

National HIV Behavioral Surveillance System

0920-0770

February 22, 2011

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests a revision and 3 year extension of the currently approved National HIV Behavioral Surveillance System (NHBS)(0920-0770, expiration date March 31, 2011). Interview data collection instruments were revised. The project activities and methods will remain the same as in the previously approved information collection request. The burden has not changed from the burden shown in the current inventory.

The following revisions were made to the OMB-approved project 0920-0770: (For detailed description, see Attachment 12)

- Modifying eligibility criteria for the men who have sex with men (MSM) cycle (see section A.2 for more detail)
- Renumbering the behavioral assessment so that each number is preceded by two letters indicating the section (e.g., DM-1 is the first question of the demographics section)
- Modifying the eligibility screener (4 questions added and 4 questions removed); some questions were moved from the behavioral assessment to the eligibility screener in order to assess eligibility using the modified criteria, and some questions were revised in order to improve respondents' understanding of the questions. These modifications are described in more detail in Attachment 12.
- Modifying the behavioral assessment (75 questions added and 80 questions removed); questions added were related to health care access and utilization, use of pre-exposure prophylaxis, homophobia, HIV stigma, and discrimination); questions were removed because they collect information that is no longer needed; some questions were revised from the previously approved instrument to make them easier for respondents to understand and respond appropriately. These modifications are described in more detail in Attachment 12.
- Adding an instrument to be used to debrief peer recruiters by asking 7 questions to assess coupon distribution and coupon refusal. This information will help assess non-response bias.

Background

Historically, surveillance to describe the HIV/AIDS epidemic in the United States has primarily involved reporting of HIV and AIDS cases, although some supplemental surveillance systems and surveys have been used to provide additional information about behaviors related to HIV infection. Because many years may pass between the time when a person is infected with HIV and the time that HIV infection is diagnosed, case surveillance for HIV infection and AIDS does not reflect recent trends in the behaviors that fuel the epidemic. Therefore, surveillance of HIV-related behaviors is an important component of an integrated surveillance system.

The need for a national behavioral surveillance system for persons at risk for HIV infection was articulated in CDC's HIV Prevention Strategic Plan. NHBS was designed to address this need. The purpose of NHBS is to provide ongoing, systematic collection of data on behaviors related to HIV acquisition. NHBS addresses the goal of strengthening the capacity nationwide to monitor the epidemic to better direct and evaluate prevention efforts.

The limitations of previous, locally-driven studies and the need to meet the goals of the HIV Prevention Strategic Plan led to the development of NHBS. Through NHBS, CDC works with state and local health departments to obtain HIV-related behavioral data from three groups at highest risk for infection: men who have sex with men, injecting drug users, and heterosexuals at increased risk.

More than 25 years into the HIV epidemic, there remains a critical need to understand HIV related risk behaviors and the reach of prevention to groups at high risk (Lansky, et al., 2010, see Attachment 17 for complete references). The rate of new HIV infections continues to be high: an estimated 56,300 Americans become infected with HIV each year. In order to target HIV prevention programs to populations most affected by HIV, CDC must continue to monitor the front line of the epidemic (those at highest risk for HIV) through NHBS.

CDC'S HIV/AIDS surveillance system is the nation's source for timely information used to track the epidemic (Lansky, et al., 2010). CDC funds and assists state and local health departments to collect the information. Health departments report their data to CDC so that information from around the country can be analyzed to determine who is being affected and why. The ultimate surveillance goal is a nationwide system that combines information on AIDS cases, new HIV infections, and behaviors and characteristics of people at high risk. By meeting this goal, CDC can track the epidemic and direct HIV prevention funding to where it is needed most. Continuing a specific behavioral surveillance component that is focused on populations at highest risk for HIV infection is consistent with the goals of HIV/AIDS surveillance.

Collection of HIV/AIDS surveillance data is regulated by Title III - General Powers and Duties of Public Health Service, Section 301 (241.)a. Research and investigations generally (Attachment 1a).

CDC awarded a contract in 2008 to maintain a Data Coordinating Center, which was operational as of January 2009. The Data Coordinating Center (DCC) is a system with a secure file data server where NHBS data are transmitted and stored securely. The DCC uses the secure data transfer algorithm, FIPS 140-2 (Federal Information Processing Standards Publication). The data transfer methodology is compliant with the guidelines set forth in OMB memorandum M-0404 (E-Authentication Guidance for Federal Agencies) as well as with OMB, HHS, and CDC Certification and Accreditation Guidelines outlined in NIST SP 800-37 (Guide for the Security Certification and Accreditation of Federal Information Systems). The DCC has received approval through the Certification and Accreditation process (Attachment 1b). In addition to the technical requirements listed above, data management processes are in compliance with *The Guidelines for HIV/AIDS Surveillance - Security and Confidentiality*.

Privacy Impact Assessment

The previously approved data collection was assessed for privacy impact.

Overview of the Data Collection System

A total of 25 project areas are eligible to apply for NHBS.

NHBS sites comprise the state and local health departments with the highest AIDS prevalence, limiting eligibility to one metropolitan statistical area (MSA) or Division per health department jurisdiction. These partners are funded to collect all data for NHBS.

The overall strategy for NHBS involves conducting rotating 12-month cycles of data collection among three populations: men who have sex with men (MSM), injecting drug users (IDU) and heterosexuals at increased risk (HET) in the selected MSAs. During the MSM cycle of NHBS, venue-based sampling will be used to recruit participants for an interviewer-administered, face-to-face, computer-assisted behavioral assessment. Venues eligible for consideration include bars, dance clubs, retail businesses, cafes and restaurants, health clubs, social and religious organizations, adult bookstores and bathhouses, high-traffic street locations, parks, beaches, and special events such as gay pride festivals, raves, and circuit parties. During the IDU and HET cycles of NHBS, respondent-driven sampling (RDS) will be used to recruit participants for an interviewer-administered, face-to-face, computer-assisted behavioral assessment. Except for a few initial ("seed") recruits, persons will be recruited by peers for participation in the IDU and HET cycles of NHBS.

Regardless of the cycle, for each person recruited, a short computer-based eligibility screening survey will be administered by an interviewer to assess eligibility and collect limited demographic information (Attachment 2a). If the respondent is eligible for the survey and consents to an interview, the interviewer will administer the behavioral assessment (Attachment 2b-d, depending on cycle). For the IDU and HET cycles, in which respondent-driven sampling is used, after the interview, the interviewer will train the respondent to recruit up to five of his peers. The recruiter will be offered a small reward for each person recruited. When he returns to the field site, he will be debriefed using a computer-assisted, interviewer-administered recruiter debriefing instrument (Attachment 2e). This instrument collects information about those who refused recruitment attempts. Each of these data collection instruments is also available in Spanish (Attachments 3a-e).

