

National HIV Behavioral Surveillance System (NHBS)
OMB NO. 0920-0770 EXPIRES 5/31/2020

Supporting Statement A

REVISION

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**National HIV Behavioral Surveillance System
0920-0770**

TABLE OF CONTENTS

SECTION

A. Justification

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Business or Other Small Entities
6. Consequences of Collecting the Information Less Frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Protection of the Privacy and Confidentiality of Provided by Respondents
11. Institutional Review Board (IRB) and Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
14. Annualized Cost to the Federal Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions

Section

B. Statistical Methods

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with Non-response
4. Test of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

EXHIBITS

- | | |
|--------------|--|
| Exhibit 12.A | Estimated Annualized Burden Hours |
| Exhibit 12.B | Estimated Annualized Burden Costs |
| Exhibit 14.A | Estimated Annualized Costs to the Government |

LIST OF ATTACHMENTS**Attachment****Number****Document Description**

1	Section 301 of the Public Health Service Act
2	60-Day FRN
3a	Eligibility Screener
3b	Behavioral Assessment - MSM
3c	Behavioral Assessment - IDU
3d	Behavioral Assessment - HET
3e	Recruiter Debriefing
4a	Eligibility Screener (Spanish)
4b	Behavioral Assessment - MSM (Spanish)
4c	Behavioral Assessment - IDU (Spanish)
4d	Behavioral Assessment - HET (Spanish)
4e	Recruiter Debriefing (Spanish)
5	NHBS Publications
6a	Assurance of Confidentiality for HIV/AIDS Surveillance
6b	Privacy Impact Assessment
7	Agreement to Abide by Restrictions on Release of Surveillance Data
8	NHBS Cycle Overview
9	List of Consultants
10	Model Consent Form
11	CDC IRB Project Determination Form
12	Sample Analysis Tables
13	Summary of Changes to Data Collection
14	Model Recruitment Coupon
15	Recruiter Training Script
16	Response Rate Calculations
17	References
18	Authorization to Operate for the Data Coordinating Center

- **Goal:** The National HIV Behavioral Surveillance system (NHBS) is a supplemental surveillance project designed to describe the HIV prevalence and behaviors related to HIV acquisition and prevention among the three populations at highest risk for HIV in the United States: men who have sex with men, persons who inject drugs, and heterosexually active persons at increased risk for HIV infection.
- **Intended Use:** To guide national and local prevention efforts and to monitor trends in HIV prevalence, receipt of HIV prevention services, and HIV-risk related behaviors.
- **Methods:** Interviewer-administered survey of persons in select cities recruited using statistical methodologies appropriate for sampling hard-to-reach or hidden populations.
- **Subpopulation:** Adult men who have sex with men, injecting drug users, and heterosexually active persons at increased risk for HIV infection in up to 25 U.S. cities with high prevalence of HIV.
- **Analysis:** Descriptive statistics and multivariable analyses to assess the prevalence of and trends in: 1) prevalence and awareness of HIV infection, 2) risk behaviors for HIV transmission, 3) receipt of HIV prevention services.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests a 3 year revision of the currently approved National HIV Behavioral Surveillance System (NHBS) (0920-0770, expiration date May 31, 2020). Interview data collection instruments were revised. Project activities and methods will remain the same as in the previously approved information collection request. The number of health departments participating in the NHBS System will increase (from 23 to 25). However, due to a 20% reduction to the estimated burden per response for all 3 behavioral assessment information collection instruments, the total burden will decrease.

The following revisions were made to the OMB-approved project 0920-0770: (For detailed description, see **Attachment 13**)

- Revision of the eligibility screener: 3 questions assessing census tract and zip code were deleted as it is no longer needed as an eligibility requirement.
- Addition of high priority topics to the behavioral assessment: To improve data collection of a priority emerging issue related to HIV risk and prevention, questions on Pre-Exposure Prophylaxis (PrEP) measuring stages along the prevention continuum for HIV-negative persons were added.
- Deletion of lower priority topics from behavioral assessment: To reduce burden, items measuring low priority or repetitive content were deleted.
- Measurement improvements in the behavioral assessment: All items were reviewed for data quality, cognitive ease, and interview flow. Improvements (additions, deletions, and modifications) were made where possible.
- Changes to reduce repetitive language and improve interview flow in the behavioral assessment: Wording of introductory text and questions was modified to reduce repetitive language and information read to participants. Location of some items was changed to improve flow and participant experience.

