, project sites can use Epi Map, a GIS module included in Epi Info 7. Although Epi Map has limited capabilities, it is easy to use and can be downloaded for free with Epi Info 7 from the CDC website: <http://wwwn.cdc.gov/epiinfo/7/index.htm>.

CDC will provide project sites with the poverty data needed to create and map their HRAs. The data will come from the 2010-2014 American Community Survey (ACS) and will include the poverty rate (proportion of residents living below the poverty threshold) for each census tract in the project site's MSA or MSA Division. Project sites will then have to order the data by poverty rate (from the census tract with the highest poverty rate to the tract with the lowest rate) and select the 25% of tracts that have the highest poverty rates. These census tracts will constitute their HRAs.

Project sites should produce at least two HRA maps: one showing the entire MSA or MSA Division and the other showing the principal city where project operations will be conducted. Multiple maps of the principal city may be necessary if it is large and cannot be depicted on a single map. Additional instructions for creating the HRA maps are listed below:

1. Title the maps with the name of the project site (e.g., Atlanta) and the type of map (e.g., HRA Map of the Principal City).

2. Indicate the total number of census tracts in the MSA or MSA Division and the number of census tracts that are HRAs.
3. Clearly mark census tract boundaries.
4. Color census tracts that are HRAs blue and color tracts that are *not* HRAs white.
5. Divide HRA census tracts into 3 to 5 groups based on their poverty rates. Color the tracts in each group with a different shade of blue and grade the shades of blue using the lightest shade for HRA census tracts that are in the group with the lowest poverty rates and the darkest shade for those that are in the group with the highest poverty rates. Include a legend showing the range of poverty rates in each group and the corresponding shade of blue. When deciding how many groups to select, consider the number of HRA census tracts in the MSA or MSA Division, the range of poverty rates in the HRA census tracts, and how well the various color gradations can be viewed on the maps.
6. Add a simple hatch or symbol to census tracts with < 500 residents to mark these tracts. Poverty rates in census tracts with few residents can be easily skewed too high or too low and should be viewed cautiously.
7. Include any important explanatory notes at the bottom of the map.
8. Save the maps as .pdf files or insert copies in the HRAs and Maps Report.

4.3 Race/Ethnicity Maps (Required)

To help ensure that field site locations are readily accessible to the racial and ethnic sub-populations most affected by the local HIV epidemic among heterosexuals, project sites should supplement their HRA maps with maps showing the proportion of residents in each census tract who are black or Hispanic. Because both these racial and ethnic sub-populations are disproportionately impacted by the HIV epidemic among heterosexuals at the national level, it is likely that they will be disproportionately impacted at the local level as well. However, if one of these racial and ethnic sub-populations is not impacted locally, project sites may request permission from their CDC project officer to not produce a map for that sub-population. The data needed to create the race/ethnicity maps will be provided by CDC and, like the poverty data used in the HRA maps, will come from the 2010-2014 ACS. The ACS data for the black sub-population will be restricted solely to non-Hispanic blacks.

Unless instructed otherwise by their CDC project officer, project sites should produce two race/ethnicity maps of their principal cities: one showing the proportion of residents

in each census tract who are black and the other showing the proportion who are Hispanic. More than one map may be required for each racial and ethnic sub-population if the principal city is too large to fit on a single map. Additional instructions for creating the race/ethnicity maps are listed below:

1. Title the maps with the name of the project site and the type of map.
2. Clearly mark census tract boundaries.
3. On the map for the black sub-population, color census tracts with black residents red and color tracts *without* black residents white; and on the map for the Hispanic sub-population, color census tracts with Hispanic residents green and color tracts *without* Hispanic residents white. Project sites with large black or Hispanic sub-populations could also color census tracts with small proportions of black or Hispanic residents white. For example, on the map for blacks, they could color census tracts with $\geq 10\%$ black residents red and color tracts with $< 10\%$ black residents white.
4. Divide census tracts into 3 to 5 groups based on the proportion of residents who are black or Hispanic. Color the tracts in each group with a different shade of red on the map for the black sub-population or green on the map for the Hispanic sub-population. Grade the shades of red or green using the lightest shade for census tracts that are in the group with the lowest proportion of residents who belong to the racial/ethnic sub-population and the darkest shade for those that are in the group with the highest proportion. Include a legend showing the range of proportions in each group and the corresponding shade of red or green. When deciding how many groups to select, consider the number of census tracts in the principal city, the range of proportions of black or Hispanic residents, and how well the various color gradations can be viewed on the maps.
5. Add a simple hatch or symbol to census tracts with < 500 residents to mark these tracts. Proportions in census tracts with few residents can be easily skewed too high or too low and should be viewed cautiously.
6. Include any important explanatory notes at the bottom of the map.
7. Save the maps as .pdf files or insert copies in the HRAs and Maps Report.

In addition to the HRA and race/ethnicity maps, project sites may choose to create another set of maps which overlay the race/ethnicity data on the HRA maps. For example, on an HRA map, census tracts with the highest proportion of residents who are black or Hispanic could be marked with a hatch, symbol, or bold border. Project sites may also produce maps of any other racial or ethnic sub-populations that they consider to be important to the local HIV epidemic among heterosexuals.

4.4 HIV Case Surveillance Maps (Strongly Recommended)

CDC strongly recommends that project sites map their heterosexual HIV and AIDS cases to identify those areas of their principal cities most heavily impacted by the HIV epidemic among heterosexuals. This information will help project sites determine the optimal areas for locating field sites and recruiting seeds.

Project sites should obtain the data needed to create the HIV case surveillance maps from their local HIV Surveillance System. The data should be the same as that used in **Table 3** of the Secondary Data Report. It should include HIV and AIDS cases that were reported through December 2015 and should be restricted to those cases that were newly diagnosed with HIV between January 2010 and December 2014. (*Note: AIDS cases should be selected by the date of HIV diagnosis; not the date of AIDS diagnosis.*) The data should also be restricted to cases that have an HIV transmission category of “heterosexual contact.” If possible, cases should be adjusted for reporting delays and cases that do not have a known HIV transmission category should be adjusted using the multiple imputation (MI) method developed by CDC’s HIV Incidence and Case Surveillance Branch (HICSB) or a redistribution method developed by the local health department. Questions regarding the HICSB MI method should be directed to the CDC Division of HIV/AIDS Prevention (DHAP) Informatics Customer Support at 1-877-659-7725 or DHAPSupport@cdc.gov.

The HIV surveillance data used in the maps should not include cases whose residence address is a hospital, jail, HIV counseling and testing site, or other facility where people are routinely tested for HIV. Including such cases would skew the geographic distribution of new HIV diagnoses to areas that contain these facilities. If the cases cannot be excluded, project sites should indicate the locations of the facilities on their HIV case surveillance maps using symbols. Providing this information will help prevent misinterpretation of the data on the maps.

Project sites should *not* geocode their HIV surveillance data solely to create their HIV case surveillance maps. If the data are already geocoded, project sites can map their cases by census tract; but if they are not already geocoded, project sites should map their cases by zip code. Lastly, since the objective of the HIV case surveillance maps is to identify areas in the principal city where new HIV diagnoses (and presumably, new HIV infections) are concentrated, project sites should present counts of new HIV diagnoses on their maps and *not* rates of new diagnoses.

Project sites should produce at least one map showing the number of new HIV diagnoses in each census tract or zip code of their principal city. Multiple maps of the principal city may be necessary if it is large and cannot be depicted on a single map. Additional instructions for creating the HIV case surveillance maps are listed below:

1. Title the maps with the name of the project site and the type of map.

2. Indicate the total number of new HIV diagnoses among heterosexuals in the principal city during 2010-2014 and the number and proportion of these new HIV diagnoses that are included on the map.
3. Clearly mark census tract or zip code boundaries.
4. Color census tracts or zip codes that have new HIV diagnoses orange and color tracts or zip codes that do *not* have any new diagnoses white.
5. Divide census tracts or zip codes into 3 to 5 groups based on the number of new HIV diagnoses. Color the tracts or zip codes in each group with a different shade of orange and grade the shades of orange using the lightest shade for census tracts or zip codes that are in the group with the smallest number of new HIV diagnoses and the darkest shade for those that are in the group with the largest number. Include a legend showing the range of numbers in each group and the corresponding shade of orange. When deciding how many groups to select, consider the number of census tracts or zip codes in the principal city, the range of numbers of new HIV diagnoses, and how well the various color gradations can be viewed on the map. Moreover, ensure that the group with the smallest number of new HIV diagnoses does not violate the local data release policy. For example, if a project site's local data release policy prohibits the release of HIV surveillance data stratified in groups of < 3 cases, the group with the smallest number of new HIV diagnoses must have an upper bound of at least 3 new diagnoses. The group with the smallest number of new HIV diagnoses could thus have a range of 1-3, 1-4, 1-5, and so on; but it should not include just 1 or have a range of 1-2.
6. If mapping by census tract, add a simple hatch or symbol to census tracts with < 500 residents to mark these tracts. This will highlight census tracts that are likely to have few or no new HIV diagnoses.
7. Include any important explanatory notes at the bottom of the map.
8. Save the maps as .pdf files or insert copies in the HRAs and Maps Report.

In addition to the HRA and HIV case surveillance maps, project sites may choose to create another set of maps which overlay HARS data on the HRA maps or the race/ethnicity maps. For example, on an HRA or race/ethnicity map, census tracts with the largest number of new HIV diagnoses could be marked with a hatch, symbol, or bold border. Alternatively, a dot or another symbol could be added to an HRA or race/ethnicity map to indicate the census tract of residence of each new HIV case.

