



Centers for Disease Control and Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

National HIV Behavioral Surveillance (NHBS)

CDC-RFA-PS16-1601

Application Due Date: 08/03/2015

Signature

Date

National HIV Behavioral Surveillance (NHBS)

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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-PS16-1601. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC)

B. Funding Opportunity Title:

National HIV Behavioral Surveillance (NHBS)

C. Announcement Type: New - Type 1

This announcement is only for non-research domestic activities supported by CDC. If research is proposed, the application will not be considered Research for this purpose is defined at <http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>.

D. Agency Funding Opportunity Number:

CDC-RFA-PS16-1601

E. Catalog of Federal Domestic Assistance (CFDA) Number:

93.944

F. Dates:

1. Due Date for Letter of Intent (LOI):

06/10/2015

2. Due Date for Applications:

08/03/2015, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Date for Informational Conference Call:

06/17/2015

An informational conference call will be held on Wednesday June 17, 2015 from 1:30 - 3:00 PM EDT.

Dial in number: 1-866-742-9957

Passcode: 4052267

Questions may also be directed to nhbsquestions@cdc.gov

G. Executive Summary:

1. Summary Paragraph:

According to the CDC, by the end of 2011 an estimated 1,201,100 persons aged 13 years and older were living with HIV infection in the U.S. (CDC 2014), with over 45,000 new infections occurring each year (CDC 2012). Of the estimated new infections in 2010, 63% were among men who have sex with men (MSM), 25% high-risk heterosexuals, and 8% persons who report injection drug use (IDU) (CDC 2013). The purpose of National HIV Behavioral Surveillance (NHBS) is to continue an ongoing bio-behavioral surveillance system among high-risk populations, including MSM, IDU and heterosexuals at increased risk (referred to as NHBS-MSM, NHBS-IDU and NHBS-HET respectively). NHBS conducts rotating cycles of surveillance and anonymous HIV testing over time among these different populations in Metropolitan Statistical Areas (MSAs) with the highest HIV prevalence in the United States. This FOA will fund awardees for several required Core NHBS strategies and activities related to preparing for and conducting annual recruitment and data collection, data management and dissemination, quality assurance, and collaboration. If funds are available, applicants may be funded to conduct up to two additional optional NHBS activities (anonymous hepatitis testing during NHBS-IDU cycles and anonymous STI testing during

NHBS-MSM and NHBS-HET cycles) and to conduct NHBS with up to two additional optional populations (NHBS among young men who have sex with men (YMSM) and NHBS among transgender women). The short-term aim of this 5-year project is for NHBS data to be used by state and local partners to measure testing, treatment, and prevention efforts; to guide the development and strengthening of these efforts; and to inform policy makers regarding important prevention issues. In the long-term, ongoing use of NHBS data nationally will result in improved HIV prevention, testing and treatment services for and reduced HIV incidence among populations at high risk for HIV infection.

a. Eligible Applicants:	Limited
b. FOA Type:	Cooperative Agreement
c. Approximate Number of Awards:	25
Subject to availability of funds, up to 25 awards	
d. Total Project Period Funding:	\$76,600,000
e. Average One Year Award Amount:	\$550,000
For Fiscal Year 2016, \$470,000 (required core NHBS), \$80,000 (optional STI testing during NHBS-HET)	
f. Number of Years of Award:	5
g. Estimated Award Date:	01/01/2016
h. Cost Sharing and / or Matching Requirements:	N
Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this FOA exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.	

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

For over 30 years, HIV has been an epidemic affecting millions globally. According to CDC, by the end of 2011 an estimated 1,201,100 persons aged 13 years and older were living with HIV infection in the U.S. (CDC 2014), with over 45,000 new infections occurring each year (CDC 2012). The burden of HIV infection is disproportionately concentrated among few high-risk populations. Of the estimated new infections in 2010, 63% were among men who have sex with men (MSM), 25% high-risk heterosexuals, and 8% persons who report injection drug use (IDU) (CDC 2013). This FOA will aid in reducing HIV incidence among populations at high risk for HIV infection and improve HIV prevention, testing, and treatment services for them through the continuation of National HIV Behavioral Surveillance (NHBS) which is the nation's only source of national data monitoring of HIV associated outcomes among populations at high risk for HIV infection.

Monitoring prevalence of HIV and other infections, awareness of infection, risk behaviors, and access to and utilization of prevention services including HIV testing and PrEP among members of high-risk populations is critical to achieving the goals of the National HIV/AIDS Strategy (NHAS) and CDC's High Impact Prevention (HIP) approach. NHBS has previously proven effective at monitoring key outcomes among high-risk populations.

Recent publications of NHBS-MSM data show that the overall HIV prevalence among MSM has remained stable at 18% since 2008, and efforts to increase the percentage of HIV-positive MSM who are aware of their infection are having a positive effect (Wejnert, Le et al. 2013): NHBS data show that from 2008 to 2011, the

percentage of MSM who reported testing in the past 12 months has increased significantly (Cooley, Oster et al. 2014). Similarly, the percentage of HIV-positive MSM who are aware of their infection has increased from 56% to 66% overall (Wejnert, Le et al. 2013). Despite these advances, NHBS data also highlight areas of need among the MSM population. For example, NHBS data have shown that among racial/ethnic MSM groups, black MSM are most likely to be infected with HIV but least likely to be aware of their infection (Wejnert, Le et al. 2013). Furthermore, a recent NHBS analysis showed that larger numbers of MSM are engaging in anal sex without a condom than in previous years (Paz-Bailey, Hall et al. 2013).

A 2012 analysis of NHBS data presented the first national estimate of HIV prevalence among IDU in over 10 years. The estimated prevalence, 9%, was approximately one half that estimated previously and suggested substantial progress in the fight against HIV among the IDU population (CDC 2012). However, NHBS-IDU data also show that additional effort is needed to reduce the large numbers of IDU who continue to engage in sexual and drug-use behaviors that increase their risk of infection (Broz, Pham et al. 2014).

NHBS data among heterosexuals at increased risk for HIV infection (NHBS-HET) have shown prevalence among low SES, urban heterosexuals to be 2.3%, five times the 0.45% estimated for persons aged ≥ 13 years in the U.S. (Miles, Le et al. 2013). Further, NHBS data have shown that HIV prevention strategies that address socioeconomic factors can help maximize the effectiveness of the public health response to the HIV epidemic among African American women (Ivy, Miles et al. 2013).

NHBS is a strong surveillance platform that allows CDC to monitor emerging infections among high-risk populations such as sexually transmitted infections (STI) and hepatitis viruses. Other high-risk groups such as young MSM (YMSM) and transgender women (persons born male who identify as female or anything other than male) have also been surveyed through NHBS.

b. Statutory Authorities

This program is authorized under Sections 317(k) (2) and 318 (c) of the Public Health Service Act [42 U.S.C. Sections 247b (k) (2) and 247c (c)], as amended.

c. Healthy People 2020

This program specifically addresses or contributes to the following Healthy People 2020 objectives:

- HIV-14.2: (Measureable) Increase the proportion of men who have sex with men (MSM) who report having been tested for HIV in the past 12 months.
- HIV-18: (Measureable) Reduce the proportion of men who have sex with men (MSM) who reported unprotected anal intercourse with a partner of discordant or unknown status during their last sexual encounter.

For additional details on the Healthy People 2020 objectives listed above, visit <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=22>.

d. Other National Public Health Priorities and Strategies

This program specifically addresses or contributes to the following National HIV/AIDS Strategy (NHAS) goals:

- Reducing new HIV infections
- Increasing access to care and improving health outcomes for people living with HIV
- Reducing HIV-related disparities and health inequities

For additional details on the NHAS goals listed above, visit <https://www.whitehouse.gov/administration/eop/onap/nhas/>

e. Relevant Work

This new FOA builds upon the work of the three previous National HIV Behavioral Surveillance (NHBS) FOAs (PA 04-017, PS08-001 and PS11-001). NHBS is CDC's comprehensive system for conducting behavioral surveillance among persons at highest risk for HIV infection in the US. The overall strategy for NHBS involves conducting rotating cycles of surveillance and anonymous HIV testing over time among different populations at high risk for HIV in Metropolitan Statistical Areas (MSAs) with the highest HIV prevalence in the United States. The findings from NHBS will be used to guide local and national HIV prevention programs and to evaluate existing programs and services by assessing exposure to and use of prevention services over time, and to determine gaps in provision of, access to or use of HIV prevention services. In particular, the prevalence of HIV infection and the percent of HIV-positive individuals who are unaware of their HIV-positive status can be used to target testing, treatment and other preventions efforts and to evaluate uptake of current HIV testing and other prevention guidelines. Additional information can be found at <http://www.cdc.gov/hiv/statistics/systems/nhbs/>

2. CDC Project Description

a. Approach

The following logic model depicts the main activities and resulting outputs that constitute the strategies the awardee is to undertake, and the outcomes expected in the short-term as a result of these efforts, and the mid-term outcomes and the long-term public health achievements to which these short-term outcomes will contribute.