Data are collected by trained health department personnel through face-to-face interaction with participants. Interviewers collect the data using a software application

loaded onto handheld or laptop computers. Response data are encrypted and computers used for data collection are password protected so that unauthorized users will be unable to view, export, or modify collected data. Electronic data collected for NHBS are maintained indefinitely at CDC. The survey is anonymous; no names or phone numbers are collected.

Items of information to be collected

Eligibility Screener

Data collected using the eligibility screener will include age calculated from date of birth, race/ethnicity, previous participation, county of residence and length of time residing there, and gender (Attachment 2a). For the MSM cycle, eligibility will be determined by whether the participant has ever had oral or anal sex with a male partner. For the IDU and HET cycles, eligibility will be determined by (for IDU) whether the participant has injected drugs in the past 12 months or (for HET) whether they have had sex with at least one partner of the opposite sex in the previous 12 months.

Behavioral Assessment Interview

The NHBS interview collects data on demographics, access to health care, HIV testing, sexual behavior, substance use, and access to HIV prevention services. (Attachment 2b-d).

Peer Recruitment Debriefing

The items in the peer recruitment debriefing instrument include the number of coupons the recruiter has distributed, whether anyone has refused the coupons, the race/ethnicity of those refusing coupons, and the reason for refusal (Attachment 2e).

The only information collected in identifiable format is date of birth, which is collected through the eligibility screener. Date of birth is being collected for two reasons: first, it is used to determine eligibility for the NHBS survey. Second, it is used to identify potential duplicate records or participants who have been interviewed more than once per cycle. Date of birth is sent to CDC, but is not shared beyond the CDC team conducting the data collection (i.e., it is not included in analysis datasets). No other information in identifiable form (IIF) is being collected

for NHBS interview. Therefore, individuals cannot be indirectly identified through NHBS data.

Data collected through NHBS, both locally and at CDC, are stored and accessed by a survey identification number. Other data collected through NHBS, while sensitive, are not personally identifying; these survey questions are described in Appendix 2b. The sensitive information collected will not be linked to any other personal identifiable information and cannot be used to reveal the identity of any one person. There is no link to any name, either locally or at CDC, and data will not be collected on paper forms.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The information collection system will not involve a web-based data collection method, nor will it host a website. There is no website content directed at children under 13 years of age.

2. Purpose and Use of Information Collection

The primary objective of NHBS is to conduct behavioral surveillance among persons at high risk for HIV infection in the United States in order to assess prevalence of and trends in: 1) risk behaviors for HIV infection, 2) HIV testing behaviors, 3) HIV seroprevalence and incidence, and 4) exposure to, use of, and impact of HIV prevention services. The focus of NHBS is on behaviors directly related to transmission and those that are amenable to intervention through prevention programs. The explicit ability to identify gaps in HIV prevention services for HET, MSM, and IDU is a unique aspect of NHBS. CDC has two data collections related to NHBS: the Transgender HIV Behavioral Survey (THBS, OMB # 0920-0794 exp. 12/31/2010) and the Behavioral Assessment and Rapid HIV Testing (BART) Project (OMB # 0920-10GT). These two projects share some elements with NHBS, but the data collections are focused on different populations. THBS's methods specifically target male-to-female transgender participants, whereas BART samples from attendees at social and cultural events in middle- to smaller-sized cities where a smaller catchment area and lower attendance at the venues renders the NHBS strategy inefficient.

At the national level, NHBS provides the evidence base for several policies and recommendations issued by CDC. NHBS data are useful for tracking national trends in risk behaviors, HIV testing, and prevention service access and utilization for focusing and prioritizing national initiatives to improve the provision of prevention services, and for evaluating progress towards national prevention initiatives. A large and geographically diverse sample that is obtained through NHBS provides an important data source for evaluating progress towards national public health goals, such as the following Healthy People 2020 goals related to HIV infection: reduce the number of new AIDS cases among adults and adolescents (1); reduce the number of new AIDS cases among adolescent and adult men who have sex with men (2); Reduce the number of new AIDS cases among adolescents and adults who inject drugs (3); increase the proportion of sexually active persons who use condoms (11); increase the number of seropositive persons who know they are infected (12); reduce the number of new AIDS cases among adolescent and adult heterosexuals (13); and increase the proportion of adults and adolescents who have been tested for HIV in the past 12 months (14).

National data are also relevant for evaluating prevention initiatives for persons at risk for HIV, as envisioned in CDC's HIV Prevention Strategic Plan goals for reducing the number of people at risk for transmitting HIV infection. Through NHBS, data on key indicators of behavioral risks for acquiring HIV infection as well as seroprevalence are available from multiple MSAs with high AIDS prevalence, and can be used to determine progress towards national goals for HIV prevention and identify populations in need of additional research, improved interventions, or additional funds to support prevention programs.

Data are also used at the national level to assess progress in performance goals of CDC's National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP):

1. Increase the proportion of people who consistently engage in behaviors that reduce risk of HIV transmission or acquisition (which specifically includes MSM, IDU, and at-risk, sexually active women and heterosexual men);
2. Develop an integrated monitoring system to measure incidence of new infections, track the prevalence of disease, monitor behaviors that increase the risk of

- HIV infection (for those who are HIV-uninfected);
3. Provide locally relevant data for community planning.

NHBS also addresses Goal 5 of the Government Performance and Results Act (GPRA): Strengthen the capacity nationwide to monitor the HIV/AIDS epidemic; develop and implement effective HIV prevention interventions; and evaluate prevention programs.

National data from NHBS are useful for documenting the need for prevention resources and the reach of prevention programs targeting persons at highest risk of HIV infection. Data on changing patterns of utilization of prevention resources is critical to determining resource requirements for future funding cycles for prevention programs. Data from NHBS are used to answer national questions about prevention service reach, gaps, and impact of allocated resources.

At the local level, the NHBS data have been used for local HIV prevention program planning purposes, including the development of local epidemiologic profiles and responding to data requests. NHBS provides information on the characteristics of persons receiving HIV prevention services and the types of services they are accessing and identifies needs for prevention services. Information about access to and use of these services can be used to evaluate local prevention services for people at risk for HIV. CDC provides training in data analysis and shares programs to promote local analysis and dissemination of NHBS data.

Without NHBS data, the best sources of behavioral data would come from case surveillance, which only collects a limited amount of behavioral information from medical records of persons already infected with HIV, or from small-scale, periodic or ad hoc behavioral surveys. These studies are not likely to have NHBS' large sample size, geographic diversity, or simultaneous collection of specimens for HIV testing. Not having NHBS data would adversely affect the ability to monitor the HIV/AIDS epidemic both locally and nationally.