4.5 NHBS-HET Maps (Strongly Recommended)

To assess the geographic diversity of participants in prior NHBS-HET cycles, CDC strongly recommends that project sites map the census tract of residence for participants in the previous NHBS-HET cycle. By comparing these maps with the HRA, race/ethnicity, and HIV case surveillance maps, project sites can determine how well participants have represented communities at greatest risk of HIV infection. This comparison will either validate a project site's choice of locations for its field sites in the previous cycle or demonstrate the need to more effectively identify locations in the current cycle.

Project sites should use the data from the prior NHBS-HET cycle to create their NHBS-HET maps. Data should be restricted to participants who were eligible, completed an interview (variable COMPLETE= 1), and met the HET definition (variable HETDEF= 1). It is not necessary for project sites to "clean" their NHBS-HET census tract data; they can just map whichever data can be successfully matched to a valid census tract number. Project sites should produce at least one map showing the number of NHBS-HET participants in each census tract of their principal city. Multiple maps of the principal city may be necessary if it is large and cannot be depicted on a single map. Additional instructions for creating the NHBS-HET maps are listed below:

1. Title the maps with the name of the project site and the type of map.
2. Indicate the total number of NHBS-HET participants who were eligible and completed an interview, as well as the number and proportion of these participants whose census tract of residence could be matched and mapped to a valid census tract.
3. Clearly mark census tract boundaries.
4. Color census tracts that have NHBS-HET participants purple and color tracts that do *not* have any participants white.
5. Divide census tracts into 3 to 5 groups based on the number of NHBS-HET participants. Color the tracts in each group with a different shade of purple and grade the shades of purple using the lightest shade for census tracts that are in the group with the smallest number of participants and the darkest shade for those that are in the group with the largest number. Include a legend showing the range of numbers in each group and the corresponding shade of purple. When deciding how many groups to select, consider the number of census tracts in the principal city, the range of numbers of participants, and how well the various color gradations can be viewed on the map. Furthermore, ensure that the group with the smallest number of participants does not violate the local data release policy.

6. Identify the locations of field sites using a symbol.
7. Add a simple hatch or symbol to census tracts with < 500 residents to mark these tracts. This will highlight census tracts that are likely to have few or no participants.
8. Include any important explanatory notes at the bottom of the map.
9. Save the maps as .pdf files or insert copies in the HRAs and Maps Report.

If project sites wish, they may create maps showing sub-populations of NHBS-HET participants, such as a map of black participants or a map of Hispanic participants. As described previously for the other maps, project sites may also choose to overlay their NHBS-HET data. For example, on one of the other maps, census tracts with the largest number of participants could be marked with a hatch, symbol, or bold border. Alternatively, a dot or another symbol could be added to one of the other maps to indicate the census tract of residence of each participant.

5.1 Overview

Primary data are data that the project staff will collect themselves as part of the formative assessment process. Despite a different method of collection, primary data can fulfill many of the same objectives as secondary data. They can be used to describe the target population, along with sub-populations that are most impacted by the HIV epidemic or were underrepresented in previous NHBS cycles. They can also be used to identify barriers to participation in the survey and obstacles to field operations. In addition, primary data are uniquely suited to meeting other important formative assessment objectives. They are particularly useful in collecting in-depth information to guide the implementation of the RDS methodology, such as collecting data on peer networks, characteristics of effective seeds, and field site logistics. Moreover, primary data are useful for garnering community support for NHBS, as well as for developing solutions to overcome participation and operational challenges.

Since formative assessment is an iterative process, project sites should use their primary data to provide further insight into the findings from their secondary data review and to address any information gaps in their secondary data.

5.2 Peer Networks

In NHBS, a “peer network” is defined as the group of people that a person knows in the project area. A person’s peer network is composed of friends, relatives, sex and drug use partners, and other people with whom the person associates. In NHBS-IDU, people in a person’s peer network must also inject drugs. Primary data can provide insight into the characteristics of the peer networks of the target population, which is critical to understanding how RDS sampling is likely to proceed and how recruitment can be optimized to enroll a representative sample of participants. For example, in one city, members of the target population interact as a single peer network, while in a second city, members of the target population form two separate peer networks that rarely interact with each other. In the second city, project staff would have to recruit seeds from both peer networks in order to efficiently reach the entire target population. They would also have to ensure that their field site is equally accessible to members of both peer networks. Alternatively, they could set up two field sites, with one field site readily accessible to members of one peer network and the other field site readily accessible to members of the other peer network.

By integrating findings from both secondary and primary data collection, project sites can greatly improve their knowledge of the target population’s peer networks. Sites can learn about these peer networks by analyzing the affiliation matrices from previous cycles (see

Section 3.2a of this manual); by asking key informants and focus group participants about the characteristics of their social connections; and by asking key informants and focus group participants where they go to work, shop, socialize, and for **NHBS-IDU only**, buy and use drugs. The locations where these activities occur can play an important role in shaping peer networks when segments of the target population are geographically isolated from one another. When people who live in different areas of the city go to the same areas to work, shop, socialize, or buy and use drugs, they increase the likelihood that they will meet and interact with one another. This, in turn, increases the likelihood that they will recruit one another to participate in NHBS. On the other hand, when people who live in different areas of the city work, shop, socialize, and buy and use drugs solely in their own communities, they decrease the likelihood that they will meet and interact with people from other areas. As a result, they will be less likely to recruit one another to participate in NHBS.

5.3 Seeds

There are multiple criteria to consider when identifying initial recruits, or seeds, in RDS (see **Chapter 4** of the *NHBS Round 4 Model Surveillance Protocol*). Ideal seeds are dynamic individuals who are extremely knowledgeable about the target population, well-connected to it, and have a vested interest in its well-being. They should also have network ties to the major sub-populations in the project area. Since seeds are the initial recruiters in RDS, it is essential that they be highly motivated to provide support for the project and encourage others to participate. Selecting effective and well-connected seeds facilitates recruitment, promotes longer recruitment chains, and helps reduce bias in the sample. During formative assessment, project sites should identify the demographic characteristics of individuals with network ties to the important sub-populations (e.g., young persons in NHBS-IDU) and choose seeds with those characteristics. Usually, seeds are selected from a variety of sub-populations. However, with strong justification and CDC project officer approval, sites may choose to select most, or all, of their seeds from a single sub-population if that sub-population is relevant to the local HIV epidemic, was underrepresented in previous NHBS cycles, **and** is networked to the broader target population (i.e., has weak homophily).

Project sites can identify their seeds during primary data collection through key informant interviews, focus groups, and street intercept surveys. After explaining the RDS methods and the seed criteria, sites can ask interviewees if they could refer potential seeds to the project or if they would be interested in being a seed themselves.



As a reminder, the NHBS survey is anonymous. Accordingly, project sites **cannot** collect any contact information on potential seeds identified during formative assessment. Instead, sites should provide their contact information to the potential seeds and ask the seeds to contact them at some future date.

5.4 Field Site Logistics

Field operations for NHBS-IDU and NHBS-HET are conducted at fixed field sites, like an office or a van parked at a specific location. Project sites must select field sites that are readily accessible to all members of the target population. The locations of field sites should not create a barrier to participation for any sub-populations, especially those sub-populations that have been underrepresented in previous cycles (e.g., young persons in NHBS-IDU and Hispanics in NHBS-HET). When assessing the suitability of field sites, project sites should consider the following questions:

- **Is the field site accessible, safe, and appropriate for the target population?** Project sites should investigate whether there are any barriers that would keep the target population or specific sub-populations from coming to the field site. For example, can all members of the target population easily access the field site using public transportation? Project sites should determine if the community (residents, local businesses, law enforcement, etc.) around the field site is accepting and welcoming of the target population and NHBS activities. A field site must also be safe for both the participants and the project staff.

An appropriate field site will not bias the sample of participants. Therefore, a field site should not be located in a facility that primarily or exclusively provides a specific service to the target population, such as medical or mental health care, HIV or STD testing, HIV care or prevention, or drug treatment or prevention. A facility that primarily or exclusively provides social services to the target population is also not appropriate. Based on previous RDS studies, it is likely that placing a field site in a facility that provides a specific service to the target population would bias the sample toward those who receive that service. For example, a field site in an HIV clinic would likely bias the sample toward HIV-positive participants. On the other hand, a field site may be located in a facility that provides a vast array of services since it is not likely that the sample would become biased toward those who receive any one particular service.

- **What is the proper number of field sites?** While there should be a sufficient number of field sites so that all members of the target population have access to a field site, there should not be too many field sites that the chance of cross-recruitment of participants between field sites is reduced. When there is no cross-recruitment of participants between field sites, separate RDS samples are generated at each field site, which is very challenging to analyze. Based on experience from previous NHBS cycles and other RDS studies, project sites should operate as few field sites as are necessary to reach the sub-populations that are most important to the local HIV epidemic or that have been underrepresented in previous NHBS cycles.

- **What are the ideal logistics for field site operations?** Project sites should ask members of the target population which days and hours of operation would be most convenient for them to go to the field site for an interview. Field sites should be open outside normal business hours at least one day per week to accommodate members of the target population who work or are busy during those times. Project sites should also determine whether members of the target population would prefer to set up appointments to be interviewed or to walk-in to be interviewed anytime during operating hours.
- **Are special accommodations necessary?** A field site should meet the needs of the participants. For instance, if formative assessment indicates that a large number of participants may bring children with them when they come for their interview, project sites should consider having an area of the field site set up for children to wait while their caretaker completes the interview.