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 (NHBS) 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 (MSM), person who inject drugs (IDU), and heterosexually active persons at increased risk for HIV infection (HET).

More than 30 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., 2007, see **Attachment 17** for complete references). The rate of new HIV infections continues to be high: an estimated 38,700 Americans became infected with HIV in 2016 (CDC, 2019). 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., 2007). 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 1**).

CDC awarded a contract in 2016 to maintain a Data Coordinating Center (DCC). The DCC manages a data portal system, which contains secure file data servers where NHBS data are transmitted and stored. 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 Security Assessment and Authorization (SA&A) Guidelines outlined in NIST SP 800-37 (Guide for the SA&A of Federal Information Systems). The DCC has received Authority to Operate (OAT) through the SA&A process (**Attachment 18**). In addition to the technical requirements listed above, data management processes are in compliance with *The Guidelines for HIV/AIDS Surveillance – Security and Confidentiality*.

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.

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). Further NHBS data collection is consistent with the National HIV/AIDS Strategy for the United States' recommended actions to: Focus on high-risk populations (1.A.2) and Strengthen the timely availability and use of data (4.B.1).

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 and National HIV/AIDS Strategy for the United States' recommended action to: Design and evaluate innovative prevention strategies and combination approaches for preventing HIV infection in high-risk populations and communities (1.B.1). Through NHBS, data on key indicators of behavioral risks for acquiring HIV infection as well as seroprevalence are available from multiple metropolitan statistical areas (MSAs) with high HIV 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 long-term objective 2.2 of the Government Performance and Results Act (GPRA): Decrease the rate of HIV transmission by HIV-infected persons.

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), persons who inject drugs (IDU) and heterosexually active persons at increased risk for HIV infection (HET). Data collection activities for NHBS include eligibility screening, the behavioral assessment, and the recruiter debriefing; HIV testing is also conducted. Different sampling methods are used in the different cycles to recruit participants for the behavioral assessment and HIV testing, based on what is known about reaching the specific population. During the MSM cycle of NHBS, venue-based sampling (VBS) is 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. Respondent-driven sampling (RDS), a type of chain referral sampling, is used for the IDU cycle and the HET cycle 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. For the IDU and HET cycles, in which RDS 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 incentive for each person recruited. When he returns to the field site, he will be debriefed using a computer-assisted, interviewer-administered recruiter debriefing (**Attachment 3e**). This instrument collects information about those who refused recruitment attempts. Each of these data collection instruments is also available in Spanish (**Attachments 4a-e**). These methods and the definition of heterosexually active persons at increased risk for HIV infection are explained in more detail in Part B.

NHBS collects data through face-to-face interviews. A short screening 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 3a**). If the respondent is eligible for the assessment and consents to an interview, the interviewer will administer the behavioral assessment. The data collected from the interview will include self-reported demographics, sex and substance use behaviors, access to health care, HIV testing patterns, and exposure to and use of HIV prevention services (**Attachment 3b-d, depending on cycle**).

A maximum of 25 project areas may be funded for NHBS. NHBS sites comprise the state and local health departments with the highest HIV 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 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 PS16-1601 was published May 12, 2015. From 2016 to 2020, 23 sites participate in NHBS.

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 2005, 2008, and 2011 MSM cycles of NHBS were published in *Morbidity and Mortality Weekly Report* and received media attention for demonstrating an increasing trend in the percentage of MSM who report engaging in condomless anal sex. Data from the heterosexual cycle of NHBS were presented at the 2010 International AIDS Conference and published in *Morbidity and Mortality Weekly Report* and received media attention for demonstrating the association of HIV prevalence with poverty in this population. Data from the 2012 IDU cycle were presented at the 2015 National HIV Prevention Conference and received media attention for demonstrating the association of syringe exchange programs with reduced risky injection practices. Data from 2012, 2014, and 2015 published in JAMA in 2018 showed significant missed opportunities for HIV testing by healthcare providers among MSM and IDU who were HIV-positive, but unaware of their infection. Finally, data from all three NHBS cycles were featured in CDC annual HIV focused MMWR Vital Signs issue, which received wide spread media and public health attention.. See **Attachment 5** 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 (HPTN 064). 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 MSM venues 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 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 persons who inject drugs 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 NHBS-HET to the entire population of injecting drug users or heterosexually active person at increased risk for HIV infection in each MSA.