Strategies and Activities	Outputs	Short-Term Outcomes	Mid-Term Outcomes	Long-Term Outcomes
<i>Outputs and outcomes in italics to be accomplished in project period.</i>				
Required Core NHBS (NHBS-MSM, NHBS-IDU, and NHBS-HET): 1) Preparation: - Conduct formative assessment - Conduct pre-implementation activities 2) Recruitment and Data Collection: - Recruit populations at high risk for HIV infection - Conduct standardized surveys - Offer anonymous blood-based HIV testing - Collect and store blood specimens for future testing - Send specimens to CDC or CDC designated laboratories 3) Data Management and Dissemination: - Ensure HIV data security and confidentiality - Manage and submit data - Analyze and disseminate data 4) Quality Assurance: - Attend relevant trainings and meetings - Conduct quality assurance activities - Evaluate NHBS strategies and methods 5) Collaboration: Collaborate with partners and stakeholders to: - Conduct NHBS and evaluations - Disseminate findings / promote data use - Ensure participant referrals Optional NHBS Activities: - Conduct anonymous hepatitis testing during NHBS-IDU - Conduct anonymous STI testing during NHBS-MSM and NHBS-HET Optional NHBS Populations (using strategies listed above): - Conduct NHBS among YMSM - Conduct NHBS among transgender women	<i>Effective implementation of NHBS</i> <i>Data meet all data security requirements and are reported into the national system</i> <i>Improved ability to measure prevalence of HIV-related behaviors, use of services, HIV infection, and other relevant infections (e.g. hepatitis, STIs)</i> <i>High-quality locally and nationally relevant data for resource allocation and evaluation of HIV prevention, testing and treatment efforts</i> <i>Increased dissemination of data to key stakeholders</i> <i>Improved information on methods to reach populations at high risk for HIV infection</i> <i>Enhanced collaboration among federal and local partners responsible for HIV prevention, testing and treatment</i>	<i>Ongoing use of NHBS data by state and local partners to:</i> <i>measure testing, treatment and prevention efforts</i> <i>guide the development and strengthening of these efforts</i> <i>inform policy makers regarding important prevention issues</i> Improved NHBS strategies and methods to reach populations at high risk for HIV infection	Improved national monitoring of the HIV epidemic through an ongoing HIV bio-behavioral surveillance system Improved ability to detect changes over time in HIV risk behaviors among populations at high risk for HIV infection Increased use of surveillance data to develop effective HIV prevention, testing and treatment activities Increased use of data to evaluate prevention, testing and treatment activities	Improved HIV prevention, testing and treatment services for populations at high risk for HIV infection Reduced HIV incidence among populations at high risk for HIV infection

i. Purpose

The purpose of the NHBS program is to continue an ongoing bio-behavioral surveillance system to monitor the HIV epidemic, to detect changes over time in HIV-risk behaviors and HIV prevalence among populations at high risk for HIV infection and to inform and evaluate HIV prevention activities. NHBS collects about 10,000 surveys annually. The data from NHBS are used to improve HIV prevention, testing and treatment services (by identifying sub-groups with sub-optimal treatment utilization) for and to reduce HIV incidence among populations at high risk for HIV infection.

ii. Outcomes

As depicted in the logic model (in italics), the awardee will be expected to show progress on the following outputs:

- Effective implementation of NHBS
- Data meet all data security requirements and are reported into the national system
- Improved ability to measure prevalence of HIV-related behaviors, use of services, HIV infection, and

- other relevant infections (e.g. hepatitis, STIs)
- High-quality locally and nationally relevant data for resource allocation and evaluation of HIV prevention, testing and treatment efforts
- Increased dissemination of data to key stakeholders
- Improved information on methods to reach populations at high risk for HIV infection
- Enhanced collaboration among federal and local partners responsible for HIV prevention, testing and treatment

The awardee will also be expected to show progress on the following short-term outcome:

- Ongoing use of NHBS data by state and local partners to measure testing, treatment and prevention efforts; to guide the development and strengthening of these efforts; and to inform policy makers regarding important prevention issues.

iii. Strategies and Activities

As depicted in the logic model, there are 5 required strategies (see logic model) awardees are expected to undertake each year of the FOA in order to conduct required Core NHBS in rotating data collection cycles among men who have sex with men (MSM), persons who report injection drug use (IDU) and heterosexuals at increased risk for HIV infection (referred to as NHBS-MSM, NHBS-IDU and NHBS-HET respectively).

As part of NHBS, eligible applicants may apply for up to 2 optional activities which will be awarded if funds are available: anonymous hepatitis testing during NHBS-IDU and anonymous STI testing during NHBS-MSM and NHBS-HET. In addition, eligible applicants may also apply to conduct the NHBS strategies with up to 2 optional populations: young MSM (YMSM) and transgender women, which will be awarded if funds are available.

The activities encompassed by the 5 required strategies to conduct Core NHBS will result in seven powerful outputs for which the awardee will be expected to show progress during the project period (as depicted in the logic model in italics). If funds are available, the 2 optional NHBS activities and the activities encompassed by conducting NHBS strategies among the 2 optional populations will also contribute to the same seven outputs:

- Effective implementation of NHBS
- Data meet all data security requirements and are reported into the national system
- Improved ability to measure prevalence of HIV risk behaviors, HIV infection, and other relevant infections (e.g. hepatitis, STIs)
- High-quality locally and nationally relevant data for resource allocation and evaluation of HIV prevention, testing and treatment efforts
- Increased dissemination of data to key stakeholders
- Improved information on methods to reach populations at high-risk for HIV infection
- Enhanced collaboration among federal and local partners responsible for HIV prevention, testing and treatment

Note that all activities shall be implemented according to CDC-approved guidance and procedures, including the provision of participant incentives for recruitment and data collection activities when indicated.

Required Core NHBS: NHBS-MSM, NHBS-IDU and NHBS-HET:

The following required strategies and activities will be conducted each year of the FOA as part of Core NHBS among MSM, IDU and heterosexuals at increased risk for HIV infection:

1) Preparation:

- Conduct formative assessment: Obtain regulatory approvals, if locally required, to collect primary data for formative assessment. In accordance with CDC-approved guidance, conduct review of secondary

data sources, observations, key informant interviews, focus groups and other activities to inform best operational procedures and to identify interview locations. Write and submit reports and other required documents summarizing findings from the formative assessment per CDC-approved guidance.

- Conduct pre-implementation activities: Conduct all pre-implementation activities according to CDC-approved timelines in order to initiate recruitment and data collection in time to meet annual sample size. Obtain regulatory approvals to conduct NHBS activities as required locally, including, but not limited to Institutional Review Board approval, approval to conduct Core NHBS activities under surveillance authority, or approvals to waive written consent. Develop standard operating procedures for management of adverse events, safeguards to preserve participant anonymity and data confidentiality, and activities to address urgent needs identified during contact with participants such as linkage to HIV care. Hire and train required staff needed to recruit participants, collect data, conduct anonymous blood-based HIV testing and conduct other activities. Set up interview locations and obtain all required equipment, supplies and other materials to conduct all activities. Provide input on all national operational documents and data collection instruments, including, but not limited to formative assessment manuals, operations manuals, questionnaires, interviewer guides, data management manuals and other documentation of standard operating procedures. Complete and submit checklists documenting pre-implementation activities and operational procedures (operations checklist).

2) Recruitment and Data Collection:

- Recruit populations at high risk for HIV infection: Collect bio-behavioral surveillance data in rotating data collection cycles among MSM, IDU, and heterosexuals at increased risk for HIV infection. According to CDC-approved guidance and timelines, implement recruitment strategies that include venue based, time-space sampling (VBS), respondent-driven sampling (RDS), and other CDC-approved strategies to recruit populations at high risk for HIV infection.
- Conduct standardized surveys: Complete standardized in-person surveys with eligible participants to meet the annual sample size.
- Offer anonymous blood-based HIV testing: Offer anonymous blood-based rapid testing and supplemental testing for HIV infection to participants in order to assess HIV seroprevalence. HIV screening results shall be made available to participants. Participants with preliminary positive test results shall be referred to HIV care. Oral specimens can be collected under circumstances in which blood specimens cannot be obtained from participants. Standard HIV testing can be conducted under circumstances in which rapid HIV testing cannot be administered.
- Collect and store blood specimens for future testing: Collect dried blood spots, plasma or other blood specimens for testing to detect antibodies and virus including assays that determine recent infection, viral load and antiretroviral drug resistance.
- Send specimens to CDC or CDC designated laboratories: Prepare frequent shipments of specimens to the CDC or CDC designated laboratories in compliance with CDC-approved guidance and timelines.