The overall strategy for NHBS involves conducting rotating annual "cycles" of surveillance in three different populations at high risk for HIV: men who have sex with men (MSM), injection drug users (IDU) and heterosexuals at increased risk (HET). Data collection activities for NHBS

include eligibility screening, the behavioral assessment survey, and the recruiter debriefing instrument; HIV testing is also conducted. Different sampling methods are used in the different cycles to recruit participants for the survey and HIV testing, based on what is known about reaching the specific population. The MSM cycle uses time space sampling, which is venue-based. Respondent-driven sampling (RDS), a type of chain referral sampling, is used for the IDU cycle and the HET cycle. These methods and the definition of heterosexuals at increased risk are explained in more detail in Part B.

NHBS collects data through face-to-face interviews. A short screening survey to assess various eligibility criteria and limited demographics is administered to those intercepted by field staff or recruited by peers for participation in NHBS (Attachment 2a). The data collected from the interview will include self-reported demographics, sex and substance use behaviors, HIV testing patterns, and exposure to and use of HIV prevention services (Attachment 2b-d).

The information collection described in this request is funded through cooperative agreements with state and local health departments (CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments). The five-year funding announcement FY11-001 was published June 1, 2010. Awards will be made to up to 25 applicants.

The usefulness of NHBS data are demonstrated by the amount of local, national and international press that NHBS reports have received. For example, data from the heterosexual cycle of NHBS were presented at the 2010 International AIDS Conference and received media attention for demonstrating the association of HIV prevalence with poverty in this population. Data from the 2008 MSM cycle were disseminated through the *Morbidity and Mortality Weekly Report*; the finding that a substantial proportion of men tested positive for HIV infection was cited by numerous media outlets. See Attachment 4 for a bibliography of NHBS publications.

NHBS methods have been replicated in other studies, vetted by researchers outside of CDC and are undergoing internal validation by CDC colleagues and local and state health department collaborators. For example, CDC works closely with the originator of the method used for two of three cycles - respondent-driven sampling - to keep abreast of

best practices and make recommendations for future adaptations of the method. The National Institutes of Health (NIH) have incorporated methods used for the HET cycle of NHBS for a recent HIV Prevention Trial Network. CDC and our collaborators have met once each year following data collection to debrief on methodological lessons learned in the preceding year and are planning on incorporating these into future iterations of NHBS.

As NHBS provides data for federal monitoring of populations at highest risk for HIV infection – such as for the national Monitoring and Evaluation Plan of the Division of HIV/AIDS Prevention at CDC- its role is critical.

There are limits to the generalizability of NHBS data. For the MSM cycle, data are generalizable to men meeting the eligibility criteria who attended the venues on the sampling frame during the data collection period and who reside within the selected MSAs. For the IDU and HET cycles, which use the RDS methodology, the samples may be generalizable to persons meeting the cycle-specific eligibility criteria described in Part B. According to RDS statistical theory, given enough waves (subsequent generations of recruitment stemming from initial recruits) the recruitment procedure may yield a sample in which is independent of the initial recruits (“seeds”) from which recruitment began, thereby overcoming any bias the nonrandom choice of seeds may have introduced (Heckathorn, 1997; Heckathorn, 2002). Data from RDS samples are, however, only generalizable to those persons who are able and willing to come to a field site and be screened and interviewed. For example, in NHBS-IDU, some injecting drug users were less likely to come to the field sites; in particular, younger IDU, higher-income IDU, and white IDU were less likely than older, poorer, and non-white IDU to come to the field site for an interview. These limitations may affect the generalizability of findings from NHBS-IDU and -HET to the entire population of injecting drug users or heterosexuals at increased risk of HIV infection in each MSA.

Privacy Impact Assessment Information

Information from NHBS is being collected to 1) determine eligibility, 2) inform prevention efforts by providing information about the characteristics and HIV risk behaviors of persons at high risk of HIV, and 3) describe persons who refused to participate to facilitate non-response bias analysis.

The eligibility screener is necessary to ensure that respondents meet minimum criteria for participation in the data collection, including residency in the MSA and age 18 years or older. This request includes a modification to add behavioral eligibility criteria (ever having had sex with a man) for the MSM cycle of NHBS (**see Attachment 12 for more detail about resulting revisions to eligibility screener**). Before NHBS was launched, the expectation was that asking for information on male-male sexual activity in a screener, before rapport with the interviewer is established, would erroneously screen out men who have sex with men but are unwilling to admit that activity when intercepted in a public place (where the screener for NHBS-MSM is administered). However, experience conducting NHBS since its initiation in 2003 has demonstrated that this expectation was incorrect. Analysis of NHBS data demonstrates that a very small percentage of NHBS respondents who report recent male-male sexual behavior indicate that they have not disclosed that behavior with others. Moreover, the addition of behavioral eligibility criteria to the eligibility screener will reduce the burden on respondents who would otherwise be determined eligible but are not included in NHBS analyses.

For the IDU and HET cycles, the screener includes questions about behavior. For the IDU cycle, such a screener is necessary in order to ensure that current injection drug users are being interviewed, whereas for the HET cycle, the screener ensures that sexually active heterosexuals are being interviewed. Because respondents are referred by their peers for the IDU and HET cycles, they are expected to be prepared to talk about the behaviors that may be sensitive or stigmatized.

The only information in identifiable form (IIF) collected is the respondent's date of birth. The date of birth is collected during eligibility screening (Attachment 2a). It is used to assess whether a person participated previously. To identify previous participants, records that have the exact same date of birth will be compared on date of survey and other demographic information such as race, education, and zip code. Date of birth is sent to CDC. However, it is only available to the CDC staff that oversee NHBS data collection (i.e., is it not included in analysis datasets). The response data collected will not be linked to any other personal identifiable information, therefore NHBS data

cannot be used to reveal the identity of any one person.

The core NHBS behavioral assessment involves collecting information on the respondents' sexual or drug use behaviors that increase the risk for acquisition or transmission of HIV and patterns of HIV testing. Although the information requested is sensitive, the purposes of this project cannot be accomplished without their collection. Participants will be told that they may decline to participate without penalty or if they agree to participate, they may refuse to answer any question. They will also be informed that the data will be used to improve HIV prevention services for persons at increased risk of HIV in their area, and that aggregated data may be released in published reports.

In situations in which sensitive information may be collected, as for this project, loss of confidentiality could potentially result in harm to respondents. No information that could directly identify an individual will be collected as part of the behavioral assessment interview. However, data collected for this project are protected under a Federal assurance of confidentiality **(see Attachment 5 for details)**.

Several safety precautions are in place to prevent any information from being connected to a respondent. Security of data on the handheld computers will be maintained through training, password protection, encryption of devices, and controlling access to hardware.