3. Use of Improved Information Technology and Burden Reduction

Interview data will be collected on password-protected encrypted portable 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 project areas

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 disbursement 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 in detail 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 portable computers 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 2 years to 6 months. Also, the cost of data collection using portable computers instead of paper data collection forms is also reduced despite the increased start-up costs associated with purchasing the portable computers and interview software. The incremental cost of each collected assessment decreases with each subsequent interview conducted, so that when collecting more than 195 interviews, it is less expensive to use the portable computers than paper.

CDC/DHAP has implemented the use of portable computers 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 HIV prevalence.

Within CDC, there are three complementary systems already in place that contains similar data elements to NHBS:

- National HIV Surveillance System (NHSS) (OMB 0920-0573, exp. 6/30/2019)
- Medical Monitoring Project (MMP)(OMB 0920-0740, exp. 6/30/2021)
- Barriers and Facilitators to Expanding the NHBS to Conduct HIV Behavioral Surveillance Among Transgender Women (NHBS-Trans)(OMB 0920-1262, exp. 4/30/2022)

The existing information collections above cannot be modified, used partially, nor in aggregate format to satisfy the needs of the proposed project. NHSS collects data on HIV-infected persons. MMP collects data on a population-based sample of HIV-infected patients in care. Both systems are limited to persons already infected with HIV and neither system collects data on 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, from 2006-2009, CDC collaborated on an NIH-funded HIV Prevention Trial Network (HPTN), number 064. The goal of this trial was to measure HIV seroprevalence among women in 12 U.S. cities. CDC collaborated on this project by sharing the methodology used in NHBS-HET. The project used venue-based sampling methods to recruit high risk heterosexual women into the project, which is not the method used by NHBS. In addition, 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 is different from the goal of NHBS-HET. Further, the NIH project only recruited women with high risk behaviors (such as sexual or drug use behaviors), which are not the same recruitment criteria for NHBS-HET. 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 2008-2019 and are planned to continue from 2020-2023; because it is a surveillance system from which ongoing data are needed to monitor progress, it is expected that NHBS will continue beyond 2023. 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 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 8, NHBS Cycle Overview**). Collecting data for fewer than 6 months may result in project area 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 project areas 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

A 60-day notice to solicit public comments was published in the Federal Register on July 5, 2019, Vol. 84, No. 129 page 32,184 (**Attachment 2**). No public comments were received.

Consultations with external experts and stakeholders from state and local health departments and major academic institutions in NHBS project areas are conducted on an ongoing basis, most recently in November 2018. During this two-day meeting, over 40 representatives from state and city health departments and academic institutions provided feedback and consulted on NHBS operations, key areas of interest, analysis strategies, and dissemination plans. There were no major unresolved problems

identified during the meeting. The names, affiliations, and contact information for meeting attendees are included in **Attachment 9**.

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 on average the interview takes 24-43 minutes to complete, to increase response rates, eligible persons are offered an incentive following participation. We anticipate that increased response rates will lead to improved representativeness of the underlying population of interest.

Participants are given \$20-\$50 for completing the interview, amount and form (cash, gift cards, cash cards, bus or subway tokens) are determined locally based on local regulations, city characteristics (e.g. cost of living), and previous research experience. In most sites, participants receive \$25 in cash. Participants who agree to HIV testing are offered an additional incentive. Participants who give a specimen for HIV testing are given \$10-\$50 for participation, amount and form (cash, gift cards, cash cards, bus or subway tokens) are determined locally based on local regulations, city characteristics (e.g. cost of living), and previous research experience. In most sites, participants receive \$25 in appreciation for providing a specimen for HIV testing.

In the RDS methodology, participants also receive an incentive 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 recruiting a peer to the assessment increases peer recruitment. Recruiter rewards are \$10-\$25 for each of up to five peer referrals, which is standard for RDS studies (Heckathorn, Semaan, et al., 2002; Ramirez-Valles, 2005; Wang, 2005). As for the assessment and testing, amount and form (cash, gift cards, cash cards, bus or subway tokens) are determined locally based on local regulations, city characteristics (e.g. cost of living), and previous research experience. In most sites, participants receive \$10 in appreciation for recruitment.