3) Data Management and Dissemination:

- Ensure HIV data security and confidentiality: Adhere to all local and national guidelines for maintaining HIV data security and confidentiality, including but not limited to the Centers for Disease Control and Prevention's Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action available at <http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>. Conduct annual data security and confidentiality trainings. Submit *Certification Statement* annually.
- Manage and submit data: Manage all data locally and submit data to the CDC Data Coordinating Center according to CDC-approved guidance and timelines, including but not limited to interview, HIV test results, recruitment and other data. Conduct data cleaning activities according to CDC timelines including reconciliation, reviewing and responding to error reports and other activities as needed to maintain data quality.

- Analyze and disseminate data: For each Core NHBS population, produce at least one report (fact sheets, epidemiologic profiles, surveillance reports, peer-reviewed manuscripts or other formats as appropriate) and conduct at least one presentation to community partners and stakeholders. Efforts shall be made to customize data dissemination activities to inform key decisions regarding budgeting, planning, and evaluation of HIV treatment and prevention activities. Report on annual data use and dissemination activities accomplished to CDC. Contribute to national data collection outcomes such as surveillance reports and other publications by reviewing concept proposals, table shells and manuscript drafts within specified timelines and participating in discussions during monthly conference calls and annual meetings. Work with local officials to participate in data sharing through national restricted use datasets.

4) Quality Assurance:

- Attend relevant trainings and meetings: Attend all trainings required by CDC to include field operations and data management trainings. Attend all required meetings including but not limited to the annual awardee meeting. Attend all site visits, webinars and conference calls.
- Conduct quality assurance activities: Conduct all required data quality assurance activities, including but not limited to field staff evaluations, as described in CDC-approved guidance documents.
- Evaluate Core NHBS strategies and methods: Conduct ongoing formative assessment each data collection cycle to improve operational procedures. Conduct evaluations of Core NHBS, its recruitment strategies and data collection methods as necessary to ensure that the system is meeting its goals. Awardees are expected to make recommendations for improving the quality, efficiency and usefulness of NHBS both locally and nationally.

5) Collaboration:

- Collaborate with partners and stakeholders to conduct Core NHBS and evaluations: Collaborate on Core NHBS survey development, strategies, methods and implementation with community partners and stakeholders. Academic or public health partners with expertise in qualitative and quantitative methods may strengthen the planning and implementation of bio-behavioral surveillance activities and evaluation.
- Collaborate with partners and stakeholders to disseminate findings/promote data uses: Disseminate and present Core NHBS findings to health departments, Community Based Organizations (CBOs), and other community partners to inform HIV prevention and services planning and decision-making.
- Collaborate with partners and stakeholders to ensure participant referrals: Collaborate with community partners and stakeholders to plan optimal methods and sources for referring participants to social and health services and linking participants to HIV, hepatitis and STI care.

Optional NHBS Activities:

The following 2 optional NHBS activities will be awarded if funds are available. These optional activities shall be conducted in conjunction with the NHBS platform and in accordance with CDC-approved guidance. Optional NHBS activities for which eligible applicants may apply include:

Optional activity #1: Conduct anonymous hepatitis testing during NHBS-IDU:

As part of the NHBS platform and in accordance with CDC-approved guidance and procedures, up to 10 awardees will be funded (if funds are available) for this optional activity to offer anonymous hepatitis testing to participants of the NHBS-IDU data collection cycle in accordance with CDC-approved guidance and procedures. Based on availability of funds, awardees may be funded to conduct Hepatitis B testing, Hepatitis C testing or both:

- Offer anonymous Hepatitis B testing: Offer anonymous testing for Hepatitis B to participants in order to assess Hepatitis B seroprevalence. Hepatitis B test results shall be made available to participants and those with positive test results shall be referred to care.
- Offer anonymous Hepatitis C testing: Offer anonymous testing for Hepatitis C to participants in order

to assess Hepatitis C seroprevalence. Hepatitis C results shall be made available to participants and those with positive test results shall be referred to care.

- Collect and store blood specimens: Collect blood specimens for laboratory and confirmatory testing according to CDC-approved methods and guidance.
- Send specimens to local and CDC laboratories: Prepare frequent shipments of specimens to local and CDC laboratories in compliance with CDC-approved guidance and timelines.
- Ensure data security and confidentiality: Adhere to all local and national guidelines for maintaining data security and confidentiality, including but not limited to the Centers for Disease Control and Prevention's 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.
- Manage and submit test result data: Manage all test result data locally and submit data to the CDC Data Coordinating Center according to CDC-approved guidance and timelines. Conduct data cleaning activities according to CDC timelines including reconciliation, reviewing and responding to error reports and other activities as needed to maintain data quality.

Optional activity #2: Conduct anonymous STI testing during NHBS-MSM and NHBS-HET:

As part of the NHBS platform and in accordance with CDC-approved guidance and procedures, up to 5 awardees will be funded (if funds are available) for this optional activity to offer anonymous STI testing to female participants of the NHBS-HET data collection cycles or to participants of the NHBS-MSM data collection cycles or to both populations during the specified cycles in accordance with CDC-approved guidance and procedures. Testing among female heterosexuals will be limited to participants 30 years of age and younger. Applicants can apply to conduct this optional activity in one or both populations, which will be awarded based on the availability of funds.

- Offer anonymous testing for both gonorrhea and chlamydia: Offer both anonymous gonorrhea and chlamydia testing to participants. Test results shall be made available to participants and those with positive test results shall be referred to care. Self-collected vaginal swab specimens shall be collected for female heterosexuals up to the 30 years of age and younger and self-collected pharyngeal and rectal swab specimens shall be collected from MSM.
- Collect specimens: Collect swabs for laboratory testing according to CDC-approved methods and guidance. Specimen collection may include innovative strategies such as the provision of kits for home collection.
- Send specimens to local and CDC laboratories: Prepare frequent shipments of specimens to local and CDC laboratories in compliance with CDC-approved guidance and timelines.
- Ensure data security and confidentiality: Adhere to all local and national guidelines for maintaining data security and confidentiality, including but not limited to the Centers for Disease Control and Prevention's 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.
- Manage and submit test result data: Manage all test result data locally and submit data to the CDC Data Coordinating Center according to CDC-approved guidance and timelines. Conduct data cleaning activities according to CDC timelines including reconciliation, reviewing and responding to error reports and other activities as needed to maintain data quality.

Optional NHBS Populations:

If funds are available, awardees will be funded to conduct NHBS strategies with the following 2 optional populations at high risk for HIV infection: young MSM (YMSM) and transgender women. NHBS with these 2 optional populations shall be conducted in accordance with CDC-approved guidance. Optional NHBS populations for which eligible applicants may apply include:

Optional population #1: Conduct NHBS among YMSM (NHBS-YMSM):

In accordance with CDC-approved guidance and procedures, up to 10 awardees will be funded (if funds are available) to conduct NHBS among young men who have sex with men (YMSM) ages 13-17, inclusive by performing the NHBS activities listed below. As NHBS does not routinely conduct bio-behavioral surveillance among this population, NHBS-YMSM may require start-up, extensive formative assessment and data collection phases with a total duration of up to 3 years. It is anticipated that start-up activities will begin in Year 2 pending clearances:

Start-up:

- Conduct start-up activities: Apply for regulatory approvals, if locally required, to conduct extensive formative assessment. Begin to engage community partners and to garner community support. Review available data on YMSM and write and submit reports summarizing findings.
- Collaborate with CDC on development of operational documents: Provide input on all national operational documents and data collection instruments. Attend relevant conference calls.

Extensive formative assessment:

- Conduct extensive formative assessment: Conduct observations, key informant interviews, focus groups and other activities to inform best operational procedures and to identify interview locations. Write and submit reports and other required documents summarizing findings from the formative assessment based on CDC-approved guidance.
- Collaborate with partners and stakeholders to conduct NHBS-YMSM and evaluations: Collaborate on survey development, methods and implementation with community partners and stakeholders. Academic or other public health partners with expertise in qualitative and quantitative methods to survey YMSM will strengthen the planning and implementation of bio-behavioral surveillance activities and evaluation.
- Collaborate with partners and stakeholders to ensure participant referrals: Collaborate with community partners and stakeholders to plan optimal methods for referring participants to social services, other specialized services, and linking participants to HIV care.
- Conduct pre-implementation activities: Obtain regulatory approvals to conduct NHBS-YMSM activities as required locally, including, but not limited to Institutional Review Board approval, approval to conduct NHBS-YMSM under surveillance authority, or approvals to waive written consent and approvals to waive parental consent. Develop standard operating procedures for management of adverse events, safeguards to preserve participant anonymity and data confidentiality, and strategies to address urgent needs identified during contact with participants such as linkage to HIV care and referral to specialized services. Begin to hire and train required staff needed to recruit participants, collect data, conduct blood-based HIV testing and conduct other activities. Set up interview locations and obtain all required equipment, supplies and other materials to conduct all activities. Complete checklist documenting pre-implementation activities and operational procedures.