Interviewers will complete security and confidentiality training and sign a statement indicating their understanding of security and confidentiality policies. **(Attachment 6)**. Recruiters and interviewers will also receive training from CDC staff on how to protect the security and confidentiality of the information collected.

The recruiter debriefing instrument **(Attachment 2e)** is administered to participants who meet criteria and agree to be recruiters in the IDU and HET cycles, which use RDS methods. In RDS, it is important to assess who refused to participate in the study in order to measure non-response bias. This is accomplished by administering a brief questionnaire to participants who agreed to recruit their peers; this debriefing will occur when the recruiters return to the field site to collect recruiter rewards. The recruiter debriefing instrument asks recruiters whether

anyone refused to take a coupon and, of those who refused (if any), what race/ethnicity they were and why they refused the coupon. Experience from NHBS-IDU demonstrated that approximately 98% of participants who recruited their peers into the study and were administered the recruiter debriefing instrument reported no one refused a coupon.

3. Use of Improved Information Technology and Burden Reduction

Interview data will be collected on password-protected encrypted handheld computers using the Questionnaire Development Software (QDS), NOVA Research Company, Bethesda, Maryland. It is expected that 100% of interviews will be collected using electronic applications. All interviews will be conducted by trained local NHBS staff.

CDC will conduct training and site visits to provide instructions and technical assistance on how to use the interview software, conduct the interviews, archive the collected data, and transfer the data. CDC will also provide training to participating state and local health departments and detailed written instructions on methods for conducting the interviews. CDC will require local NHBS staff providing supervision on the project to monitor interviewers regularly. CDC will convene lessons-learned meetings to identify and resolve the problems that can occur with the software and hardware that is used for conducting the interviews. Automated edit checks will be built into the computer software programs as a further quality control measure. Provision of electronic data collection software, training and technical assistance will help to reduce the burden on grantees conducting NHBS.

Data linking recruiters and recruits for the IDU and HET cycles using RDS will be entered directly into a computer program, called "Respondent Driven Sampling Coupon Manager" (RDSCM). By entering data directly into the computer, the efficiency of data collection is improved as compared to using paper and then entering the data. The RDSCM program also reduces the time and effort to validate coupons and tracks payments of incentives. During a participant's visits to the field site, data can be called up efficiently through use of search terms, such as by coupon number. With logic checks and range values programmed in, the quality of the

data is improved. Data from RDSCM linking recruiters and recruits is also used in analysis and weighting to produce adjusted estimates.

For the MSM cycle, a computer program is used for 2-stage random sampling of venues and day-time periods within venues (described more fully in Section B). The computer program will ensure that selections are made randomly. This program also records the selections that were made, and can generate a monthly calendar of recruitment events. The information generated from this program is then used to weight the data for probability of selection.

An evaluation of supplemental surveillance data using handheld interview devices such as the ones being used for NHBS has shown the following: a reduction in the duration of the interview by up to 20%; a decrease in the number of interviewer errors per interview (such as errors due to skipping questions inappropriately, out-of-range answers and missing data) from an average of 2.5 per interview to 0.3 per interview; and the elimination of the need for data cleaning associated with data entry and the errors listed above, resulting in a reduction in the time between the last interview and the production of a final analysis dataset from approximately 6 months to only 1 month. Also, the cost of data collection using handheld devices instead of paper data collection forms is also reduced despite the increased start-up costs associated with purchasing the handheld devices and interview software. The incremental cost of each collected survey decreases with each subsequent interview conducted, so that when collecting more than 195 interviews, it is less expensive to use the handheld devices than paper.

CDC/DHAP has implemented the use of handheld devices for other national surveillance systems. All state and local health departments participating in NHBS are licensed to use the software and have extensive experience with implementing interview projects using electronic data collection in the field.

Computer-assisted personal interviews conducted by an interviewer reduce burden for the respondent because they may improve comprehension (compared with a self-administered questionnaire), and may improve response time. The computer "assists" by customizing the question wording for each respondent, allowing the interviewer to focus on

explaining complex terms or definitions, giving instructions, ensuring that answers are relevant and entered accurately, and maintaining the respondent's privacy.

4. Efforts to Identify Duplication and Use of Similar Information

We reviewed currently-funded programs and did not identify potential areas of duplication. We are not aware of any department or agency that rigorously or systematically collects or maintains data on HIV risk behavioral data from the 3 groups of people at risk for HIV infection that are the focus of NHBS(i.e., MSM, IDU and HET)from the 25 MSAs with high AIDS prevalence.

Within CDC, there are some complementary systems already in place or under development that contain similar data elements to NHBS:

- Transgender HIV Behavioral Survey (THBS) (OMB 0920-0794, exp. 12/31/2010)
- Behavioral Assessment and Rapid HIV Testing (BART) Project (OMB # 0920-10GY)
- Medical Monitoring Project (OMB 0920-0740, exp. 5/31/2012).

These existing information collections above cannot be modified, used partially, nor in aggregate format to satisfy the needs of the proposed project. THBS collects HIV risk behavior information, but only from transgender persons. BART also collects risk behavior information, but from participants at gay pride and other events in small and middle-sized cities that are outside of those funded to conduct NHBS. MMP collects data on a population-based sample of HIV-infected patients in care, not specific populations at increased risk for HIV.

CDC established relationships with other federal stakeholders and consultants during the conception and development of NHBS. Beginning in December 2001, consultations have been held with state and local health department and agencies such as the Department of Health and Human Services, the American Red Cross and the National Institutes of Health (NIH). To promote collection of data that can be used by multiple agencies, ongoing communications with these federal and non-governmental

partners have continued for the duration of this project. For example, CDC has collaborated since 2006 on an NIH-funded HIV Prevention Trial Network (HPTN), number 064. The goal of this trial is to measure HIV seroprevalence among women in 12 U.S. cities. CDC collaborated on this project by sharing the methodology used in NHBS-HET. Although this project uses methods similar to those of NHBS, the specific goal of the NIH trial is to measure HIV seroprevalence and use this information to inform new prevention strategies for this population, which different from the goal of NHBS. Further, the NIH project collects more limited risk behavior information from participants. Meetings with these federal stakeholders and consultants who are aware of data collection on persons at risk for HIV infection ensured that duplicate or similar data collection efforts would have been identified if they existed. Other surveys may have obtained data related to topics covered in NHBS, but most were more limited in the questions they asked, the populations they represented, the geographic areas they covered, or all of these factors.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection effort.