5.5 Sources of Data

To address the multiple formative assessment objectives, primary data collection should utilize multiple internal and external data sources. Within the health department, possible sources of data include HIV, STD, and hepatitis surveillance staff; HIV and STD outreach and prevention workers; and behavioral scientists, epidemiologists, and other public health researchers. Outside the health department, possible sources of data are members and leaders of the target population; staff of community-based organizations (CBOs) serving the target population; providers of HIV and STD prevention and treatment services to the target population; providers of substance abuse treatment programs for the target population; police and law enforcement officials; university-based and private researchers whose work focuses on the target population; and for ***NHBS-IDU only***, staff of syringe exchange programs.

Project sites should collect data from a diverse set of individuals so that the information they obtain accurately reflects the target population, especially those sub-populations who are at greatest risk of HIV infection or have been underrepresented in previous NHBS cycles, like young persons in NHBS-IDU and Hispanics in NHBS-HET.

5.6 Data Collection Methods

For primary data collection, project sites have the option of selecting from a variety of qualitative and quantitative methods, such as key informant interviews, focus groups, observations, and street intercept surveys. Nonetheless, project sites should choose those methods which will be most effective at obtaining the information necessary to understand the local target population. A list of model formative assessment topics and interview questions is provided in **Appendix A** of this manual. Project sites can use the

model questions to develop a site-specific interview guide. During interviews, a guide can help keep the conversation on topic while still allowing for the free and open exchange of ideas.

To protect the anonymity of key informants and focus group participants, interviews and discussions cannot be audio- or video-taped. In addition, because key informant interviews and focus groups involve engagement with human subjects, project sites should obtain informed consent from individuals participating in these activities.

Appendices A, B, and C of the *NHBS Round 4 Model Surveillance Protocol* contain key informant and focus group consent forms that project sites can customize for local use.

5.6a Key Informant Interviews

Key informants are cultural and subject matter experts that can provide insight into the target population. According to Schensul (Schensul et al., 1999):

[Key informants] have gained their knowledge by virtue of their position and experience in the community, their established networks of relationships, their ability to express themselves orally, and their broad understanding of their community.

Some key informants have broad-based knowledge of the target population and will be able to provide general information on a variety of subjects, whereas others have more focused knowledge and will be able to provide in-depth information on a specific subject. It is often helpful for project sites to start primary data collection by using sources with more general information to gain an overall understanding of the target population, and then graduating to sources with more in-depth information to address any issues that remain unclear or are of particular importance locally. In addition, to help ensure the reliability and validity of the data, project sites should interview several key informants and cross-check the information they provide.

Some key informants may be members of the target population or volunteers at CBOs rather than paid professionals. These key informants are referred to as “community key informants.” Since community key informants are interviewed on their personal time, they may receive compensation for participating in the interview. Project sites should decide whether or not each of their key informants is a community key informant and is entitled to compensation. Usually, paid staff and managers who are interviewed in their professional capacities are not entitled to compensation for their time. The *NHBS Round 4 Model Surveillance Protocol* has examples of consent forms for both types of key informants (**Appendix A** for key informants and **Appendix B** for community key informants).

5.6b Focus Groups

Focus groups are interviews conducted with a group of individuals under the direction of a moderator. They are especially helpful for gaining insight into commonly held

perceptions within the target population and for eliciting information on community norms. Focus groups can also be used to confirm other formative assessment findings or to explore findings in greater depth. Due to their interactive nature, focus groups often yield information that is different from the information gathered with other data collection methods.

A skilled moderator is critical to the success of a focus group. The moderator's role is to promote interaction between members of the group and to make sure that the discussion remains on topic. Because a focus group cannot be audio- or video-taped, a note taker is needed to record the discussion. Typically, a focus group lasts from 1½ to 2 hours and has 6 to 12 members. Groups with fewer than 6 members tend to lose energy while those with more than 12 members may not allow everyone to participate fully. As with community key informants, focus group participants should be compensated for their time.

Focus group participants should be recruited from within the project area and can include the target population's members, leaders, and stakeholders, as well as staff from CBOs that serve the target population. To facilitate a free and open discussion, focus groups should be composed of members with similar demographic characteristics. For example, focus groups could be created based on age, race/ethnicity, or HIV status. It is also important for focus groups to provide a comfortable and trusting environment for all who participate.

5.6c Observations

Unlike information collected from interviews, observations rely solely on what is seen by the researcher. Observations can be used to both validate and build on information gathered through other data sources. Observations can provide insight into the behavior of the target population, issues related to field sites, or a specific topic of interest. Observations can occur in settings such as neighborhoods, service organizations, parks, or for **NHBS-IDU only**, syringe exchange programs and high drug activity areas. For example, if a particular community center is being considered as a possible field site, observations can be conducted at the community center to learn about accessibility, safety, and appropriateness.

Observations can also provide insight related to:

NHBS-IDU only:

- Contextual information about the nature of drug activity in particular neighborhoods (e.g., Where are drugs being sold? Where and how are drugs being used? Is drug activity hidden or out in the open?).
- Interactions between different sub-populations of persons who inject drugs (e.g., between younger and older persons, men and women, or different racial and ethnic groups).

NHBS-HET only:

- Interactions between different sub-populations of persons living in low income neighborhoods (e.g., between different racial and ethnic groups).

Stimson has identified aspects of observations that can help guide project staff when conducting observations (Stimson et al, 1998). These aspects have been adapted for NHBS and are summarized in **Table 3**.

Table 3. Aspects of observations

Settings	Where does the observation take place? When? What is the physical layout?
People	What types of people are present? How old are they? What is their race/ethnicity? How many are present?
Activities	What is going on? What are the people doing?
Events	Is this a regular occurrence or is it a special event?
Signs	Are there clues that provide evidence about meanings and behaviors?
Time	In what order are things happening? Is there a reason for this?
Goals	What are the people trying to accomplish?
Networks	How do the people present seem to know one another? Is it social or related to a type of business? Do the relationships change over time?

5.6d Street Intercept Surveys

Street intercept surveys are very brief surveys that focus on a few key topics, like gaging interest in participating in NHBS and assessing the feasibility of field site locations. These surveys are a quick and easy means of obtaining the spontaneous input of the target population. They can also be used to identify key informants or focus group participants. Yet, street intercept surveys do have some limitations. Because they are so brief, they allow little opportunity to ask participants follow-up questions or explore their responses in greater detail.

Street intercept surveys should not take more than five minutes to administer and they should be conducted where the person is intercepted or at a nearby location. If project sites need additional information on specific sub-populations, they can target their surveys to these groups. Basic demographic information, like age, race/ethnicity, and zip code or neighborhood, should also be collected during the survey so that responses can be

stratified by these variables. Consent is not needed for street intercepts surveys, and compensation should not be provided.

5.7 Triangulation of Data

“Triangulation” means cross-checking formative assessment findings by using multiple data sources, data collection methods, or investigators. Since formative assessment, especially qualitative assessment, that relies on only one data source or collection method is subject to the errors associated with that approach, many researchers triangulate their data to validate the results and ensure that the information is complete. One way project sites can triangulate their formative assessment data is to compare information on the same topic that has been obtained from different data sources. Another strategy is to use at least two different data collection methods (e.g., key informant interviews, focus groups, observations, or street intercept surveys). Lastly, project sites should always compare the findings from their primary and secondary data reviews; this is essential for the success of formative assessment.

When triangulating information with a variety of data sources and collection methods, project sites may obtain some inconsistent findings. If this occurs, they should collect additional data to resolve these discrepancies and better understand the results.

6

Garnering Community Support

6.1 Overview

The success of both NHBS-IDU and NHBS-HET will depend largely on a project site's ability to garner support from the community stakeholders for the target population, as well as the broader target population. Greater community acceptance of NHBS will result in a higher rate of participation in the survey. To have the most impact, sites should elicit support from a wide variety of stakeholders. Stakeholders should have diverse backgrounds and they should represent different sub-populations of the target population, especially those sub-populations most highly impacted by the HIV epidemic and those underrepresented in previous cycles (e.g., young persons in NHBS-IDU and Hispanics in NHBS-HET). Examples of stakeholders include the following:

- Staff of community-based organizations (CBOs)
- Providers of HIV and STD prevention and treatment services to the target population
- Members of community advisory boards
- Researchers whose work focuses on the target population
- Political leaders and government officials
- Police and law enforcement officials

NHBS-IDU only:

- Persons who inject drugs
- Staff of substance abuse treatment programs
- Staff of syringe exchange programs

NHBS-HET only:

- Residents of HRAs

When garnering support from stakeholders, project sites should explain the goals and objectives of NHBS and describe its data collection methods. Project sites should emphasize that the key objective of NHBS is to understand HIV and other health disparities in the target population in order to better serve their health needs and to guide the development and implementation of high impact HIV prevention programs for them.

6.2 Methods of Garnering Community Support

Project sites can garner community support through meetings with stakeholders, marketing materials, meetings with community advisory boards, and collaborations.

6.2a Meetings

Meetings with community stakeholders provide an opportunity for sites to explain the project, describe its goals, present findings from previous NHBS cycles, introduce staff members, share the project logo to increase brand recognition, and answer questions. Meetings can be one-on-one or involve multiple stakeholders. When meeting with multiple stakeholders, sites may want to conduct a more structured meeting with an agenda. To maximize participation at these meetings, sites should hold them in easily accessible locations at convenient times.

Project sites can also hold public meetings with the broader community or conduct community outreach at special events, such as health fairs. Public meetings could be held at the local community center or at a CBO. In addition, whenever sites interview key informants or conduct focus groups, they should use those meetings to garner support for the project as well.