Data collection:

- Recruit YMSM ages 13-17, inclusive: Collect behavioral surveillance data using recruitment strategies that include respondent-driven sampling (RDS), Facebook Sampling (FBS) or other CDC-approved strategies to recruit YMSM.
- Conduct standardized survey: Complete standardized in-person surveys with eligible participants to meet the sample size for NHBS-YMSM.
- Offer blood-based HIV testing: Offer blood-based rapid testing and supplemental testing for HIV infection to participants in order to assess HIV seroprevalence. HIV screening results shall be made available to participants. Participants with preliminary positive test results shall be referred to HIV care. Oral specimens can be collected under circumstances in which blood specimens cannot be obtained from participants. Standard HIV testing can be conducted under circumstances in which rapid HIV testing cannot administered.

- Collect and store blood specimens for future testing: Collect dried blood spots, plasma or other blood specimens for testing to detect antibodies and virus including assays that determine recent infection, viral load and antiretroviral drug resistance.
- Send specimens to CDC or CDC designated laboratories: Prepare frequent shipments of specimens to CDC or CDC designated laboratories in compliance with CDC-approved guidance and timelines.
- Ensure HIV data security and confidentiality: Adhere to all local and national guidelines for maintaining HIV data security and confidentiality, including but not limited to the Centers for Disease Control and Prevention's Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action available at <http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>. Conduct data security and confidentiality trainings.
- Manage and submit data: Manage all data locally and submit to the CDC Data Coordinating Center according to CDC-approved protocols and timelines, including but not limited to interview, HIV test results, recruitment and other data. Conduct data cleaning activities according to CDC timelines including reconciliation, reviewing and responding to error reports, and other activities as needed to maintain data quality.
- Analyze and disseminate data: For NHBS-YMSM, produce at least one report (fact sheets, epidemiologic profiles, surveillance reports, peer-reviewed manuscripts or other formats as appropriate) and conduct at least one presentation to community partners and stakeholders. Efforts shall be made to customize data dissemination activities to inform key decisions regarding budgeting, planning, and evaluation. Contribute to national data collection outcomes such as surveillance reports and other publications by reviewing concept proposals, table shells and manuscript drafts within specified timelines and participating in discussions during monthly conference calls and annual meetings.
- Attend relevant trainings and meetings: Attend all required trainings, meetings, site visits, webinars and conference calls.
- Conduct quality assurance activities: Conduct all required data quality assurance activities, including but not limited to field staff evaluations, as described in CDC-approved guidance documents.
- Evaluate NHBS-YMSM strategies and methods: Conduct ongoing formative assessment to improve operating procedures. Conduct evaluations of recruitment strategies and data collection methods to reach YMSM ages 13-17, inclusive.
- Collaborate with partners and stakeholders to disseminate findings/promote data uses: Disseminate and present findings to health departments, CBOs, and other community partners to inform HIV prevention and services planning and decision-making.

Optional population #2: Conduct NHBS among transgender women:

In accordance with CDC-approved guidance and procedures, up to 10 awardees will be funded (if funds are available) to conduct NHBS among transgender women by performing the NHBS activities listed below. As NHBS does not routinely conduct bio-behavioral surveillance among this population, NHBS among transgender women may require start-up, extensive formative assessment and data collection phases with a total duration of up to 3 years. It is anticipated that start-up activities will begin in Year 2 pending clearances:

Start-up:

- Conduct start-up activities: Apply for regulatory approvals, if locally required, to conduct extensive formative assessment. Begin to engage community partners and to garner community support. Review available data on transgender women and write and submit reports summarizing findings.
- Collaborate with CDC on development of operational documents: Provide input on all national operational documents and data collection instruments. Attend relevant conference calls.

Extensive formative assessment:

- Conduct extensive formative assessment: Conduct observations, key informant interviews, focus groups and other activities to inform best operational procedures and to identify interview locations. Write and submit reports and other required documents summarizing findings from the formative assessment.
- Collaborate with partners and stakeholders to conduct NHBS among transgender women and evaluations: Collaborate on survey development, methods and implementation with community partners and stakeholders. Academic or other public health partners with expertise in qualitative and quantitative methods to survey transgender women will strengthen the planning and implementation of bio-behavioral surveillance activities and evaluation.
- Collaborate with partners and stakeholders to ensure participant referrals: Collaborate with community partners and stakeholders to plan optimal methods for referring participants to social services, other specialized services, and linking participants to HIV care.
- Conduct pre-implementation activities: Obtain regulatory approvals to conduct activities with transgender women as required locally, including, but not limited to Institutional Review Board approval, approval to conduct activities under surveillance authority, or approvals to waive written consent. Develop standard operating procedures for management of adverse events, safeguards to preserve participant anonymity and data confidentiality, and strategies to address urgent needs identified during contact with participants such as linkage to HIV care and referral to specialized services. Begin to hire and train required staff needed to recruit participants, collect data, conduct anonymous blood-based HIV testing and conduct other activities. Set up interview locations and obtain all required equipment, supplies and other materials to conduct all activities. Complete checklist documenting pre-implementation activities and operational procedures.

Data collection:

- Recruit transgender women: Collect behavioral surveillance data using recruitment strategies that include respondent-driven sampling (RDS) or other CDC-approved strategies to recruit transgender women.
- Conduct standardized survey: Complete standardized in-person surveys with eligible participants to meet the sample size for NHBS among transgender women.
- Offer anonymous blood-based HIV testing: Offer anonymous blood-based rapid testing and supplemental testing for HIV infection to participants in order to assess HIV seroprevalence. HIV screening results shall be made available to participants. Participants with preliminary positive test results shall be referred to HIV care. Oral specimens can be collected under circumstances in which blood specimens cannot be obtained from participants. Standard HIV testing can be conducted under circumstances in which rapid HIV testing cannot administered.
- Collect and store blood specimens for future testing: Collect dried blood spots, plasma or other blood specimens for testing to detect antibodies and virus including assays that determine recent infection, viral load and antiretroviral drug resistance.
- Send specimens to CDC or CDC designated laboratories: Prepare frequent shipments of specimens to CDC or CDC designated laboratories in compliance with CDC-approved guidance and timelines.
- Ensure HIV data security and confidentiality: Adhere to all local and national guidelines for maintaining HIV data security and confidentiality, including but not limited to the Centers for Disease Control and Prevention's Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action available at <http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>. Conduct data security and confidentiality trainings.
- Manage and submit data: Manage all data locally and submit to the CDC Data Coordinating Center according to CDC-approved protocols and timelines, including but not limited to interview, HIV test results, recruitment and other data. Conduct data cleaning activities according to CDC timelines including reconciliation, reviewing and responding to error reports, and other activities as needed to maintain data quality.

- Analyze and disseminate data: For NHBS among transgender women, produce at least one report (fact sheets, epidemiologic profiles, surveillance reports, peer-reviewed manuscripts or other formats as appropriate) and conduct at least one presentation to community partners and stakeholders. Efforts shall be made to customize data dissemination activities to inform key decisions regarding budgeting, planning, and evaluation of HIV prevention activities among transgender women. Contribute to national data collection outcomes such as surveillance reports and other publications by reviewing concept proposals, table shells and manuscript drafts within specified timelines and participating in discussions during monthly conference calls and annual meetings.
- Attend relevant trainings and meetings: Attend all required trainings, meetings, site visits, webinars and conference calls.
- Conduct quality assurance activities: Conduct all required data quality assurance activities, including but not limited to field staff evaluations, as described in CDC-approved guidance documents.
- Evaluate strategies and methods: Conduct ongoing formative assessment to improve operating procedures. Conduct evaluations of recruitment strategies and data collection methods to reach transgender women.
- Collaborate with partners and stakeholders to disseminate findings/promote data uses: Disseminate and present findings to health departments, CBOs, and other community partners to inform HIV prevention and services planning and decision-making.