6. Consequences of Collecting the Information Less Frequently

NHBS data collection activities occurred during each calendar year from 2008-2010 and are planned to continue from 2011-2013; because it is a surveillance system from which ongoing data are needed to monitor progress, it is expected that NHBS will continue beyond 2013. The overall strategy for NHBS involves conducting rotating 12-month cycles of data collection among the three populations in the selected MSAs. In order to follow trends over time, the same 3 populations are surveyed repeatedly in the same MSAs. Thus, surveillance data are collected in the each of the three populations every three years. Survey operations run for approximately 6-8 months during each calendar year, with an additional 5-6 months to plan for and wrap up each cycle (Attachment 7, NHBS Cycle Overview). Collecting data for fewer than 6 months may result in grantee agencies not meeting their sample size goals.

Participants interviewed during an NHBS cycle are only

eligible to participate once during that cycle. Each person approached is asked if they have been interviewed for the project during the current one-year cycle; those who indicate that they have been interviewed already will not be interviewed again. It is possible that a person could be recruited for participation in NHBS in more than one cycle, as some may engage in multiple risk behaviors.

Data for prevention and resource planning must be collected on an annual basis to meet reporting requirements of CDC and local planning groups. Data from each of the three population groups are not needed annually; data collection for each group every 3 years is sufficient to be able to track trends over time. Collecting data less than every 3 years per population group would not be advantageous, nor would it meet the needs of the grantees collecting the data and planning groups that rely on the data for resource allocation. The Healthy People 2020 Objectives require that the data be available at least 3 times per decade; data collection every 3 years per group meets this requirement.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

None of the special circumstances in the guidelines of 5 CFR 1320.5 applies.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

8A. A 60-day notice to solicit public comments was published in the Federal Register on December 8, 2010 (Volume 75, Number 235, pages 76470-76471). **(See Attachment 8a for a copy of the Federal Register notice)**. One comment was received **(Attachment 8b)**.

This comment questioned the need for the NHBS data collection. As described in Section A.1, CDC depends on this data collection to provide ongoing data on behaviors related to HIV acquisition. NHBS data are used to monitor progress toward the National HIV/AIDS Strategy objectives, Division of HIV/AIDS Prevention Strategic Planning objectives, and Healthy People 2020 objectives.

8B. Several consultations were conducted with various

scientists and public health practitioners outside the agency. All names, affiliations, and contact information is included in **(Attachment 9)**.

A consultation on issues related to sampling hidden populations at high risk for acquiring HIV infection was held in December 2001. Key participants included Dr. Cornelis Rietmeijer, Dr. Mary Ann Chiasson, Ms. Miguelina Leon, Dr. Harry Haverkos, Dr. Michael Ross, Dr. John Peterson.

A technical consultation on sampling methods to reach injecting drug users was held in December 2002. Key participants included: Drs. Douglas Heckathorn, Ricky Bluthenthal, Alex Kral, Sam Friedman, Don Des Jarlais, Merrill Singer, and Tobi Saidel. A follow up consultation was held in October 2004, which included Dr. Heckathorn and numerous representatives from city and state health departments and community based organizations.

From February through April 2004 a series of consultation meetings were held via internet to solicit input on the definition of "heterosexuals at risk" and methods for sampling this group. Key participants included: Drs. Ada Adimora, Pamina Gorbach, Elisa Sobo, Judith Porter, Sharon Weir, Sheana Bull, Yasmina Katsulis; Ms. Lisa Bond, and Ms. Eve Mokotoff. These internet-based consultations were followed by an in-person meeting in October 2005 to further discuss sampling methods for heterosexuals at risk. Key participants in this consultation included Dr. Stephen Thompson (provided consultation prior to the meeting but could not attend), Dr. Brian Burke, and numerous representatives from city and state health departments and community based organizations.

NHBS Principal Investigators, field staff, and various researchers have met yearly since the beginning of NHBS data collection to identify problems in recruitment, sampling, or other methodological issues.

In October 2008, CDC and NHBS collaborators met to discuss recruitment issues from the 2008 data collection cycle and to prepare for the IDU data collection cycle in 2009. Other key participants at this meeting included experts in IDU sampling and RDS methods: Drs. Douglas Heckathorn, Larry Ouellette and Robert Broadhead. In October 2009, a similar meeting was held to discuss barriers to recruitment of

heterosexuals at increased risk of HIV infection (for 2010 data collection). Participants included all NHBS Principal Investigators as well as experts in sampling methodology, including Drs. Cyprian Wejnert and David Forest. No major problems were identified that could not be resolved within the current NHBS protocol.

CDC continues to collaborate with NIH to compare information and lessons learned from HPTN-064 (described above) to discuss ways to improve data collection for the heterosexual population. CDC convenes monthly conference calls with NHBS Principal Investigators to discuss barriers to recruitment and other methodological concerns. CDC has recently consulted with experts (specifically, Dr. Graham Kalton) to assist with possible refinement of the VBS sampling strategy used for MSM.

In October and November 2010, CDC held conference calls and meetings with NHBS Principal Investigators to discuss the eligibility criteria for the MSM cycle. NHBS Principal Investigators expressed the opinion that it would be beneficial to ask potential respondents, as part of screening for eligibility, whether they had ever had sex with a man. They advised that adding this behavioral eligibility criterion would reduce the burden by screening out non-MSM who would otherwise be considered eligible for the behavioral assessment.

NHBS does not affect the work of other federal agencies.

9. Explanation of any Payment or Gift to Respondents

Incentives are used in NHBS, as the project seeks to conduct surveys with hard-to-reach and highly selective populations and to ask them highly sensitive questions about issues such as sexual behavior and substance use (Kulka, 1995). Because the interview takes approximately 30-45 minutes to complete, to increase response rates, eligible persons are offered an incentive to participate. We anticipate that increased response rates will lead to improved representativeness of the underlying population of interest.

Participants are given approximately \$25 in cash for participation in the behavioral assessment. If local regulations prohibit cash tokens of appreciation, equivalent tokens of appreciation may be offered in the form of gift certificates, cash cards, or bus or subway tokens.

Participants who agree to HIV testing are offered an additional incentive. Participants who give a specimen for HIV testing are given approximately \$25 in cash for participation. As with the survey incentives, if local regulations prohibit cash, equivalent incentives may be offered in the form of gift certificates or cash cards.

In the RDS methodology, participants receive an incentive for participating as a respondent and another for successfully recruiting one or more of their peers. In the IDU and HET cycle in which RDS is used, providing the incentive (the "recruiter reward") for getting a peer to complete the survey increases peer recruitment. Recruiter rewards are approximately \$10 for each of up to five peer referrals, which is standard for RDS studies (Heckathorn, Semaan, et al., 2002; Ramirez-Valles, 2005; Wang, 2004). As with the survey and testing incentives, if local regulations prohibit cash, equivalent incentives may be offered in the form of gift certificates or cash cards.