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. 6/30/2021), described in section 4 above, which asks questions similar to those in NHBS and has a similar length of time for completing the behavioral assessment. These incentives were used to help increase participation rates; participants were offered approximately \$25. Incentives have been shown to increase response rates, which in turn improves the validity and reliability of the data (Abreu and Winters, 1999; Shettle and Mooney, 1999; Whiteman et al., 2003). A meta-analysis (Church, 1993) of survey methodologies found that studies using monetary incentives yielded an average increase in response rates of 19.1 percentage points, representing a 65% average increase in response. 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. Protection of the Privacy and Confidentiality of Information Provided by Respondents

A. The CDC Privacy Office has assessed this package for applicability of 5 U.S.C. § 552a. The Privacy Act is not applicable because PII is not being collected under this CDC funded activity (**Att 6b**).

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 assessment, 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 assessment 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 identified (PII) information collected, NHBS is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data (**Attachment 6a**). 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 previously approved data collection was assessed for privacy impact (**Attachment 6b**).

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. For each cycle, the eligibility screener includes questions about behavior. For the MSM cycle, such an eligibility screener is necessary in order to ensure that men with previous male-male sexual activity are being interviewed; for the IDU cycle, the

eligibility screener is necessary in order to ensure that current injection drug users are being interviewed; whereas for the HET cycle, the eligibility screener ensures that sexually active heterosexuals are being interviewed.

The only personally identifiable information (PII) collected is the respondent's date of birth. The date of birth is collected during eligibility screening (**Attachment 3a**). It is used to determine eligibility for the NHBS and 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.

The recruiter debriefing (**Attachment 3e**) 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 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 reported no one refused a coupon.

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 in section 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 "Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs" available at (www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf).

A number of required protections ensure the security of the data on the portable computers. The portable computers are solely used for NHBS data collection activities. NHBS data are encrypted when stored on a portable device. Portable computers are protected by using a coded password only known by authorized NHBS project staff. NHBS data are deleted from the portable computers after the last interview of the day by uploading the collected interviews to the main database. The portable 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 portable 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 Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action. Centers for Disease Control and Prevention; 2011 available at:

<http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf> 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 Office of Financial Resources 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 7**), to 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 portable computer. An example model consent document is included as **Attachment 10**. Consent must be obtained for the assessment and HIV testing separately. Participants may elect to complete the behavioral assessment and not be tested; however, they may not be tested without completing the behavioral assessment (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.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The approved Project Determination Form (**Attachment 11**) indicates that because the project is a routine disease surveillance activity, the protocol will not be reviewed by CDC's IRB. Each participating health department will be required to obtain approval for this project from their IRB as required by their local review and approval processes and federal regulations before data collection.

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, 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 portable computers for data collection addresses concerns the respondent might have about privacy (that others can see their answers).
- If at any point respondents feel uncomfortable, they may skip any questions or stop the survey altogether.

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

NHBS data collections occur in annual cycles and focus on a different population each year: MSM, IDU, and HET, successively. The number of participants is expected to vary from cycle to cycle, as described in Table B1 in Supporting Statement B. The annualized estimates of respondent burden for each data collection form provided below represent averages across the three years. Because HIV testing is a clinical procedure, it is not included in the burden estimates. An eligibility 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 sexual behavior or drug injection (**Attachments 3a and 4a**). Approximately 15,000 individuals will complete the eligibility screener annually. We estimate that it will take five minutes to complete the eligibility screener. We anticipate that, on average, 2,500 of the respondents (16.66%) will be either not interested in completing a behavioral assessment (MSM, IDU, or HET) or will be ineligible after completing the eligibility screener, yielding a total of 12,500 eligible respondents over a 12-month period: 4,167 MSM (**Attachments 3b and 4b**); 4,167 IDU (**Attachments 3c and 4c**), and 4,167 HET (**Attachments 3d and 4d**). We estimate that it will take 24 minutes for a respondent to complete behavioral assessment-MSM, 31 minutes for behavioral assessment-HET and 43 minutes for behavioral assessment-IDU. The time for completion varies because the different behavioral

assessment forms focus on different risk behaviors. Only 50% of respondents in the IDU and HET cycles will complete the recruiter debriefing (**Attachments 3e and 4e**). We estimate 4,167 individuals will complete the recruiter debriefing annually, which will take 2 minutes per respondent. The recruiter debriefing does not apply to MSM respondents.

The estimates in Table A.12.1 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 in a separate instrument (**Attachment 3e and 4e**) to reflect the fact that not all respondents will return and be asked these questions.