1. Collaborations

a. With CDC-funded programs:

Awardees are required to collaboratively partner with CDC. Awardees shall maintain local collaborations with HIV prevention program staff, HIV case surveillance staff, CDC-funded health department program staff, and other CDC-funded surveillance or prevention program staff, as appropriate for the successful implementation of the required Core NHBS strategies during NHBS-MSM, NHBS-IDU and NHBS-HET data collection cycles. Awardees funded to conduct optional anonymous hepatitis testing during NHBS-IDU and anonymous STI testing during NHBS-MSM and NHBS-HET and awardees funded to conduct NHBS among the optional populations of YMSM and transgender women (if applicable) shall also maintain local collaborations for these activities.

b. With organizations external to CDC:

Awardees are required to build or maintain collaborations with community partners and stakeholders when performing required NHBS strategies and activities. Community partners and stakeholders may include but are not limited to CBOs and HIV-related service and care organizations that serve MSM, IDU, heterosexuals at increased risk for HIV infection and other populations at high risk of HIV infection. As part of these collaborations, awardees shall incorporate feedback from community partners and stakeholders into activities, shall plan for optimal service referrals and linkage to HIV care, and shall plan for optimal dissemination of data for prevention planning. Awardees have the option to collaborate with academic and public health partners with expertise in qualitative and quantitative methods to conduct behavioral surveillance activities and evaluation. Awardees will be required to collaborate with public health or private laboratories to conduct anonymous HIV testing. Where applicable, awardees shall work with local health departments to carry out program strategies and activities. Awardees may convene community advisory boards to assist with planning NHBS activities (optional).

Awardees funded (if funds are available) to conduct any of the 2 optional activities as part of the NHBS platform will be required to build or maintain additional collaborations with community partners and stakeholders:

Optional anonymous hepatitis testing during NHBS-IDU:

For the anonymous hepatitis testing during NHBS-IDU optional activity, awardees will be required to collaborate with CBOs and other public health partners to plan for optimal service referrals and linkage to hepatitis care. Awardees will also be required to collaborate with public health or private laboratories to conduct hepatitis testing activities. Awardees will be required to collaborate with local prevention partners to disseminate the data to inform hepatitis prevention strategies among the population surveyed.

Optional anonymous STI testing during NHBS-MSM and NHBS-HET:

For the anonymous STI testing during NHBS-MSM and NHBS-HET optional activity, awardees will be required to collaborate with CBOs and other public health partners to plan for optimal service referrals and linkage to STI care. Awardees will also be required to collaborate with public health or private laboratories to conduct STI testing activities. Awardees will be required to collaborate with local prevention partners to disseminate the data to inform STI prevention strategies among the populations surveyed.

Awardees funded (if funds are available) to conduct NHBS among any of the 2 optional populations will also be required to build or maintain additional collaborations with community partners and stakeholders:

Optional NHBS among YMSM:

For the optional NHBS- YMSM population, awardees will be required to collaborate with CBOs, service providers and academic or public health partners who have expertise in working with YMSM ages 17 and younger and with prevention partners who serve this population.

Optional NHBS among transgender women:

For the optional NHBS among transgender women population, awardees will be required to collaborate with CBOs, service providers and academic or public health partners who have expertise in working with transgender women and with prevention partners who serve this population.

2. Target Populations

Individuals at risk of acquiring HIV infection including: 1) sexually-active men who have sex with men (MSM); 2) persons who report active injection drug use (IDU); 3) sexually-active heterosexuals at increased risk for HIV infection; 4) young MSM ages 13-17, inclusive (optional); and 5) transgender women (optional).

a. Inclusion

Required Core NHBS:

Persons aged 18 or older who reside in a funded MSA and meet the CDC definition of sexually active MSM, persons who report active injection drug use (IDU), and heterosexuals at increased risk for HIV infection, as defined in CDC-approved NHBS guidance documents. The heterosexual target population includes only men and women who do not have a history of male-male sex or injection drug use. Each of the 5 required strategies is to be conducted with each of these 3 Core NHBS target populations.

Optional NHBS Activities:

The target population for the optional anonymous hepatitis testing activity includes only participants in the NHBS-IDU data collection cycle. The target population for the optional anonymous STI testing activity includes all participants in the NHBS-MSM data collection cycles and female participants 30 years of age and younger in the NHBS-HET data collection cycles. Targeting of these optional strategies reflects the relative burden of hepatitis and STIs among the Core NHBS target populations and is consistent with current CDC screening recommendations for hepatitis and bacterial STIs among the Core NHBS target populations.

Optional NHBS Populations:

The optional NHBS-YMSM will be conducted with MSM ages 13-17, inclusive (the age criterion for Core NHBS does not apply).

The optional NHBS among transgender women will be conducted among persons aged 18 or older who are born male and identify as female or anything other than male.

iv. Funding Strategy (for multi-component FOAs only)

N/A

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

CDC will work with awardees to develop a feasible scheme for measurement and evaluation that ensures successful monitoring of the implementation of the strategies and activities (process evaluation and measures) and assesses progress in achieving the project period outcomes and/or understanding of the barriers to such progress (outcome evaluation and measures).

Required Core NHBS: NHBS-MSM, NHBS-IDU and NHBS-HET:

Awardees must meet the following benchmarks yearly in order to achieve the required strategies and activities and meet outcomes for Core NHBS:

1) Preparation:

- Conduct formative assessment:
 - If locally required, submit paperwork for regulatory approvals to conduct formative assessment within 4 weeks after receipt of CDC-approved guidance documents.
 - Submit formative assessment reports and other required documents within the timeline provided by CDC.
- Conduct pre-implementation activities:
 - If locally required, submit paperwork for regulatory approvals to conduct NHBS activities within 2 months after receipt of CDC-approved guidance documents.
 - Hire and train required staff needed to recruit participants, collect data, and conduct HIV testing within 6 months from the start of each budget period.
 - Submit completed operations checklist within 6 months from the start of each budget period.
 - At least 1 staff attends annual field operations training as provided by CDC.
 - At least 1 staff attends data management training as provided by CDC.

2) Recruitment and Data Collection:

- Recruit populations at high risk for HIV infection: Begin implementation of recruitment strategies that include venue based, time-space sampling (VBS), respondent-driven sampling (RDS), and other CDC-approved strategies to recruit populations at high risk for HIV infection within 7 months from the start of each budget period.
- Conduct standardized surveys: Complete at least 500 standardized surveys with eligible participants annually.
- Offer anonymous blood-based HIV testing: Conduct anonymous blood-based rapid testing for HIV infection on at least 90% of NHBS participants consenting to the survey. Provide justification if oral testing or standard testing was conducted.
- Collect and store blood specimens for future testing: Collect dried blood spots, plasma or other blood specimens for testing to detect antibodies and virus including assays that determine recent infection, viral load and antiretroviral drug resistance according to CDC-approved methods and guidance from at least 90% of NHBS participants consenting to the survey.
- Send specimens to CDC or CDC designated laboratories: Prepare frequent shipments of all specimens to CDC or CDC designated laboratories in compliance with CDC-approved guidance and timelines.

3) Data Management and Dissemination:

- Ensure HIV data security and confidentiality: Adhere to all data security and confidentiality guidelines, document trainings and submit *Certification Statement* annually (available at <http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>).
- Manage and submit data: Adhere to all data management procedures and timelines per guidance documents provided by CDC. Submit data to the CDC Data Coordinating Center in adherence to CDC data submission timelines. Complete data cleaning per CDC timelines.
- Analyze and disseminate data: For each Core NHBS population, produce at least one report (fact sheet, epidemiologic profile, surveillance report, peer-reviewed manuscript or other format as appropriate) and conduct at least one presentation to community partners and stakeholders. Submit information on specific data uses and dissemination activities in a template to be provided by CDC. Submit a list of annual data uses and dissemination activities as described in the APR section. Submit documentation of all data uses and dissemination activities to the CDC project officer by the end of the 5-year project period.

4) Quality Assurance:

- Attend relevant trainings and meetings: Attend all required trainings, meetings, site visits, webinars, and conference calls.
- Conduct quality assurance activities: Conduct field staff evaluations annually according to the frequency and timelines recommended in the CDC-approved guidance documents.
- Evaluate Core NHBS strategies and methods: Conduct all evaluation activities as required.

5) Collaboration:

- Collaborate with partners and stakeholders to conduct Core NHBS and evaluations: Collaborate on Core NHBS survey development, strategies, methods and implementation with community partners and stakeholders.
- Collaborate with partners and stakeholders to disseminate findings/promote data uses: Share Core NHBS findings with local prevention partners every year through a presentation or report.
- Collaborate with partners and stakeholders to ensure participant referrals: Collaborate with community partners and stakeholders to plan optimal methods for referring participants to services and linking participants to HIV care.

Optional NHBS Activities:

Awardees for the optional NHBS activities shall meet additional benchmarks for the specified data collection cycle(s):

Optional activity #1: Conduct anonymous hepatitis testing during NHBS-IDU:

- Offer anonymous Hepatitis B testing: Conduct anonymous Hepatitis B testing on at least 90% of NHBS-IDU participants consenting to the survey.
- Offer anonymous Hepatitis C testing: Conduct anonymous Hepatitis C testing on at least 90% of NHBS-IDU participants consenting to the survey.
- Collect and store blood specimens: Collect blood specimens for laboratory and confirmatory testing according to CDC-approved methods and guidance on at least 90% of NHBS-IDU participants consenting to the survey.
- Send specimens to local and CDC laboratories: Prepare frequent shipments of blood specimens to local and CDC laboratories in compliance with CDC-approved guidance and timelines.
- Ensure data security and confidentiality: Adhere to all data security and confidentiality guidelines and document trainings and compliance with guidelines.
- Manage and submit data: Adhere to all data management procedures and timelines per guidance documents provided by CDC. Submit data to CDC Data Coordinating Center in adherence to CDC data submission timelines. Complete data cleaning per CDC timelines.