6.2b Marketing materials

Sites should create a logo and marketing materials, like informational flyers or posters, to identify the project and promote community awareness of it. During primary data collection, stakeholders and members of the target population should be asked about the types of logos and marketing materials that would be most appealing to potential participants. They should also be asked about the most effective marketing strategies for reaching the local target population.

The logos and marketing materials developed by project sites should be culturally appropriate and respectful of the target population. Before logos and marketing materials are printed and distributed, they must be reviewed by the local program review panel and the site's CDC project officer, and approvals must be obtained. Of particular importance, sites should not include the CDC logo or name on any of their marketing materials.

Facebook and social media

If project sites wish to use Facebook to market NHBS, they should create a Facebook Page. With a Facebook Page, sites can control privacy settings and ensure that the page adheres to local policies regarding content and the handling of user comments. Sites should note that NHBS-related content posted on social media sites should be treated the same as all other NHBS marketing materials; the content must be reviewed by the local program review panel and the site's CDC project officer, and it should not display the CDC logo or name. Information from CDC on social media tools, guidelines, and best practices for public health can be found at: www.cdc.gov/SocialMedia/Tools/guidelines.

6.2c Community advisory boards

Another means of garnering support for NHBS is through meetings with health department community advisory boards (CABs), such as the local HIV prevention planning group or HIV care consortium. Unlike other stakeholders, CAB members already have a vested interest in the health department's public health activities, and thus, would be ideal allies for NHBS. Project sites could introduce the project to their CABs, describe its goals, and present findings from previous cycles. CAB members, in turn, could become ambassadors for promoting the project in the target community and they could provide access to other stakeholders. Depending on their experience and expertise, CAB members may also be able to provide technical assistance and advice to sites.

6.2d Collaborations

Project sites should collaborate with CBOs, other health department programs that conduct HIV prevention outreach and research among the NHBS target population, and for **NHBS-IDU only**, syringe exchange programs and substance abuse treatment programs. Sites should meet with the managers of these organizations and programs to explain NHBS goals and objectives, the target population sampled, the overall methods and field operations, and discuss the opportunity to collaborate to provide appropriate referrals to health and social programs. These collaborations foster cooperation and positive community relations.

NHBS-HET only: Because the NHBS definition of heterosexuals at increased risk of HIV infection likely varies from that used by potential collaborators, it would be especially important to explain the NHBS definition to them. Project sites should explain the background of NHBS-HET, including the pilot cycle which guided the selection of the recruitment method and the analyses that led to the current HET definition. Information can be found in the *NHBS Round 4 Model Surveillance Protocol*, the MMWR Weekly Report entitled, *Characteristics Associated with HIV Infection Among Heterosexuals in Urban Areas with High AIDS Prevalence – 24 Cities, United States, 2006-2007*, and the DiNenno et al, 2012 publication *Piloting a system for behavioral surveillance among heterosexuals at increased risk of HIV in the United States* (see **Chapter 9** of this manual for complete references). Below is suggested language for these discussions:

The NHBS-HET pilot study was conducted in 2006 and 2007 to better define “heterosexuals at high risk of HIV infection” and to determine the best method of recruiting these individuals for the survey. The study enrolled more than 18,000 participants in cities across the United States that have high AIDS prevalence. Based on an examination of the predictor variables for newly diagnosed HIV infection among heterosexual participants, CDC and its local health department collaborators concluded that the definition of a heterosexual at increased risk of HIV infection should be a person with a disadvantaged socioeconomic status (SES), specifically a low income or limited

education. Subsequent NHBS-HET cycles would therefore focus on this population.

The NHBS-HET pilot study was an important step in the effort to better conceptualize heterosexual risk of HIV infection. Earlier research on the topic defined heterosexuals at risk solely on the basis of high risk sexual behavior, such as sex with multiple partners. Results from the pilot study, however, indicated that the definition of heterosexuals at risk should shift from individual-level risk behaviors to structural-level risks, like having a disadvantaged SES.

7.1 Overview

Ongoing formative assessment is the collection and examination of additional quantitative and qualitative data to improve field operations and ensure the successful recruitment and enrollment of participants. Project sites should conduct ongoing formative assessment throughout the survey data collection period to maintain community support, identify and address barriers to survey participation, and monitor participant enrollment and demographic characteristics. Project sites do not have to hire additional staff to conduct ongoing formative assessment. They can use their existing staff, including the project coordinator, field supervisor, interviewers, and data manager. Sites will receive further guidance on conducting ongoing formative assessment in the *NHBS Operations Manual*.

7.2 Data Collection Methods

To conduct ongoing formative assessment, sites should employ many of the same methods they used during formative assessment. These include data reviews, observations, interviews, and focus groups. Sites should always begin with the least labor-intensive and time-consuming methods (e.g., reviews of recruitment and enrollment data, observations, and informal conversations with participants and field staff) 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, street intercept surveys, and focus groups). Whenever sites 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.

7.3 Data Monitoring

Project sites should continuously monitor their recruitment, coupon distribution and demographic data to assess field operations and participant enrollment. Some specific problems that can be identified with these data include the following:

- **Enrollment.** Low or declining participant enrollment may be the first sign of a barrier to recruitment and survey participation. Project sites should evaluate strategies to improve participant enrollment, such as adding new seeds, changing the number of coupons, or strengthening recruiter training.
- **Coupon Distribution.** A low proportion of the distributed coupons that are returned indicates a barrier to survey participation, and thus, should be

evaluated further to identify the cause and to develop a solution. The number of coupons circulating in the community may also help project sites manage differential coupon distribution and the phasing out of coupons at the end of the project cycle. Software such as NetDraw may be used to assess the effectiveness of seeds and recruitment patterns and waves.

- **Demographics.** A sub-population will become underrepresented among enrollees when there is a participation barrier among that sub-population (e.g., young persons who inject drugs in NHBS-IDU). Recruitment of sub-populations that have been underrepresented in previous NHBS cycles should be closely monitored and barriers to participation should be further evaluated and addressed early in the recruitment process. Project sites should evaluate strategies to improve participant enrollment of these sub-populations, including adding new seeds, changing the number of coupons, ensuring available appointment slots for scheduling interviews, and strengthening recruiter training.

NHBS-IDU only:

- **Injection Drug Use.** A low proportion of participants who report injecting drugs in the past 12 months may indicate a need to improve recruiter training, so that participants recruit current persons who inject drugs. Furthermore, an extremely high or low proportion of participants who do not have signs of recent drug injection may indicate gaps in the interviewers' ability to assess signs of recent injection.

8

Formative Assessment Documents

8.1 Overview

As part of the formative assessment process, project sites are required to submit four documents to their CDC project officer: 1) the Implementation Timeline; 2) the Secondary Data Report; 3) for **NHBS-HET only**, the HRAs and Maps Report; and 4) the Primary Data Report. The purpose and content of each of these documents is described in this chapter and the due dates for submitting them to the site's CDC project officer are shown in the table below.

Document	Due to CDC Project Officer	Feedback Due to Site
Implementation Timeline	<i>Draft:</i> 3 rd Friday in January <i>Final:</i> 1 week after receiving feedback from the CDC project officer	Approximately 1 week after submission to the CDC project officer
Secondary Data Report	<i>Draft:</i> 2 nd Friday in February <i>Final:</i> 1 week after receiving feedback from the CDC project officer	Approximately 1 week after submission to the CDC project officer
NHBS-HET only: HRAs and Maps Report	<i>Draft:</i> 1 st Friday in March <i>Final:</i> 1 week after receiving feedback from the CDC project officer	Approximately 1 week after submission to the CDC project officer
Primary Data Report	<i>Draft:</i> 6 weeks after the CDC project officer has approved the Secondary Data Report (including the Primary Data Collection Plan) <i>or</i> 6 weeks after local IRB approval has been received, whichever is later <i>Final:</i> 2 weeks after receiving feedback from the CDC project officer	Approximately 1 week after submission to the CDC project officer

After the formative assessment documents have been submitted, the site's CDC project officer will review them to ensure that they contain the information needed to effectively manage and conduct NHBS locally. The CDC project officer will then provide feedback to the site, and the site will be responsible for revising the documents to address any concerns. In these reports, project sites should not merely recount the information they have collected during formative assessment; they must also interpret the findings and explain how the findings will be used to guide operations.

8.2 Implementation Timeline

The Implementation Timeline will help project sites plan and manage formative assessment activities and other activities conducted in preparation for field operations. By completing these preparatory tasks on schedule, sites will have more time to collect survey data in the field.

Appendix B of this manual contains model Implementation Timelines for NHBS-IDU and NHBS-HET that project sites can customize for local use. Each timeline should show the period when tasks will be performed and the dates when they will be completed. The following items should be included on the timeline:

- IRB package
- Secondary data review and report
- HRA identification, mapping, and report
- Primary data collection and report
- Local questionnaire development
- Field site identification
- Field staff hiring and training
- Acquisition of incentives and supplies
- Seed identification and recruitment
- Operations Checklist
- Start of survey data collection

The timeline should also include any other tasks that may impact formative assessment or preparation for field operations, especially those tasks that have delayed the start of survey data collection in the past. If the timeline has to be modified after it has been submitted, project sites should discuss the needed changes with their CDC project officer and send a revised timeline to them.

8.3 Secondary Data Report

The Secondary Data Report summarizes the findings from the secondary data review and is composed of three sections: 1) the Secondary Data Core Document, which describes the general characteristics of adults residing in the principal city of the funded metropolitan statistical area (MSA) or MSA Division; 2) the Population-specific Document, which describes the target population in the principal city; and 3) the Primary Data Collection Plan, which outlines the project site's plans for collecting primary data during the second phase of formative assessment. Possible sources of secondary data are listed in **Section 3.2** of this manual.