The need for and amount of the incentive is based, in part, on the fact that other, similar research projects that ask HIV risk behavior questions of the 3 NHBS populations in the participating areas offer similar incentives. Thus, NHBS would be competing with local researchers who do offer incentives; without incentives, it is likely that participation in NHBS would be reduced (McKnight, 2006; Stueve, 2001; Valleroy, 2000). Incentives have been used in other complementary CDC data collection efforts such as for the Medical Monitoring Project (OMB 0920-0740, exp. 5/31/2012) and the Transgender HIV Behavioral Survey (OMB # 0920-0794 exp. 12/31/2010), described in section 4 above, both of which ask questions similar to those in NHBS and have a similar length of time for completing the behavioral assessment. These incentives were used to help increase participation rates; in both of these other projects, participants were offered approximately \$25 as compensation for their time. Other studies have also found that incentives modestly improve response rates (Whiteman et al. 2003). Incentives - particularly, the dual-incentive structure in which participants who agree to recruit others are given a small incentive for recruiting their peers to participate - are an important aspect of respondent driven sampling (Heckathorn, 1997). The incentive increases the likelihood that a participant will identify a member of his or her network that would be eligible for the study, thereby improving response rates and increasing the overall

proportion of eligible participants.

10. Assurance of Confidentiality Provided to Respondents

A. This section has been reviewed by ICRO, who determined that the Privacy Act does not apply because the survey does not collect name, social security number, or other personally identifying information.

NHBS is anonymous (neither names nor social security numbers are collected). Full date of birth is collected for two reasons; to ensure participants meet the eligibility criteria for participation in the survey, and for the purpose of identifying potential duplicate records or participants who have participated more than once per cycle. Records that have the exact same date of birth are compared on date of survey and other demographic information such as race, education, and zip code; determinations of whether a record is a duplicate or a participant has already participated during the cycle are made based on how closely this information matches. Data collected through NHBS, both locally and at CDC, are stored and accessed by a survey identification number. Other data collected through NHBS, while sensitive, are not personally identifying; these survey questions are described in Section 11.

Full date of birth is sent to CDC, but is only available to CDC staff overseeing data collection (i.e., date of birth is not maintained in analysis datasets).

B. In addition to limiting the amount of personally identifying information collected, NHBS is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data (**Attachment 5**). The Assurance provides the highest level of legal confidentiality protections to the individual persons who are the subject of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the

release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

Privacy Impact Assessment

The NHBS interview will be conducted by trained NHBS staff in a private location where the questions and responses cannot be overheard by others. NHBS data will be transmitted to CDC via the secure system described above on page 1, the Data Coordinating Center (DCC). Encryption security for all NHBS data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). See the document "Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines" for further information (www.cdc.gov/hiv/surveillance.htm).

A number of required protections ensure the security of the data on the handheld computers. The handheld computers are solely used for NHBS data collection activities. NHBS data are encrypted when stored on a handheld device. Handheld computers are protected by using a coded password only known by authorized NHBS project staff. NHBS data are deleted from the handheld computers after the last interview of the day by uploading the collected interviews to the main database. The handheld computers must be kept with the staff at all times in the field; the computers are collected and secured by the field supervisor after the last interview each day. When not in use in the field, the handheld computers are to be locked in a drawer or an office.

The Assurance of Confidentiality is enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. State and local health department personnel who conduct HIV/AIDS surveillance are subject to the confidentiality obligations described in the CDC guidelines for the security and confidentiality of HIV/AIDS Reporting System (HARS) data (<http://www.cdc.gov/hiv/topics/surveillance/index.htm>) and are required to undergo security and confidentiality training.

NHBS interviewers and data managers undergo the same security and confidentiality training as required for health department staff. CDC's Procurement and Grants Office will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement (Attachment 6) will attach this and to update their confidentiality agreements on an annual basis. Contractors must sign a "Contractor's Pledge of Confidentiality." Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the "Agreement to Abide by Restrictions on Release of Data" CDC-funded cooperative agreements with state and local health departments reference the Assurance of Confidentiality as a condition of award. Any NHBS data maintained at CDC that are released to persons other than project staff will not include full date of birth.

C. The informed consent process for respondents may be fulfilled by obtaining oral consent. All sites must obtain consent from respondents and document it in the data collection form on the handheld computer. An example model consent document is included as Attachment 10. Consent must be obtained for the survey and HIV testing separately. Participants may elect to complete the behavioral assessment survey and not be tested; however, they may not be tested without completing the survey (those persons who only want an HIV test may be given information on where to seek an HIV test elsewhere). Respondents will be informed that data collected from them for NHBS will be kept private and secure and that the data will be reported in aggregate format.

The approved Project Determination Form (**Attachment 11**) indicates that because CDC is not directly engaged with human subjects in connection with this project, the protocol will not be reviewed by CDC's IRB. Each participating health department will be required to obtain IRB approval before data collection.

11. Justification for Sensitive Questions

The collection of HIV/AIDS status itself is sensitive because of stigma associated with HIV infection. In addition, the modes of transmission of HIV (through sexual

contact and the sharing of HIV-contaminated needles and syringes) necessitate the collection of sensitive data regarding sexual practices and drug use. In keeping with the purpose of this data collection, other sensitive data are collected about specific behaviors, experiences or conditions that have been shown to be associated with HIV infection. For NHBS, this includes the collection of STD and HIV diagnosis and testing, hepatitis diagnosis and vaccinations, history of incarceration in the past 12 months alcohol use, and income. Geographic information such as ZIP code and, for the HET cycle only, census tract, is collected for the purposes of spatial analysis of the data to understand the geographic distribution of disease and risk. Questions about race and ethnicity will be asked using OMB's two question format. These questions will be used to report on racial and ethnic disparities that have been well documented in other research on HIV risk and risk behaviors.

Although the information requested from participants is highly sensitive, the purposes of NHBS cannot be accomplished without their collection. Collection of the data is used to understand barriers to engaging in protective behaviors and to using HIV prevention services. These data are also used to enhance HIV prevention programs designed to reduce high-risk behaviors in persons most likely to acquire or transmit HIV.

The context in which questions are asked helps to overcome their potential sensitivity. There are several steps taken in NHBS to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

- Nearly all questions allow for responses of "don't know" or "refuse to answer."
- Consent scripts make it clear that the survey is sponsored by CDC and the local health department and that the information will be put to important uses.
- Toll-free phone numbers are provided if the respondent has questions about the survey.
- The questionnaire is carefully organized to lead smoothly from one topic to another. Transitions are made clear to respondents and the need for the information explained. Assurances about the privacy and confidentiality of the data are reiterated.
- The use of handheld computers for data collection addresses concerns the respondent might have about privacy (that others can see their answers).

- The payment of an incentive indicates clearly to the respondent that the information is important to the survey sponsors.