Optional activity #2: Conduct anonymous STI testing during NHBS-MSM and NHBS-HET

- Offer both anonymous gonorrhea and chlamydia testing: Conduct both anonymous gonorrhea and chlamydia testing on at least 90% of the targeted participants consenting to the survey.
- Collect specimens: Collect anal or vaginal swabs for laboratory and confirmatory testing according to CDC-approved methods and guidance on at least 90% of the target population consenting to the survey.
- Send specimens to local and CDC laboratories: Prepare frequent shipments of specimens to local and CDC laboratories in compliance with CDC-approved guidance and timelines.
- Ensure data security and confidentiality: Adhere to all data security and confidentiality guidelines and document trainings and compliance with guidelines.
- Manage and submit data: Adhere to all data management procedures and timelines per guidance documents provided by CDC. Submit data to the CDC Data Coordinating Center in adherence to CDC data submission timelines. Complete data cleaning per CDC timelines.

Optional NHBS Populations:

Awardees for the optional NHBS populations shall also meet additional benchmarks for the project period:

Optional population #1: Conduct NHBS among YMSM (NHBS-YMSM)

Start-up:

- Conduct start-up activities:
 - If locally required, submit paperwork for regulatory approvals to conduct extensive formative assessment within 4 weeks after receipt of CDC-approved guidance documents.
 - Hire project coordinator or similar position to begin community engagement and to begin coordination of extensive formative assessment and data collection activities.
 - Review available data on YMSM and write and submit reports summarizing findings according to timelines in CDC-approved guidance documents.
- Collaborate with CDC on development of operational documents: Provide input on all national operational documents and data collection instruments as requested. Attend relevant conference calls as requested.

Extensive formative assessment:

- Conduct extensive formative assessment: Submit formative reports and other required documents according to timelines in CDC-approved guidance documents.
- Collaborate with partners and stakeholders to conduct NHBS-YMSM and evaluations: Collaborate on NHBS-YMSM survey development, methods and implementation with community partners and stakeholders.
- Collaborate with partners and stakeholders to ensure participant referrals: Collaborate with community partners and stakeholders to plan optimal methods for referring participants to social services and linking participants to HIV care.
- Conduct pre-implementation activities:
 - If locally required, submit paperwork for regulatory approvals to conduct NHBS-YMSM activities within 8 weeks after receipt of CDC-approved guidance documents.
 - Hire and train required staff needed to recruit participants, collect data, and conduct HIV testing according to timelines in CDC-approved guidance documents.
 - Submit completed operations checklist according to timelines in CDC-approved guidance.
 - At least 1 staff attends annual field operations training as provided by CDC.
 - At least 1 staff attends data management training as provided by CDC.

Data collection:

- Recruit YMSM ages 13-17, inclusive: Implement recruitment strategies according to timelines in CDC-approved guidance documents.
- Conduct standardized survey: Complete standardized in-person surveys with at least 300 eligible participants.
- Offer blood-based HIV testing: Conduct blood-based rapid testing for HIV infection on at least 90% of NHBS-YMSM participants consenting to the survey. Provide justification if oral testing or standard testing was conducted.
- Collect and store blood specimens for future testing: Collect dried blood spots, plasma or other blood specimens for testing to detect antibodies and virus including assays that determine recent infection, viral load and antiretroviral drug resistance according to CDC-approved methods on at least 90% of NHBS-YMSM participants consenting to the survey.
- Send specimens to CDC or CDC designated laboratories: Prepare frequent shipments of all specimens to CDC or CDC designated laboratories in compliance with CDC-approved guidance and timelines.
- Ensure HIV data security and confidentiality: Adhere to all data security and confidentiality guidelines and document trainings and compliance with guidelines.
- Manage and submit data: Adhere to all data management procedures and timelines per guidance documents provided by CDC. Submit data to CDC Data Coordinating Center in adherence to CDC data submission timelines. Complete data cleaning per CDC timelines.
- Analyze and disseminate data: Produce at least one report (fact sheet, epidemiologic profile, surveillance report, peer-reviewed manuscript or other format as appropriate) and conduct at least one presentation to community partners and stakeholders. Submit information on specific data uses and dissemination activities in a template to be provided by CDC. Submit documentation of all data uses and dissemination activities to the CDC project officer by the end of the project period.
- Attend relevant trainings and meetings: Attend all required trainings, meetings, site visits, webinars and conference calls.
- Conduct quality assurance activities: Conduct field staff evaluations according to the frequency and timelines recommended in the CDC-approved guidance documents.
- Evaluate NHBS-YMSM strategies and methods: Conduct all evaluation activities as required.
- Collaborate with partners and stakeholders to disseminate findings/promote data uses: Share findings with local prevention partners through a presentation or report by the end of the project period.

Optional population #2: Conduct NHBS among transgender women

Start-up:

- Conduct start-up activities:
 - If locally required, submit paperwork for regulatory approvals to conduct extensive formative assessment within 4 weeks after receipt of CDC-approved guidance documents.
 - Hire project coordinator or similar position to begin community engagement and to begin coordination of extensive formative assessment and data collection activities.
 - Review available data on transgender women and write and submit reports summarizing findings according to timelines in CDC-approved guidance documents.
- Collaborate with CDC on development of operational documents: Provide input on all national operational documents and data collection instruments as requested. Attend relevant conference calls as requested.

Extensive formative assessment:

- Conduct extensive formative assessment: Submit formative reports and other required documents according to timelines in CDC-approved guidance.

- Collaborate with partners and stakeholders to conduct NHBS among transgender women and required evaluations: Collaborate on survey development, methods and implementation with community partners and stakeholders.
- Collaborate with partners and stakeholders to ensure participant referrals: Collaborate with community partners and stakeholders to plan optimal methods for referring participants to social services and linking participants to HIV care.
- Conduct pre-implementation activities:
 - If locally required, submit paperwork for regulatory approvals to conduct NHBS among transgender women within 8 weeks after receipt of CDC-approved guidance documents.
 - Hire and train required staff needed to recruit participants, collect data, and conduct HIV testing according to timelines in CDC-approved guidance documents.
 - Submit completed operations checklist according to timelines in CDC-approved guidance.
 - At least 1 staff attends annual field operations training as provided by CDC.
 - At least 1 staff attends data management training as provided by CDC.

Data collection:

- Recruit transgender women: Implement recruitment strategies according to timelines in CDC-approved guidance documents.
- Conduct standardized survey: Complete standardized in-person surveys with at least 200 eligible participants.
- Offer anonymous blood-based HIV testing: Conduct anonymous blood-based rapid testing for HIV infection on at least 90% of participants consenting to the survey. Provide justification if oral testing or standard testing was conducted.
- Collect and store blood specimens for future testing: Collect dried blood spots, plasma or other blood specimens for testing to detect antibodies and virus including assays that determine recent infection, viral load and antiretroviral drug resistance according to CDC-approved methods on at least 90% of participants consenting to the survey.
- Send specimens to CDC or CDC designated laboratories: Prepare frequent shipments of all specimens to CDC or CDC designated laboratories in compliance with CDC-approved guidance and timelines.
- Ensure HIV data security and confidentiality: Adhere to all data security and confidentiality guidelines and document trainings and compliance with guidelines.
- Manage and submit data: Adhere to all data management procedures and timelines per guidance documents provided by CDC. Submit data to CDC Data Coordinating Center in adherence to CDC data submission timelines. Complete data cleaning per CDC timelines.
- Analyze and disseminate data: Produce at least one report (fact sheet, epidemiologic profile, surveillance report, peer-reviewed manuscript or other format as appropriate) and conduct at least one presentation to community partners and stakeholders. Submit information on specific data uses and dissemination activities in a template to be provided by CDC. Submit documentation of all data uses and dissemination activities to the CDC project officer by the end of the project period.
- Attend relevant trainings and meetings: Attend all required trainings, meetings, site visits, webinars and conference calls.
- Conduct quality assurance activities: Conduct field staff evaluations according to the frequency and timelines recommended in the CDC-approved guidance documents.
- Evaluate NHBS among transgender women strategies and methods: Conduct all evaluation activities as required.
- Collaborate with partners and stakeholders to disseminate findings/promote data uses: Share findings with local prevention partners through a presentation or report by the end of the project period.