Project sites should structure the Secondary Data Report according to the following outline:

I. Secondary Data Core Document

1. Structural and Contextual Factors (2-3 pages)

2. Demographic Characteristics (1 page)

Table 1. Characteristics of the adult population

3. HIV Epidemic (1 page)

Table 2. New HIV diagnoses among adults

II. Population-specific Document

1. HIV Epidemic among the target population (1 page)

Table 3. New HIV diagnoses among the target population

Table 4. HIV-positive test results and HIV prevalence among the target population

2. Demographic Characteristics of the target population (1 page)

Table 5. Characteristics of the target population in previous NHBS cycles

3. Barriers to Participation in previous NHBS cycles (2-4 pages)

III. Primary Data Collection Plan (1-2 pages)

Sites should use the titles in the outline to label each part of the report, specify the target population based on the cycle (IDU or HET), and try to adhere to the recommended number of pages listed for each part. References should be provided for the sources of all data included in the report.

8.3a Secondary Data Core Document

The Secondary Data Core Document provides an overview of the principal city's structural and contextual factors, demographic characteristics, and HIV epidemic. If it is more appropriate, project sites may base this document on the entire MSA or MSA Division rather than just the principal city. The Secondary Data Core Document is produced during the first year of each new funding period, and as such, will have to be

written during the NHBS-HET4 cycle. If in a later year there are any substantial changes to the information in the document that could affect field operations, sites should update the document to note the changes. For example, if redevelopment in a project area has resulted in a major population change of residents in that area, the site should add a notation to their Secondary Data Core Document to highlight this important information:

***NHBS-IDU Update:** Gentrification in the past few years in the west side of the city has pushed drug markets and locations where persons who inject drugs congregate to the east side.*

Although the Secondary Data Core Document is only produced during the first year of the funding period, a copy should be included in the Secondary Data Report every year.

Part 1 – Structural and Contextual Factors

In the first part of the Secondary Data Core Document, project sites should report any structural and contextual factors in the principal city that could impact field operations, like:

- Geographic region
- Weather
- Housing (specifically, as it relates to the NHBS target populations)
- Education and literacy
- Socioeconomic status and poverty
- Sex work
- Laws that may impact HIV transmission or prevention (e.g., HIV testing laws, laws related to injection drug use and sex work, criminalization of HIV transmission)
- Stigma and discrimination toward high-risk populations
- Stigma and discrimination toward individuals living with HIV
- Neighborhood violence, gangs, and drug presence as it relates to field operations
- Prevention and care for HIV infection and substance use
- Other factors that could adversely impact field operations

Part 2 – Demographic Characteristics

The next part of the Secondary Data Core Document describes the demographic characteristics of the adult residents of the principal city. Project sites should complete **Table 1 (Appendix C)** using Census Bureau data and discuss the findings in this part of

the Secondary Data Core Document. Sites may customize **Table 1** to add other demographic and socioeconomic variables that are important to their principal city.

Part 3 – HIV Epidemic

The third part of the Secondary Data Core Document summarizes the demographic characteristics and transmission categories of adults diagnosed with HIV infection in the principal city. In the report, project sites should be sure to indicate which sub-populations are most impacted by the HIV epidemic in their localities. Sites should complete **Table 2 (Appendix C)** using HIV Surveillance System data and describe the findings. To show the geographic distribution of HIV cases in their locality, sites should include a geographic variable, such as county, district, or neighborhood, in the table. They may select whichever geographic variable they believe would be most helpful. Socioeconomic characteristics, like education and income, should be included as well if these data are collected in the local surveillance system. The HIV Surveillance System data needed for **Table 2** are outlined in **Section 3.2a** of this manual. If sites wish, they have the option of including additional tables of HIV surveillance data, like a table of trends in HIV diagnoses or a table of recent HIV diagnoses. Tables such as these could help sites identify emerging trends in the HIV epidemic.

8.3b Population-specific Document

The Population-specific Document provides detailed information about the HIV epidemic among the target population in the principal city, either persons who inject drugs or heterosexuals at increased risk for HIV. Furthermore, the Population-specific Document describes the demographic characteristics of NHBS-IDU or NHBS-HET participants in prior cycles, as well as barriers to survey participation during these cycles. As with the Secondary Data Core Document, project sites may base this document on the entire MSA or MSA Division rather than just the principal city if it is more appropriate to do so.

Part 1 – HIV Epidemic among the Target Population

The first part of the Population-specific Document describes the demographic characteristics of members of the target population who were diagnosed with HIV infection in the principal city. Project sites should complete **Table 3** using HIV Surveillance System data and complete **Table 4** using NHBS data (both tables are provided in **Appendix C**). The HIV Surveillance System data included in **Table 3** should be restricted to persons whose transmission category is injection drug use or heterosexual contact, depending on the NHBS cycle.

NHBS-IDU only: HIV risk for persons whose transmission category is male-to-male sexual contact *and* injection drug use (MSM-IDU) may be different from other persons who inject drugs. If the MSM-IDU transmission category is relevant to the HIV epidemic in the MSA or Division, project sites may include HIV surveillance data for MSM-IDU in **Table 3** or produce a separate table with these data.

Project sites may also include additional tables of HIV surveillance data, like trends in diagnoses or recent diagnoses, or they could include tables showing HIV prevalence data from other studies conducted among the target population in the project area. Data from the sexually transmitted disease (STD) and hepatitis surveillance systems may provide further insight into the characteristics of those who are engaging in sexual risk behaviors and may be at increased risk for HIV infection.

In their discussion of the HIV epidemic among the target population, project sites should indicate which sub-populations are most highly impacted by the epidemic in both absolute terms (i.e., number of HIV diagnoses in the HIV Surveillance System) and relative terms (i.e., HIV prevalence in NHBS and other studies).

Part 2 – Demographic Characteristics of the Target Population

The second part of the Population-specific Document is a summary of the demographic characteristics of participants recruited in previous NHBS-IDU or NHBS-HET cycles. Project sites should complete **Table 5 (Appendix C)** using data from each of the prior NHBS-IDU or NHBS-HET cycles and describe the findings. Sites should also compare the characteristics of participants enrolled in NHBS with the characteristics of those diagnosed with HIV infection (**Tables 3 and 4**) and assess how well NHBS participants have represented the sub-populations most highly impacted by the HIV epidemic.

NHBS-IDU only: In **Table 5**, project sites may include a stratum (row) for MSM-IDU data if it is relevant to the local HIV epidemic.



To further understand characteristics of sub-populations that have been underrepresented in previous NHBS cycles, sites may also consider conducting additional analyses to describe these sub-populations. For example, if young persons have been underrepresented in previous NHBS-IDU cycles, sites could compare younger persons to older persons by key characteristics, such as gender, race/ethnicity, geography, and type of drug injected most often. A table summarizing these additional analyses should be included in the Population-specific Document. Sites may wish to modify **Table 5** for this purpose, with the columns representing the sub-populations being compared (e.g., younger persons vs. older persons).

Part 3 – Barriers to Participation in NHBS

The third part of the Population-specific Document is a discussion of the barriers to survey participation that project sites experienced during previous NHBS cycles, especially barriers to participation by important sub-populations that have been underrepresented in the past (e.g., young persons in NHBS-IDU and Hispanics in NHBS-HET). Sites should review their past NHBS formative assessment reports, findings from ongoing formative assessment, and recruitment monitoring reports to identify recruitment and enrollment challenges and successes from prior cycles. Other studies in the project

area may provide additional information on possible barriers to participation in surveys, research, and HIV testing.

When discussing challenges and successes to recruitment and enrollment, project sites should describe the individual-level and community-level motivators and challenges they identified during the previous NHBS cycles. Areas of consideration include:

- Project marketing
- Peer-recruiter training
- Field site locations
- Days and hours of field site operation
- Peer network characteristics (e.g., network size, insularity, and demographic composition)
- Incentive type and amount
- HIV testing method
- Participant time commitment
- HIV apathy
- Research fatigue or distrust

Sites should also describe any actions they took in previous NHBS cycles to address barriers to recruitment and participation, and report the results of those interventions. Additional areas to examine are barriers to participation by sub-populations that were underrepresented in previous NHBS cycles (e.g., young persons in NHBS-IDU and Hispanics in NHBS-HET). After summarizing the findings from their review, sites should discuss the gaps in information that they will explore during primary data collection.

8.3c Primary Data Collection Plan

Based on the findings from their secondary data review and the gaps in information identified, project sites should develop a plan for primary data collection. The plan should focus on the following topics:

- Garnering community support
- Identifying field site locations and hours of operation
- Identifying and recruiting seeds
- Identifying and addressing barriers to survey participation
- Identifying and addressing obstacles to field operations

In the plan, project sites should summarize the additional information they need to obtain during the second phase of formative assessment and they should describe the methods they will use to collect the data, such as key informant interviews, focus groups, observations, and street intercept surveys.

For the final component of the primary data collection plan, project sites should attach a copy of their interview guide for key informant interviews and focus groups. If applicable, they should include questionnaires for street intercept surveys as well. **Appendix A** of this manual contains a list of formative assessment topics and example interview questions that sites can use to develop their own interview guides and street intercept surveys.

8.4 NHBS-HET only: High Risk Areas and Maps Report

As described in **Chapter 4** of this manual, HRAs are defined as the 25% of census tracts in a project site's MSA or Division that have the highest proportion of residents who live below the Census Bureau's poverty threshold. Project sites should create maps of their HRAs and other relevant information to determine the best locations for field sites and to identify neighborhoods where seeds can be recruited. The HRAs and Maps Report summarizes the findings from the analysis of these maps and describes how this information will be used for project operations.