All interviews will be conducted by trained field staff in a private location during established operating hours at local field site locations. Interviewers will be trained to administer the consent script and all interview questions by reading each item verbatim, thus ensuring that all respondents receive the same information for the consent and each question. No interviews will be conducted without the verbal consent of the respondent.

Social security numbers will not be collected from respondents.

No data will be collected from agencies regarding their policies, performance data or other practices.

12. Estimates of Annualized Burden Hours and Costs

The estimate of annualized burden hours has not been changed from the current inventory. Estimates of respondent burden for each data collection form are provided below. For NHBS-MSM, approximately 17,500 individuals will be approached to participate in the behavioral assessment interview in a 12-month period. A screener will be used to determine eligibility by assessing the respondent's race/ethnicity, previous participation, county of residence and length of time residing there, gender, and history of male-male sexual behavior. We estimate that it will take five minutes to complete the screener. We anticipate that 29% of respondents will be either not interested in completing the behavioral assessment or will be ineligible after completing the screener, yielding a total of 12,500 eligible respondents over a 12-month period. We estimate that it will take 1 hour for each respondent to complete the interview.

For the IDU and HET data collection cycles, approximately 13,750 individuals will be approached to participate in the behavioral assessment interview. We estimate that it will take five minutes to complete the screener, totaling 1,146 hours per year. We anticipate that 9% of respondents will be either not interested in completing the behavioral assessment or will be ineligible after completing the screener, yielding a total of 12,500 eligible respondents.

We estimate that it will take 39-54 minutes for each respondent to complete the interview, which will vary slightly for each NHBS cycle due to the number of risk behaviors each group is queried about (e.g., injecting drug users are asked about both sex and drug use risk behaviors, which will increase the length of surveys during this cycle). For IDU and HET, we anticipate that 50% of respondents will either not be eligible to recruit other participants or will not return to the interview site, and therefore will not answer the recruiter debriefing instrument, which will take 2 minutes per respondent. These estimates cover the time that each respondent will spend communicating with the project staff and answering interview questions. For the currently approved data collection, the recruiter debriefing questions are included in the behavioral assessment. Although the questions have not changed, we have separated this section into a separate instrument to reflect the fact that not all respondents will return and be asked these questions. These changes are described in Attachment 12. This has resulted in a slight decrease in the burden for the behavioral assessment and the addition of the recruiter debriefing instrument; however, overall burden is not changed.

The goal is to interview 12,500 persons per year. In order to achieve this goal, an additional 1,250 - 5,000 persons must be screened for eligibility, depending on the cycle. For the MSM cycle, approximately 5,000 additional respondents are anticipated to be screened but will not participate in the survey because they are not eligible or do not have time to participate in the survey. Fewer respondents in the IDU and HET cycles will need to be screened because they will more likely be eligible for the survey; this is due to the recruitment process, in which a peer invites people they know to be IDU or HET (depending on the cycle) to participate in the survey. Because HIV testing is a clinical procedure, it is not included in the burden estimates.

Table A-12-1: Estimate of Annualized Burden Hours

Respondent	Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (hours)	Total Burden (in hours)
Year 1:					
Men Approached at Eligible Venues:	Screeners	17,500	1	5/60	1,458
Eligible Men:	Behavioral Assessment	12,500	1	30/60	6,250
Year 2 :					
Injecting Drug Users Referred by Peer Recruiters:	Screeners	13,750	1	5/60	1,146
Eligible Injecting Drug Users:	Behavioral Assessment	12,500	1	54/60	11,250
Peer Recruiters:	Recruiter Debriefing	6,250	1	2/60	208
Year 3 :					
Heterosexual Men and Women Referred by Peer Recruiters:	Screeners	13,750	1	5/60	1,146
Eligible Heterosexual Men and Women:	Behavioral Assessment	12,500	1	39/60	8,125
Peer Recruiters:	Recruiter Debriefing	6,250	1	2/60	208
Total		45,000	1		29,791
Total Annualized Burden *					9,931

* Burden averaged over three years

B. Estimated Annualized Cost to Respondents

Table A-12-2: Annualized Cost to Respondents

Note: The hourly rate was determined by using information obtained from the US Department of Labor, Bureau of Labor Statistics:

<ftp://ftp.bls.gov/pub/suppl/empsit.ceseeb2.txt>

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Burden Hours	Hourly wage rate	Total Respondent Cost
Screened, MSM	17,500	1	1,458	\$19.07	\$27,810
Interviewed, MSM	12,500	1	6,250	\$19.07	\$119,187
Screened, IDU	13,750	1	1,146	\$19.07	\$21,851
Interviewed, IDU	12,500	1	11,250	\$19.07	\$214,537
Debriefed, IDU	6,250	1	208	\$19.07	\$3,973
Screened, HET	13,750	1	1,146	\$19.07	\$21,851
Interviewed, HET	12,500	1	8,125	\$19.07	\$154,944
Debriefed, HET	6,250	1	208	\$19.07	\$3,973
Total					\$568,127
Total Annualized Cost*					\$189,376

*Annualized cost averaged over three cycles

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents associated with this proposed collection of information.

14. Annualized Cost to the Federal Government

The cost of this project for the three years is estimated to be \$41,667,900. The annualized cost is summarized in

Exhibit 14.A.

Exhibit 14.A. NHBS Annualized Cost to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	NHBS - Personnel	\$1,022,509
	Epidemiologist-14	1 100% \$107,770
	Epidemiologist-14	2 75% \$80,828
	Behavioral Scientist-14	1 75% \$80,828
	Epidemiologist-13	4 75% \$72,750
	Behavioral Scientist-13	2 75% \$72,750
	Statistician-14	1 25% \$26,942
	Public Health Advisor-13	1 75% \$72,750
	Support Staff	
	Data Analyst (GS-13)	1 75% \$64,162
Data Analyst (GS-12 equiv.)	1 100% \$71,901	
	Cooperative agreement funds to project areas	\$9,875,000
Contractor and Other Expenses	Data Coordinating Center (CDC Contractor for data collection)	1,500,000
	Contracted Project Coordinators (2)	\$160,000
	Contracted Data Analyst (1)	\$80,000
	Contracted Administrative Assistant (1) 0.5 FTE	\$20,000
	Contracted Questionnaire Programmer (1) 0.1 FTE	\$8,000
	Travel	\$30,000
	Meetings	\$10,000
	Spanish language translation	\$2,500
	Printing	\$2,000
		TOTAL COST TO THE GOVERNMENT

*Salary estimates were obtained from the US Office of Personnel Management salary scale at <http://www.opm.gov/oca/11TABLES/>.