Outcomes:

- Ongoing use of NHBS data by state and local partners to measure testing, treatment and prevention

efforts, to guide the development and strengthening of these efforts, and to inform policy makers regarding important prevention issues: Submit documentation on how NHBS data were used by state and local partners during the project period, including planning, prevention and policy activities as a result of NHBS data. For each Core NHBS population and each optional NHBS population (if applying), produce at least one report (fact sheet, epidemiologic profile, surveillance report, peer-reviewed manuscript or other format as appropriate) and conduct at least one presentation to state and local partners.

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must describe the types of evaluation that will be conducted locally and key evaluation questions to be asked. This plan should include but is not limited to the performance measures listed in section 2.b.i. and should incorporate local area performance measurement plans. Applicants must also describe how evaluation results will be used for quality improvement in their local area.

c. Organizational Capacity of Awardees to Execute the Approach

All applicants must demonstrate the capacity to successfully implement the required Core NHBS strategies and activities and achieve the project period outputs and outcomes. Applicants submitting applications to conduct the 2 optional NHBS activities and NHBS among the 2 optional populations must also demonstrate the ability to execute the specified activities.

Applicants should demonstrate experience administering public health surveillance, conducting community-level surveys and must be able to conduct anonymous HIV testing and other anonymous testing (if applying for the optional hepatitis testing during NHBS-IDU and STI testing during NHBS-MSM and NHBS-HET activities). Applicants should also have experience collaborating with local organizations that work with populations at high risk for HIV infection. In addition, applicants should have the capacity to conduct analysis of bio-behavioral surveillance data and report findings. Applicants must also be fully capable of financial reporting, budget management and administration. This includes managing the required procurement efforts, including the ability to write and award contracts in accordance with applicable grants regulations. This also includes submitting a budget with resources to conduct all required Core NHBS strategies and activities, the 2 NHBS optional activities (if applicable) and NHBS among the 2 optional populations (if applicable), including support for in- and out-of-state travel; incentives for participants; supplies and shipping for HIV testing and other testing (if applicable); and necessary equipment and software needed to conduct NHBS.

Applicants shall have a clear staffing plan and project management structure for the required strategies to include a principal investigator (20% or less), project coordinator (1 FTE or less), field supervisor (1 FTE or less), data manager/data analyst (1 FTE or less), and sufficient number of field staff to conduct the required Core NHBS activities. Applicants shall also have clear staffing plans and project management structures for conducting each of the 2 optional NHBS activities (if applicable) and NHBS among each of the 2 optional populations (if applicable). Please include CVs for key staff or note whether hiring new staff will be required. Applicants should state whether key staff members have the following capacity and experience:

- Principal investigators must be able to assume responsibility for overseeing that program outputs and outcomes are achieved, that data security and confidentiality procedures are followed, and that awarded funds are used in compliance with the terms and conditions of this cooperative agreement.
- Project coordinators should have considerable knowledge of HIV/AIDS and surveillance activities, strong leadership and supervisory skills and high attention to detail.
- Field supervisors should have considerable knowledge of the communities in which NHBS is conducted, HIV/AIDS and surveillance activities.
- Data analysts should have considerable experience conducting epidemiological analysis.

Applicants must have the capacity to ensure that the security and confidentiality procedures of the program

are consistent with the requirements delineated 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* (available at: http://www.cdc.gov/hiv/resources/guidelines/security_confidentiality_hiv.htm). Applicants must have a designated Overall Responsible Party (ORP) who accepts overall responsibility for implementing and enforcing the security standards and may be liable for breaches of confidentiality. The ORP should be a high-ranking public official (e.g., division director or department chief) who has the authority to make decisions about surveillance operations that may affect programs outside the HIV surveillance unit.

Applicants are required to self-certify their adherence to the standards for ensuring the security, confidentiality, and appropriate use of the data they collect, store, and share. Applicants must annually submit a *Certification Statement* from the Guidelines signed by the ORP. The certification statement should:

- Identify one or more persons as the ORP for ensuring adherence to the standards.
- Attest to adherence to all standards, or explain any lapses.
- If reporting lapses to CDC, describe the lapses and steps to meet the standards in the future.
- Describe policies and procedures instituted to ensure continued adherence to the standards.

d. Work Plan

Applicants must provide a detailed work plan for the first year of this award and a high level work plan for the entire five-year project period, including for conducting each of the 2 optional NHBS activities and NHBS among each of the 2 optional populations, if applicable. Each detailed work plan must include discussion of the applicant's approach to conduct the strategies and activities and their ability to meet each benchmark, including for data submission to the CDC Data Coordinating Center and data cleaning. The work plan must also include a timeline and person responsible for completing each activity. The budget(s) submitted for the required Core NHBS strategies, for conducting each of the 2 optional activities (if applicable), and for conducting NHBS among each of the 2 optional populations (if applicable) must be consistent with the respective work plan and include resources needed to conduct these activities based on the annual benchmarks.

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and awardees, site visits, and awardee reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking awardee progress in achieving the desired outcomes.
- Ensuring the adequacy of awardee systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that awardees are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with awardees on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Other activities deemed necessary to monitor the award, if applicable.

These activities may include monitoring and reporting activities that assist grants management staff (e.g.,

grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk grantees.

Awardees performing at a less than sufficient level to achieve program activities and outputs within stated timeframes will be placed on a time-phased Corrective Action Plan (CAP) developed by CDC in collaboration with the awardee. The CAP is a comprehensive tool used to assist awardees to improve program performance through identifying factors contributing to less than sufficient performance and developing specific action steps to address areas in need of improvement.

f. CDC Program Support to Awardees (THIS SECTION APPLIES ONLY TO COOPERATIVE AGREEMENTS)

In a cooperative agreement, CDC staff are substantially involved in the program activities, above and beyond routine grant monitoring. CDC staff will provide support by:

- Facilitating the development and implementation of the standardized, multisite guidance documents and questionnaires.
- Facilitating the development of local operational plans.
- Providing training in methodology (including formative assessment), program planning, management and evaluation.
- Providing technical assistance to support implementation of agreed upon methods to execute the strategies and activities.
- Providing assistance in establishing and maintaining the computerized database to record information collected for the activities.
- Participating in the analysis and dissemination of the data. Conduct or coordinate analyses of the multisite data and distribute information to support national HIV prevention efforts.
- Facilitating the development of methods and computer programs to evaluate performance indicators and data quality.
- Assisting in the evaluation of overall effectiveness of program operations. Provide timely feedback on reported data for quality assurance purposes.
- Facilitating the development of evaluation activities.
- Maintaining a secure and confidential national database.
- Facilitating the development of supplemental guidance for extension of recruitment activities in project sites with geographic areas adjacent to the MSA or Division where HIV morbidity remains high.
- Participating in joint conference calls, awardee meetings and site visits.
- Monitoring progress in participant recruitment, HIV testing and other activities for all awardees.

B. Award Information

1. Funding Instrument Type:	Cooperative Agreement CDC's substantial involvement in this program appears in the CDC Program Support to Awardees Section.
2. Award Mechanism:	U62 Prevention/Surveillance Activities/Studies of AIDS
3. Fiscal Year:	2016
Estimated Total Funding:	\$76,600,000
4. Approximate Total Fiscal Year Funding:	\$12,100,000
5. Approximate Project Period Funding:	\$76,600,000
6. Total Project Period Length:	5 year(s)
7. Expected Number of Awards:	25

Subject to availability of funds, up to 25 awards

8. Approximate Average Award: \$550,000 Per Budget Period

For Fiscal Year 2016, \$470,000 (required core NHBS), \$80,000 (optional STI testing during NHBS-HET)

9. Award Ceiling: \$6,500,000 Per Project Period

If the applicant is addressing the required Core NHBS strategies, the 2 optional NHBS activities, and conducting NHBS with the 2 optional populations. This amount is subject to the availability of funds.

10. Award Floor: None

11. Estimated Award Date: 01/01/2016

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the awardee (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total project period comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

12. Budget Period Length: 12 month(s)

13. Direct Assistance

Direct Assistance (DA) is available through this FOA.

Consistent with the cited authority for this announcement, Direct Assistance may be available in the form of equipment, supplies and materials, and/or federal personnel. If DA is provided as a part of the award, CDC will reduce the financial assistance award amount provided directly to the awardee as a part of the award. The amount by which your award is reduced will be used to provide DA; the funding shall be deemed part of the award and as having been paid to the awardee.

Moreover, DA may include provision of material support, including but not limited to computer hardware, software, or other materials as needed. Please review CDC's policy on direct financial assistance to Grant and Cooperative Agreement Recipients (http://www.cdc.gov/stltpublichealth/GrantsFunding/direct_assistance.html)

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:	State governments
	County governments
	City or township governments

2. Additional Information on Eligibility

Please refer to the FOA, Section C.2. "Additional Information on Eligibility."