Project sites should structure the HRAs and Maps Report according to the following outline:

- I. Map Statistics** (*< 1/2 page*)
- II. Map Findings** (*1-2 pages*)
- III. Maps**
 - Map 1a. HRA Map of MSA/Division** (*Required*)
 - Map 1b. HRA Map of Principal City** (*Required*)
 - Map 2a. Race/Ethnicity Map for Blacks** (*Required*)
 - Map 2b. Race/Ethnicity Map for Hispanics** (*Required*)
 - Map 3. HIV Case Surveillance Map** (*Recommended*)
 - Map 4. NHBS-HET Map** (*Recommended*)

Sites should use the titles in the outline to label each part of the report and they should try to adhere to the recommended number of pages listed for each part.

8.4a Map Statistics

In the first part of the HRAs and Maps Report, project sites should list the statistics for the maps included in the report. Sites may wish to provide this information in a table or in a bulleted list. For the HRA maps, sites should state the total number of census tracts

in the MSA or Division and the number of tracts that are HRA tracts. Sites should also state the median, minimum, and maximum poverty rates (proportion of residents living below the poverty threshold) for those census tracts that are HRA tracts.



If a project site creates an HIV case surveillance map, they should indicate the total number of new HIV cases among heterosexuals in the principal city during 2010-2014, along with the number and proportion of new cases that could be geocoded and included on the map. Similarly, if a site creates an NHBS-HET map, they should indicate the total number of NHBS-HET participants who were eligible, completed an interview, and met the HET definition, as well as the number and proportion of these participants whose census tract of residence could be geocoded and mapped.

8.4b Map Findings

The second part of the HRAs and Maps Report summarizes the findings from the project site's analysis of their maps. In this part of the report, sites should identify the following:

- Areas of the MSA or Division that constitute the HRA
- Neighborhoods or sections of the principal city with the highest poverty rates
- Neighborhoods or sections of the principal city with the highest proportions of black residents
- Neighborhoods or sections of the principal city with the highest proportions of Hispanic residents
- If an HIV case surveillance map is created, neighborhoods or sections of the principal city most heavily impacted by the HIV epidemic among heterosexuals

In addition, if an NHBS-HET map is created, project sites should compare this map with their HRA, race/ethnicity, and HIV case surveillance maps to determine how well participants have represented the communities at greatest risk of HIV infection. They should also explain how the location of field sites may have helped or hindered representation.

Project sites should triangulate the information on their maps to identify the optimal areas for locating field sites and selecting seeds, and they should describe these findings in the report. They should also discuss how the locations of field sites could present potential barriers to participation and identify how these barriers could be overcome. For example, if Hispanics are disproportionately impacted by the HIV epidemic in a project site, but they were underrepresented among participants in the previous NHBS-HET cycle, the project site could use its race/ethnicity map for Hispanics to determine the best location for a field site that is readily accessible to Hispanics.



If data from just a small proportion of new HIV cases or NHBS-HET participants could be geocoded and included on the HIV case surveillance or NHBS-HET maps, project site should interpret the findings from the maps with caution.

8.4c Maps

The last part of the HRAs and Maps Report contains the required and recommended maps. **Chapter 4** of this manual provides a description of each map and instructions for creating it. In addition to the maps listed, project sites may create any other maps that they think would help with the planning of project operations.

8.5 Primary Data Report

The Primary Data Report consists of two sections: 1) the Primary Data Core Document, which summarizes the findings from primary data collection and 2) the Ongoing Formative Assessment Plan, which outlines the project site's plans for conducting additional formative assessment activities after the start of field operations. Sources of primary data and methods of data collection are provided in **Sections 5.5** and **5.6** of this manual, respectively.

Project sites should structure the Primary Data Report according to the following outline:

I. Primary Data Core Document

- 1. Methods** (1-2 pages)
- 2. Garnering Community Support for NHBS** (1-2 pages)
- 3. Field Site Logistics and Seed Characteristics** (1-3 pages)
- 4. Barriers to Participation in NHBS** (3-5 pages)
- 5. Obstacles to Field Operations in NHBS** (1-3 pages)

II. Ongoing Formative Assessment Plan (1 page)

Sites should use the titles in the outline to label each part of the report and they should try to adhere to the recommended number of pages listed for each part.

8.5a Primary Data Core Document

The Primary Data Core Document provides a brief overview of the methods used for primary data collection, along with an in-depth discussion of the findings on garnering community support, field site logistics and seed characteristics, barriers to survey participation, and obstacles to field operations.

Part 1 – Methods

The first part of the Primary Data Core Document summarizes how the primary data were collected. Project sites should describe the roles of staff members who gathered

information and conducted interviews, report the methods used to collect the data (e.g., key informant interviews, focus groups, observations, street intercept surveys), and describe the characteristics of those interviewed. Characteristics to include are:

- Age < 30 or ≥ 30
- Gender
- Race/ethnicity
- **NHBS-IDU only:** Type of drug injected
- **NHBS-HET only:** Resident of an HRA

Sites should differentiate between those who were interviewed as key informants, focus group members, or street intercepts. They should also note whether an individual provided information specifically on a sub-population that is disproportionately impacted by the HIV epidemic (e.g., black women in NHBS-HET) or was underrepresented in previous NHBS cycles (e.g., young persons in NHBS-IDU). When reporting the characteristics of those interviewed, sites may find it helpful to present the data in a table or set of tables.

Part 2 – Garnering Community Support for NHBS

The second part of the Primary Data Core Document focuses on garnering community support for NHBS (see **Chapter 6** of this manual). Project sites should describe their efforts to obtain support from both the community stakeholders and the broader target population. The discussion should include marketing strategies and materials recommended by the primary data sources and indicate which strategies will be adopted for NHBS. If any obstacles to garnering community support are identified, sites should explain how these obstacles will be overcome. Sites should also describe how they will promote NHBS among sub-populations that may have been underrepresented in previous NHBS cycles (e.g., young persons in NHBS-IDU and Hispanics in NHBS-HET).

Part 3 – Field Site Logistics and Seed Characteristics

In the third part of the Primary Data Core Document, project sites should summarize how their findings will be used to identify field site locations and determine other field site logistics, such as days and hours of operation. They should also discuss how their findings will be used to determine the number and characteristics of seeds needed to ensure the successful recruitment of a diverse sample of participants. Sites should triangulate findings collected through primary data sources with those described in the Secondary Data Report, including data from previous NHBS cycles. In particular, if sites experienced difficulty with the recruitment of specific sub-populations, they should describe how field site logistics and seed characteristics will be used to help improve recruitment of these sub-populations. Specific topics to consider are:

- Field site location and type (i.e., storefront office or van)

- Number of field sites
- Days and hours of operation
- Appointment and walk-in systems for interviews
- Number of seeds
- Characteristics of seeds and their peer networks (e.g., network size, insularity, and demographic composition)

Part 4 – Barriers to Participation in NHBS

In the fourth part of the Primary Data Core Document, project sites should discuss potential barriers to recruitment and survey participation. The discussion should complement the findings on barriers to participation that were included in the Secondary Data Report. Unresolved barriers and gaps in information identified in the Secondary Data Report should be addressed in the Primary Data Report. Furthermore, sites should describe any additional recruitment and enrollment challenges identified by primary data sources and they should propose solutions based on their formative assessment findings. Specific topics to consider are:

- Project marketing
- Peer-recruiter training
- Field site logistics and seed characteristics (sites should focus on factors that were not discussed in Part 3 of the Primary Data Core Document)
- Incentive type and amount
- HIV testing method
- Participant time commitment
- HIV apathy
- Research fatigue or distrust

Sites should note whether any barriers to participation occurred in specific sub-populations, particularly those sub-populations most highly impacted by the HIV epidemic and those underrepresented in previous NHBS cycles (e.g., young persons in NHBS-IDU and Hispanics in NHBS-HET).

Part 5 – Obstacles to Field Operations in NHBS

In the fifth part of the Primary Data Core Document, project sites should describe any factors that may adversely affect their ability to effectively conduct field operations or enroll a diverse sample of participants. Examples of obstacles sites may encounter are safety concerns at field sites; logistical barriers to blood-based or rapid HIV testing; lack

of cooperation from CBOs, service providers, or local law enforcement agencies; and for **NHBS-IDU only**, a high number of persons misrepresenting their mode of drug use. For each obstacle identified, project sites should describe how they overcame that obstacle in previous cycles or plan on overcoming it in the current cycle. If there are potential obstacles that cannot be resolved, sites should explain why they are insurmountable.

8.5b Ongoing Formative Assessment Plan

Even after the start of field operations, project sites will have to continue to conduct certain formative assessment activities (see **Chapter 7** of this manual). These activities include:

- Maintaining community support
- Identifying and addressing barriers to recruitment and survey participation
- Monitoring enrollment among sub-populations that are most highly impacted by the HIV epidemic or were underrepresented in previous NHBS cycles

In the Ongoing Formative Assessment Plan, project sites should briefly describe how they will conduct the needed formative assessment activities. They should also indicate which staff members will carry out the activities.

9

References and Additional Resources

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Appendix A

Model Formative Assessment Topics and Interview Questions

Below is a list of model formative assessment topics and interview questions that project sites can use to develop interview guides and street intercept surveys. The Word file **Appendix A – Model Interview Questions.docx** contains a copy of the list that sites can modify for local use. Sites should adapt the questions to the type of interview being conducted and to the background of the individual(s) being interviewed. Sites can also modify the questions to focus on sub-populations, like young persons in NHBS-IDU or racial and ethnic minority groups in NHBS-HET.