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)
Persons Screened	Eligibility Screener (att 3a/4a)	15,000	1	5/60	1,250
Eligible Participants	Behavioral Assessment MSM (att 3b/4b)	4,167	1	24/60	1,667
Eligible Participants	Behavioral Assessment IDU (att 3c/4c)	4,167	1	43/60	2,986
Eligible Participant	Behavioral Assessment HET (att 3d/4d)	4,167	1	31/60	2,153
Peer Recruiters	Recruiter Debriefing (att 3e/4e)	4,167	1	2/60	139
Total Annualized Burden					8,195

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:

<http://www.bls.gov/cps/cpsaat39.htm>

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Burden Hours	Hourly wage rate	Total Respondent Cost
Persons Screened, (Att 2a/3a)	15,000	1	1,250	\$22.15	\$27,688
Eligible Participants MSM (Att 2b/3b)	4,167	1	1,667	\$22.15	\$36,924
Eligible Participants IDU, (Att 2c/3c)	4,167	1	2,986	\$22.15	\$66,140
Eligible Participants HET (Att 2d/3d)	4,167	1	2,153	\$22.15	\$47,689
Peer Recruiters (Att 2e/3e)	4,167	1	139	\$22.15	\$3,079
Total Annualized Cost					\$181,520

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 annualized cost to the government is \$12,058,565. The cost of this project for the three years is estimated to be \$36,175,695. 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	\$1,484,565
	Epidemiologist-14	3 100% \$117,581
	Epidemiologist-14	2 50% \$58,791
	Epidemiologist-13	3 100% \$99,500
	Epidemiologist-13	5 75% \$74,625
	Epidemiologist-13	1 50% \$49,750
	Epidemiologist-12	3 100% \$83,676
	Epidemiologist-12	1 50% \$41,838
	Cooperative agreement funds to project areas	\$9,200,000
Contractor and Other Expenses	Data Coordinating Center (CDC Contractor for data collection)	\$950,000
	Contracted Project Coordinator (1)	\$80,000
	Contracted Data Analyst (1)	\$80,000
	Contracted Administrative Assistant (1) 0.5 FTE	\$20,000
	Contracted Questionnaire Programming	\$200,000
	Travel	\$40,000
	Meetings	\$0
	Spanish language translation	\$3,000
	Printing	\$1,000
	TOTAL COST TO THE GOVERNMENT	\$12,058,565

*Salary estimates were obtained from the US Office of Personnel Management salary scale at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2019/general-schedule/>.

The personnel related to the NHBS data collection include project officers (epidemiologists) at the GS-12, 13, and 14 levels, a project coordinator, an administrative assistant, and a data analyst. 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 that will be held in government space at no cost.

The information collection described in this request will be funded through cooperative agreements with state and local health departments starting in fiscal year 2021. 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.

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

15. Explanation for Program Changes or Adjustments

The number of health departments participating in the NHBS System will increase (from 23 to 25). However, due to a 20% reduction to the estimated burden per response for all 3 behavioral assessment information collection instruments (**Attachments 3b-d and 4b-d**), the total burden will decrease. As a result, the total annualized burden will decrease from 9,138 hours to 8,195.

The following revisions were made to the eligibility screener and behavioral assessments of the OMB-approved project 0920-0770:
(For detailed description, see **Attachment 13**)

- Revision of the eligibility screener: 3 questions assessing census tract and zip code were deleted as it is no longer needed as an eligibility requirement.
- Addition of high priority topics to the behavioral assessment: To improve data collection of a priority emerging issue related to HIV risk and prevention, questions on Pre-Exposure Prophylaxis (PrEP) measuring stages along the prevention continuum for HIV-negative persons were added.
- Deletion of lower priority topics from behavioral assessment: To reduce burden, items measuring low priority or repetitive content were deleted.
- Measurement improvements in the behavioral assessment: All items were reviewed for data quality, cognitive ease, and interview flow. Improvements (additions, deletions, and modifications) were made where possible.

- Changes to reduce repetitive language and improve interview flow in the behavioral assessment: Wording of introductory text and questions was modified to reduce repetitive language and information read to participants. Location of some items was changed to improve flow and participant experience.

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 8** 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	2 months after OMB approval
End interviewing MSM participants	7 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 18 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 12** 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 12 months - 18 months of the end of each

cycle of data collection. For instance, the MSM5 data collection results (end of data collection: December 2017) were published in February 2019.

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, and 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;
- Prevalence of HIV infection, including previously undiagnosed HIV infection;
- Prevalence of receiving prevention services, including PrEP use and receiving 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, and 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 heterosexually active persons at increased risk of HIV infection. 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 **Attachment 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.

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