The personnel related to the NHBS data collection include project officers (epidemiologists and behavioral scientists) at the GS-12, 13, and 14 levels, a GS-14 level statistician, a GS-13 level public health analyst, two project coordinators, an administrative assistant, and data managers/analysts. Travel is related to providing technical assistance and conducting site visits. Examples of meetings that will be held include field operations training and the local principal investigators' meeting.

The information collection described in this request will be

funded through cooperative agreements with state and local health departments (CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments).

Data for NHBS are compiled by staff in local health departments and sent via a secure network to a central processing location, called the Data Coordinating Center (DCC). The DCC will be funded through a separate contract. The purpose of the DCC is to receive data from data managers at the local health departments, track the progress of the data, and distribute monthly monitoring reports to health department staff. The DCC will process all data sent from local health departments and produce a clean, final data set for use by CDC and each health department at the completion of each data collection cycle.

NHBS data analysts will have responsibility for analyzing the final data set. They will work with NHBS epidemiologists and behavioral scientists to create data tables to be displayed in surveillance reports and other products.

15. Explanation for Program Changes or Adjustments

The burden has not changed from the burden shown in the current inventory.

The following revisions were made to the OMB approved project 0920-0770. These changes are explained in more detail in **Attachment 12**.

- Modifying eligibility criteria for the men who have sex with men (MSM) cycle. It was determined that changing the eligibility criteria would reduce the burden on non-MSM who would no longer be eligible for the behavioral assessment.
- Renumbering the eligibility screener and behavioral assessment
- Revision of the eligibility screener (4 questions added, 4 questions removed); some questions were moved from the behavioral assessment to the eligibility screener in order to assess eligibility using the modified criteria, and some questions were revised in order to improve respondents' understanding of the questions. Changes to the previously approved eligibility screener are outlined in **Attachment 12**.

- Revision of the behavioral assessment (75 questions added, 80 questions removed)
 - o some questions were added to address emerging information needs, including health care access and utilization, use of pre-exposure prophylaxis, homophobia, HIV stigma, and discrimination.
 - o some questions were removed because they collected information that is no longer needed
 - o other questions were revised from the previously approved instrument to make them easier for respondents to understand and respond appropriately
- Adding an instrument to be used to debrief peer recruiters by asking questions to assess coupon distribution and coupon refusal (7 questions added). This information will help assess non-response bias.

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be collected in 12-month cycles for 3 different populations; clearance is requested for 3 years. **Attachment 7** provides an overview of NHBS activities for each cycle across the 3-year funding period. The following is a brief overview of the NHBS Timeline for the next MSM cycle; other cycles are expected to follow a similar time schedule in the subsequent years.

Activities	Time Schedule
Interviewer Training	1 month after OMB approval
Begin interviewing MSM participants	3 months after OMB approval
End interviewing MSM participants	6 months after OMB approval
Evaluate the MSM cycle	9 months after OMB approval
Analysis of MSM data	12 months after OMB approval
Publication of MSM data	No more than 16 months after OMB approval

Data from NHBS will continue to inform prevention programs services and increase existing knowledge in the behaviors that lead to acquisition of HIV infection. See Attachment 13 for sample analysis tables.

Most of the results are expected to be useful at the local level, while other results will be more meaningful aggregated across sites. Each participating health

department has responsibility for the release of local data. CDC has primary responsibility for the release of cycle-specific data aggregated from all geographic areas. These data are distributed to the participating agencies, researchers, policy makers and other interested parties through presentations at local, national and international conferences, publications in peer reviewed journals, and presentations at different forums such as continuing medical education courses and seminars. Furthermore, CDC regularly publishes surveillance reports using data collected annually; depending on publication schedules, these reports have been published within 16 months - 2 years of the end of each cycle of data collection. For instance, the MSM data collection results (end of data collection December 2008) were published in September 2010. The time required from the end of data collection to the dissemination of results is expected to improve as CDC now has an established contracting arrangement to procure a clean, final NHBS data set more rapidly; for example, the IDU2 data collection (December 2009) reports are expected to be available 18 months from data collection (June 2010).

Community members will continue to be informed of NHBS findings through multiple conduits of information. National data results will be released through national publications and presentations at conferences. Local data results will be reported back to the community through means such as local publications, Epidemiologic Profile reports, presentations to local AIDS Service Organizations and community planning bodies and at local conferences and workshops.

CDC analyses will focus on the following key behavioral outcomes:

- Prevalence of unprotected vaginal and anal sex in the past 12 months;
- Prevalence of multiple (opposite sex) partners;
- Prevalence of non-injection drug use in past 12 months;
- Prevalence of HIV testing and among those tested, percentage who got their results;
- Prevalence of HIV infection, including previously undiagnosed HIV infection;
- Prevalence of receiving prevention services and free condoms

Data for the MSM cycle, which uses venue-based, time-space

sampling, will be weighted to account for bias in attendance of sub-groups of MSM at venues. These analyses will require the use of statistical packages, such as SAS®, STATA® or SPSS®. Weights will be determined at the end of the MSM data collection cycle through consultation with statisticians and NHBS Principal Investigators.

Data for the IDU and HET cycles, which use RDS, will be weighted to account for the complex sampling design. This includes the effects of network sizes and within-group recruitment; these analyses will require the use of software that accounts for the sampling design, such as the Respondent Driven Sampling Analysis Tool (RDSAT). RDSAT is a publically available statistical package used to weight RDS datasets.

There are several potential sources of bias in RDS:

- Groups that are more insular (i.e., more likely to recruit only within their own group) are more likely to be overrepresented in the sample.
- Groups with larger networks may be overrepresented in the sample because more recruitment paths lead to their members.
- Some groups may be less willing or able to participate in the survey and would be underrepresented in the sample.

However, there are several ways to assess this bias and compensate for it. Some of the potential sources of bias are controlled by project staff; for instance, staff are encouraged to ensure that their initial peer-recruits, or seeds, are diverse according to race/ethnicity, gender, age, geographic location to minimize the insularity of recruitment and homophily (i.e., population subgroups recruiting only within their own group). It is also important for project sites to conduct adequate formative research regarding placement of field sites so as to minimize participants' barriers to participation (Magnani 2005; McKnight 2006).

Other sources of bias are taken into account during data analysis, using information obtained during the survey. To calculate the population estimates and sample variances derived from RDS, participants' network size and information on who recruited whom (made possible through the coupon tracking system) are factored in to arrive at population estimates that reflect the underlying population. If these sources of bias cannot be satisfactorily controlled and

measured, or if there are unknown barriers to peer-recruitment, some assumptions on which RDS is based may not be met and the resulting estimates may not reflect the true population of heterosexuals at elevated risk of HIV. Formative research and monitoring the sample throughout data collection is critical to minimize and adjust for the effect of these sources of bias.

An illustrative table is presented in Appendix 16.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.