The model interview questions use the term target population and specific sub-population. Please replace “target population” with some other locally-acceptable terminology. For example, in NHBS-IDU, project sites could use “people who inject drugs.” In NHBS-HET, when interviewing members of the target population (including community key informants), sites could use “people in your community;” and when interviewing professional staff, sites could use “socioeconomically disadvantaged people” or “low-income people.” Please replace the term “specific sub-population” with any sub-population that is at high risk for HIV or that has been underrepresented in previous NHBS cycles.

Before interviewing each primary data source, project sites should briefly describe NHBS, including the respondent-driven sampling (RDS) method and the process of recruiting survey participants through their peer networks.

A.1 Garnering Community Support

Project sites can modify these questions for local use to identify the target population’s stakeholders and to establish collaborations with other programs or organizations with similar research or services.

Identifying the target population’s stakeholders

- Who are the community leaders among *[target population]*?
 - Do they represent any specific sub-populations? *If yes:* What sub-populations do they represent?

- Which key individuals or groups provide services to *[target population]*?
 - Do they provide services to any specific sub-populations? *If yes:* To what sub-populations do they provide services?

- Which key individuals or groups advocate for issues affecting *[target population]*?
 - Do they advocate for any specific sub-populations? *If yes:* For what sub-populations do they advocate?
- Which key individuals or groups could advocate for our survey?
 - Who could promote our survey among *[target population/specific sub-population]*?
 - Who could promote our survey among: community leaders, service providers, and advocates?
- What is the best way for us to gain support for our survey?
 - What is the best way for us to gain support from *[target population/specific sub-population]*?
 - What is the best way for us to gain support from: community leaders, service providers, and advocates?
- What study findings would be beneficial to you or your organization?
 - Are there any key HIV risk or prevention topics that we should explore with local questions?

Establishing collaborations

- Is your program or organization currently conducting research among *[target population/specific sub-population]* in *[project area]*?
 - *If yes:* How can we coordinate so that we are not operating in the same location at the same time?
- Does your program or organization conduct prevention outreach or provide other health or social services to *[target population/specific sub-population]* in *[project area]*?
 - *If yes:* How can we collaborate so that appropriate referrals are provided to participants in our survey?

A.2 Learning about the Target Population and Sub-Populations

Project sites can modify these questions for local use to learn about demographic, peer network, and other key characteristics of the target population and specific sub-populations. This information will help sites develop and implement NHBS methods and field operations.

Demographics

- What are the demographic characteristics of *[target population/specific sub-population]* (e.g., age, race/ethnicity, gender, income, residence)?
- What specific sub-populations among *[target population]* are most important to the HIV prevention efforts in *[project area]*?
- How do the different sub-populations of *[target population]* interact with one another?
 - *For sub-populations that do not interact: Why not? How could this impact peer recruitment in our survey?*

Peer networks

NHBS-IDU only: A “peer network” in the NHBS-IDU cycle is defined as the group of people that a person knows in *[project area]* and who *also* inject drugs. This includes friends, relatives, sex and drug use partners, and other people with whom the person associates.

NHBS-HET only: A “peer network” in the NHBS-HET cycle is defined as the group of people that a person knows in *[project area]*. This includes friends, relatives, sex partners, and other people with whom the person associates.

- What are the typical demographic compositions of the peer networks of *[target population]*?
 - How do the demographic compositions of the peer networks vary among different sub-populations?
- What are the typical sizes of the peer networks of *[target population]*?
 - How do the sizes of the peer networks vary among different sub-populations?
- How could the demographic composition or size of the peer networks of *[target population/specific sub-population]* impact peer-recruitment in our survey? For example, if black and white people do not associate with one another, efforts will be needed to ensure that black and white seeds are selected and produce chains of peer recruits.

NHBS-IDU only: Drug use

- What are the major injection and non-injection drugs used by people who inject drugs in *[project area]*?

- Are the types of drugs used different for *[specific sub-population]*?
- What are the local terms or brand names used for different types of drugs?
- Within the past 12 months, have there been any new brand names on the drug market?
- Where do people who inject drugs live in *[project area]*?
 - Where do *[specific sub-population]* live?
- Where do people who inject drugs buy their drugs in *[project area]*?
 - Where do *[specific sub-population]* buy drugs?
- Where do people who inject drugs use their drugs in *[project area]*?
 - Where do *[specific sub-population]* use drugs?
- Where do people who inject drugs obtain new, sterile needles and syringes in *[project area]*?
 - Where do *[specific sub-population]* obtain new, sterile needles and syringes?

NHBS-IDU only: Syringe exchange programs

- Do syringe exchange programs operate in *[project area]*? *If yes: Where?*
 - What are the demographic and drug use characteristics of the syringe exchange program attendees?
- What are the local and state laws prohibiting or permitting syringe exchange in *[project area]*?

NHBS-IDU only: Signs and knowledge of drug injection

- What is the local terminology used to talk about drugs and drug paraphernalia in *[project area]*?
- What criteria should we use to determine if someone injects drugs or not?
 - What physical signs should we look for?
 - How can we distinguish between current and past drug injection?
- How is *[drug type]* prepared for injection? How is it injected?

A.3 Exploring Field Operations

Project sites can modify these questions for local use to ensure successful field operations by assessing the feasibility of potential field site locations and hours of operation; identifying acceptable incentives for the survey and HIV test; determining ideal staff characteristics; and identifying which local prevention, health care, and social services are available for making referrals and linkages to care.

Field site locations and hours of operation

- Do you know of an appropriate office space or storefront where we can conduct this survey in *[project area]*?
- We're thinking of using *[proposed field site location]* as a survey site.
 - Would *[target population/specific sub-population]* feel comfortable going there to do an interview? *If no:* Why not?
 - Is *[proposed field site location]* accessible to *[target population/specific sub-population]*?
 - Is the area around *[proposed field site location]* safe for participants and project staff?
 - Are the people in the area around *[proposed field site location]* accepting of *[target population/specific sub-population]*?
 - What kinds of barriers would keep *[target population/specific sub-population]* from coming to *[proposed field site location]* for an interview?
 - What could we do to make it easier or more appealing for *[target population/specific sub-population]* to come to this site?
- What days of the week and times of the day would be best for *[target population/specific sub-population]* to go to *[proposed field site location]* to do an interview?
- Should we set up appointments for participants to do the interview or should we allow them to walk-in anytime during operating hours?

Incentives

- We will give participants an incentive for completing the survey and another incentive for taking the HIV test. The survey takes approximately 40 minutes to complete and the HIV test, 20 minutes. What would appropriate incentive amounts be for each?

- What type of incentive, like cash, Visa gift card, or retail gift card, would be most desirable to the participants?

Staffing

- What criteria should we consider when hiring survey staff to work with *[target population/specific sub-population]*?
- What are the characteristics of the ideal interviewer for this project?

Names of local public health insurance programs

This information is collected to help interviewers code the types of public health insurance reported by participants.

- What are the names of the public health insurance programs that are available in *[project area]*? Are there acronyms or “street names” for these programs?

Local prevention and social services

- We provide referrals to our survey participants for a variety of HIV prevention, health care, and social services. What HIV prevention, health care, or social service information would be most helpful to provide to *[target population/specific sub-population]*?
- We also provide linkage to HIV care and treatment services. For participants who test positive for HIV, where would *[target population/specific sub-population]* feel comfortable going for HIV care and treatment?

A.4 Identifying and Addressing Barriers to Survey Participation

Project sites can modify these questions for local use to identify barriers to survey participation and HIV testing. Whenever a primary data source identifies a barrier to survey participation, project sites should follow-up and ask the source to propose a solution to overcome that barrier.

General

- What are the barriers to *[target population]* participating in our survey or testing for HIV?
 - What suggestions do you have for overcoming these barriers?

- Are there any barriers to survey participation that are specific to any sub-populations?
(*This question is particularly important if any sub-populations were underrepresented in previous NHBS cycles [e.g., young persons in NHBS-IDU or Hispanics in NHBS-HET].*)
 - What suggestions do you have for overcoming these barriers?
- What challenges have you encountered when working with **[target population/specific sub-population]**? (e.g., trust, HIV testing, incentive type or amount, field site location, community support)?
 - How do you think these challenges will affect the success of our survey?
 - What suggestions do you have for overcoming these challenges?
- How can we foster trust among **[target population/specific sub-population]**?
 - Do **[target population/specific sub-population]** perceive researchers or other community outsiders differently?
- How can we motivate **[target population/specific sub-population]** to participate in our survey?

HIV testing, additional testing and blood specimen for future testing

- What are the perceptions of HIV testing among **[target population/specific sub-population]**?
 - Is there stigma or fear about being tested?
 - What are the barriers to using **[testing method]** HIV tests?
 - Would **[target population/specific sub-population]** avoid participating in the survey if HIV testing is offered?
 - What suggestions do you have for overcoming barriers to HIV testing in **[target population/specific sub-population]**?
- What are the perceptions of HIV-positive persons among **[target population/specific sub-population]**?
 - Is there stigma or fear about disclosing an HIV-positive status?
 - What suggestions do you have for overcoming barriers to disclosing an HIV-positive status among **[target population/specific sub-population]**?
- *For sites that plan on offering additional tests:* In addition to the HIV test, we plan on offering **[types of tests]**.
 - How will these tests be perceived by **[target population/specific sub-population]**?

- Will these tests present a barrier to participation in our survey or will they motivate *[target population/specific sub-population]* to participate?
If yes to barriers: Please describe the specific barriers. What suggestions do you have for overcoming these barriers?
If yes to motivation: Please describe specific ways in which these additional tests will help motivate *[target population/specific sub-population]* to participate.
- *For sites that plan on collecting blood specimens for long-term storage for future testing:* We plan on collecting blood specimens for long-term storage for future testing.
 - How will the collection of blood specimens for long-term storage and future testing be perceived by *[target population/specific sub-population]*?
 - What are the barriers to agreeing to provide blood specimens for long-term storage and future testing? What suggestions do you have for overcoming these barriers?

Appendix B

Model Implementation Timelines

Model Implementation Timelines for the NHBS-IDU and NHBS-HET cycles are shown below. The actual forms can be modified using the Excel file named **Appendix B – Model Implementation Timelines.xlsx**.

Model NHBS-IDU4 Implementation Timeline:

Task	Due Date	2014			2015														
		December	January	February	March	April	May	June											
Develop Implementation Timeline																			
Submit Implementation Timeline	1/16																		
Prepare IRB package																			
Submit IRB package	1/9																		
Obtain IRB approval	2/20																		
Review secondary data																			
Write Secondary Data Report																			
Submit Secondary Data Report	2/13																		
Collect primary data																			
Write Primary Data Report																			
Submit Primary Data Report	4/3																		
Identify field site location(s)																			
Hire field staff																			
Train field staff																			
Obtain incentives																			
Obtain testing/other supplies																			
Develop local questions																			
Complete Operations Checklist																			
Submit Operations Checklist	5/18																		
Identify and recruit seeds																			
Start survey data collection	6/1																		

Appendix C

Shells for Tables 1 to 5

As described in **Section 8.3** of this manual, the Secondary Data Report must include the following five tables:

Table 1. Characteristics of the adult population

Table 2. New HIV diagnoses among adults

Table 3. New HIV diagnoses among the target population

Table 4. HIV-positive test results and HIV prevalence among the target population

Table 5. Characteristics of the target population in previous NHBS cycles

Shells for the five tables are illustrated below. The Excel file **Appendix C – Tables 1 to 5.xlsx** contains the actual table shells which project sites can modify if necessary and then complete with the required data. The data source for each of the five tables is listed below.

Table	Data Source
1	Census Bureau (including American Community Survey) and other population-based surveys
2	HIV Surveillance System
3	HIV Surveillance System
4	Previous NHBS data and any other local HIV prevalence studies among the target population
5	Previous NHBS data

Table 1. Characteristics of the adult population in [principal city, metropolitan statistical area (MSA), or MSA Division], [data source], [year(s)]*

CHARACTERISTIC**	Female n (%)	Male n (%)	Total n (%)
Face/Ethnicity			
American Indian/Alaska Native			
Asian			
Native Hawaiian/Pacific Islander			
Black			
Hispanic			
White			
Multiple			
Age group (years)			
18 – 19			
20 – 24			
25 – 29			
30 – 34			
35 – 39			
40 – 44			
45 – 49			
50 – 59			
≥ 60			
Highest level of education completed			
< High school			
High school diploma or equivalent			
Some college or technical degree			
College degree or post-graduate education			
Annual household income			
\$0 – \$19,999			
\$20,000 – \$39,999			
\$40,000 – \$74,999			
≥ \$75,000			
Poverty status			
At or below poverty limit			
Above poverty limit			
Health insurance***			
None			
Private only			
Public only			
Other			
Employment status***			
Employed full-time			
Employed part-time			
Unemployed			
Disabled			
Full-time student			
Other			
TOTAL			

NOTE: The proportions in the table are column percentages.

*Indicate the project area, the source of the data, and the year(s) the data were collected.

**Categories may be modified as necessary based on the data available or collapsed due to small cell sizes.

***If the data are available.

Table 2. New HIV diagnoses among adults in [principal city, metropolitan statistical area (MSA), or MSA Division], by selected characteristics, HIV Surveillance System, [years]*

CHARACTERISTIC**	Female n (%)	Male n (%)	Total n (%)
Race/Ethnicity			
American Indian/Alaska Native			
Asian			
Native Hawaiian/Pacific Islander			
Black			
Hispanic			
White			
Multiple			
Age group (years)			
18 – 19			
20 – 24			
25 – 29			
30 – 34			
35 – 39			
40 – 44			
45 – 49			
50 – 59			
≥ 60			
Country of birth			
United States			
Other			
[Geographic variable (e.g., county, district, or neighborhood)]***			
<i>[Selected categories...]</i>			
Highest level of education completed***			
< High school			
High school diploma or equivalent			
Some college or technical degree			
College degree or post-graduate education			
Annual household income***			
\$0 – \$19,999			
\$20,000 – \$39,999			
\$40,000 – \$74,999			
≥ \$75,000			
Transmission category			
Male-to-male sexual contact			
Injection drug use (IDU)			
Heterosexual contact			
Male-to-male sexual contact and IDU			
Other			
TOTAL			

NOTE: The proportions in the table are column percentages.

*Indicate the project area and the years the data were collected.

**Categories may be modified as necessary based on the data available or collapsed due to small cell sizes.

***If the data are available.

Table 3. New HIV diagnoses among [target population] in [principal city, metropolitan statistical area (MSA), or MSA Division], by selected characteristics, HIV Surveillance System, [years]*

CHARACTERISTIC**	Female n (%)	Male n (%)	Total n (%)
Race/Ethnicity			
American Indian/Alaska Native			
Asian			
Native Hawaiian/Pacific Islander			
Black			
Hispanic			
White			
Multiple			
Age group (years)			
18 – 19			
20 – 24			
25 – 29			
30 – 34			
35 – 39			
40 – 44			
45 – 49			
50 – 59			
≥ 60			
Country of birth			
United States			
Other			
[Geographic variable (e.g., county, district, or neighborhood)]***			
<i>[Selected categories...]</i>			
Highest level of education completed***			
< High school			
High school diploma or equivalent			
Some college or technical degree			
College degree or post-graduate education			
Annual household income***			
\$0 – \$19,999			
\$20,000 – \$39,999			
\$40,000 – \$74,999			
≥ \$75,000			
TOTAL			

NOTE: The proportions in the table are column percentages.

*Indicate the target population, the project area, and the years the data were collected.

**Categories may be modified as necessary based on the data available or collapsed due to small cell sizes.

***If the data are available.

Table 4. HIV-positive test results and HIV prevalence among [target population] in previous NHBS cycles and [other local studies] in [principal city, metropolitan statistical area (MSA), or MSA Division], by selected characteristics*

CHARACTERISTIC**	NHBS-[Cycle]1***		NHBS-[Cycle]2		NHBS-[Cycle]3		Other Study [dates]	
	HIV+ n (%)	HIV Prevalence (%)	HIV+ n (%)	HIV Prevalence (%)	HIV+ n (%)	HIV Prevalence (%)	HIV+ n (%)	HIV Prevalence (%)
Gender								
Male								
Female								
Race/Ethnicity								
American Indian/Alaska Native								
Asian								
Native Hawaiian/Pacific Islander								
Black								
Hispanic								
White								
Multiple								
Age group (years)								
18 – 19								
20 – 24								
25 – 29								
30 – 34								
35 – 39								
40 – 44								
45 – 49								
50 – 59								
≥ 60								
Country of birth								
United States								
Other								
[Geographic variable (e.g., county, district, or neighborhood)]***								
[selected categories...]								
Highest level of education completed								
< High school								
High school diploma or equivalent								
Some college or technical degree								
College degree or post-graduate education								
Annual household income								
\$0 – \$19,999								
\$20,000 – \$39,999								
\$40,000 – \$74,999								
≥ \$75,000								
For IDU Only: Drug injected most often								
Heroin								
Speedball								
Cocaine/Crack cocaine								
Methamphetamine								
Painkillers								
Other								
TOTAL								

NOTE: The numbers in the table are the numbers of confirmed HIV+ participants and the proportions are column percentages. HIV prevalence is a percentage calculated by dividing the number of confirmed HIV+ participants by the number of participants with a final HIV test result.

*Indicate the target population, the project area, and if applicable, the source(s) of the data from any other local studies.

**Categories may be modified as necessary based on the data available or collapsed due to small cell sizes.

***If the data are available.

Table 5. Characteristics of [target population] in previous NHBS cycles in [principal city, metropolitan statistical area (MSA), or MSA Division]*

CHARACTERISTIC**	NHBS-[Cycle]1 n (%)	NHBS-[Cycle]2 n (%)	NHBS-[Cycle]3 n (%)
Gender			
Male			
Female			
Race/Ethnicity			
American Indian/Alaska Native			
Asian			
Native Hawaiian/Pacific Islander			
Black			
Hispanic			
White			
Multiple			
Age group (years)			
18 – 19			
20 – 24			
25 – 29			
30 – 34			
35 – 39			
40 – 44			
45 – 49			
50 – 59			
≥ 60			
Country of birth			
United States			
Other			
[Geographic variable (e.g., county, district, or neighborhood)]*** [selected categories...]			
Highest level of education completed			
< High school			
High school diploma or equivalent			
Some college or technical degree			
College degree or post-graduate education			
Annual household income			
\$0 – \$19,999			
\$20,000 – \$39,999			
\$40,000 – \$74,999			
≥ \$75,000			
For IDU Only: Drug injected most often			
Heroin			
Speedball			
Cocaine/Crack cocaine			
Methamphetamine			
Painkillers			
Other			
TOTAL			

NOTE: The proportions in the table are column percentages.

*Indicate the target population and the project area.

**Categories may be modified as necessary based on the data available or collapsed due to small cell sizes.

***If the data are available.