Eligible applicants:

Local Health Departments Directly Funded for HIV Surveillance or their Bona Fide Agents containing the following Metropolitan Statistical Areas (MSAs) or specified Divisions within MSAs:

- New York City Department of Health and Mental Hygiene [New York Division]
- Los Angeles County Department of Public Health [Los Angeles Division]
- City of Chicago Department of Public Health [Chicago Division]

- Houston Department of Health and Human Services [Houston-The Woodlands-Sugarland MSA]
- City of Philadelphia Department of Public Health [Philadelphia Division]
- San Francisco Department of Public Health [San Francisco Division]

State and Territorial Health Departments or their Bona Fide Agents containing the following MSAs or specified Divisions within MSAs:

- District of Columbia Department of Health [Washington Division]
- Florida Department of Health [Miami Division]
- Georgia Department of Public Health [Atlanta-Sandy Springs-Roswell MSA]
- Maryland Department of Health and Mental Hygiene [Baltimore-Columbia-Towson MSA]
- Texas Department of State Health Services [Dallas Division]
- New Jersey Department of Health [Newark Division]
- Puerto Rico Department of Health [San Juan-Carolina-Caguas MSA]
- California Department of Public Health [San Diego-Carlsbad MSA]
- Arizona Department of Health Services [Phoenix-Mesa-Scottsdale MSA]
- Colorado Department of Public Health and Environment [Denver-Aurora-Lakewood MSA]
- Louisiana Department of Health and Hospitals [New Orleans-Metairie MSA]
- Massachusetts Department of Public Health [Boston Division]
- Washington State Department of Health [Seattle Division]
- Tennessee Department of Health [Memphis MSA]
- North Carolina Department of Health and Human Services [Charlotte-Concord-Gastonia MSA]
- Michigan Department of Community Health [Detroit Division]
- Missouri Department of Health and Senior Services [St. Louis MSA]
- Virginia Department of Health [Virginia Beach-Norfolk-Newport News MSA]
- Minnesota Department of Health [Minneapolis-St. Paul-Bloomington MSA]
- Nevada State Department of Health and Human Services [Las Vegas-Henderson-Paradise MSA]
- New York State Department of Health [Nassau County Division]
- Ohio Department of Health [Columbus MSA]
- Indiana State Department of Health [Indianapolis-Carmel-Anderson MSA]
- Oregon Department of Human Services [Portland-Vancouver-Hillsboro MSA]

Additionally, to be eligible, applicants must provide a brief signed letter from a high-ranking authority in the applying health department affirming that anonymous HIV testing is permissible for NHBS.

The award ceiling for this FOA is \$6,500,000. CDC will consider any application requesting an award higher than this amount as non-responsive and it will receive no further review. If a pre-application is required, then specify here and include it in the special eligibility requirements section. ([http:// www.hhs.gov/ asfr/ ogapa/ aboutog/ hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf))

3. Justification for Less than Maximum Competition

Since 2003, the National HIV Behavioral Surveillance (NHBS) system has served as CDC's comprehensive and ongoing system for conducting behavioral surveillance among persons at highest risk for HIV infection in the United States (US). Competition for previous NHBS FOAs (PA 04017, PS08-001 and PS11-001) was limited to the top US Metropolitan Statistical Areas (MSAs) or Divisions with the highest disease burden. This successfully ensured that the behavioral surveillance system would cover geographic areas of the US where the epidemic had the most impact and ensured that trends over time could be estimated and reported.

Eligible applicants are the US state, local and territorial health departments which include the top 30 MSAs or Divisions by the highest prevalence of diagnosed HIV infection (as reported by the latest available published data through the National HIV Surveillance System) and can conduct anonymous HIV testing. The MSA or Division with the highest prevalence of diagnosed HIV infection in the state or territorial health department jurisdiction will be selected for eligibility, not accounting for MSAs or Divisions in directly funded local health department jurisdictions (see Table 1). Eligibility of one jurisdiction per state (excluding

directly-funded city/county health department jurisdictions) helps obtain geographic diversity while ensuring inclusion of areas with high HIV prevalence. As NHBS is anonymous, applicants must provide documentation that anonymous HIV testing can be conducted in the MSA or Division.

Eligibility is limited to US state, local and territorial health departments as they have the authority to promulgate rules, regulations and laws to conduct HIV surveillance activities in their jurisdictions. If competition is not limited to the MSAs or Divisions with the highest HIV prevalence and with the ability to conduct anonymous HIV testing, recruitment for NHBS will be limited and sample size requirements will not be met. Without the required sample size, NHBS data would not be powerful enough to report national estimates, trends and indicators. These reported data are needed to monitor the goals and action steps of the National HIV/AIDS Strategy and to develop and direct national HIV prevention efforts.

Date of Less than Maximum Competition Approval: 10/29/2014

Table 1. Metropolitan Statistical Areas (MSAs) or Divisions with highest prevalence of diagnosed HIV infection, year-end 2012
— US State, Local and Territorial Health Departments

US MSA or Division	Prevalence of diagnosed HIV infection, year-end 2012		Comments
	Estimated No.	Rank	
~New York Division	121,892	1	Directly funded health department
~Los Angeles Division	45,633	2	Directly funded health department
~Washington Division	29,465	3	
~Chicago Division	27,976	4	Directly funded health department
~Miami Division	26,904	5	
Atlanta-Sandy Springs-Roswell, GA	26,020	6	
Houston-The Woodlands-Sugar Land, TX	24,270	7	Directly funded health department
Baltimore-Columbia-Towson, MD	18,288	8	
~Philadelphia Division	18,151	9	Directly funded health department
~Dallas Division	17,690	10	
~Fort Lauderdale Division	16,624		Not eligible because Miami is already selected for FL
~San Francisco Division	16,327	11	Directly funded health department
~Newark Division	15,291	12	
San Juan-Carolina-Caguas, PR	13,169	13	
San Diego-Carlsbad, CA	12,427	14	
Tampa-St. Petersburg-Clearwater, FL	10,321		Not eligible because Miami is already selected for FL
Orlando-Kissimmee-Sanford, FL	10,093		Not eligible because Miami is already selected for FL
Phoenix-Mesa-Scottsdale, AZ	9,696	15	
Denver-Aurora-Lakewood, CO	9,054	16	
New Orleans-Metairie, LA	8,101	17	
Riverside-San Bernardino-Ontario, CA	8,085		Not eligible because San Diego is already selected for CA
~Boston Division	7,959	18	
~West Palm Beach Division	7,821		Not eligible because Miami is already selected for FL
~Seattle Division	7,571	19	
~Oakland Division	7,342		Not eligible because San Diego is already selected for CA
Memphis, TN-MS-AR	7,233	20	
Charlotte-Concord-Gastonia, NC-SC	7,104	21	
~Detroit Division	7,006	22	
St. Louis, MO-IL	6,784	23	
~Anaheim Division	6,720		Not eligible because San Diego is already selected for CA
Virginia Beach-Norfolk-Newport News, VA-NC	6,602	24	
Minneapolis-St. Paul-Bloomington, MN-WI	6,260	25	
Las Vegas-Henderson-Paradise, NV	6,160	26	
Jacksonville, FL	6,108		Not eligible because Miami is already selected for FL
~Nassau County Division	5,826	27	
San Antonio-New Braunfels, TX	5,289		Not eligible because Dallas is already selected for TX
~Cambridge Division	5,100		Not eligible because Boston is already selected for MA
Columbus, OH	5,019	28	
Nashville-Davidson-Murfreesboro-Franklin, TN	4,974		Not eligible because Memphis is already selected for TN
Austin-Round Rock, TX	4,851		Not eligible because Dallas is already selected for TX
Kansas City, MO-KS	4,794		Not eligible because St. Louis is already selected for MO
Cleveland-Elyria, OH	4,745		Not eligible because Columbus already selected for OH
Indianapolis-Carmel-Anderson, IN	4,615	29	
~Fort Worth Division	4,564		Not eligible because Dallas is already selected for TX
Richmond, VA	4,510		Not eligible because Virginia Beach is already selected for VA
Baton Rouge, LA	4,425		Not eligible because New Orleans is already selected for LA
Portland-Vancouver-Hillsboro, OR-WA	4,299	30	

Source: Table 22. Centers for Disease Control and Prevention. HIV Surveillance Report, 2013; vol. 25. Published February 2015

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:

No

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this FOA exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Required Registrations

Additional materials that may be helpful to applicants: <http://www.cdc.gov/od/pgo/funding/docs/FinancialReferenceGuide.pdf>.

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

a. Data Universal Numbering System: All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or Internet at <http://fedgov.dnb.com/webform/displayHomePage.do>. The DUNS number will be provided at no charge. If funds are awarded to an applicant organization that includes sub-awardees, those sub-awardees must provide their DUNS numbers before accepting any funds.

b. System for Award Management (SAM): The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as an awardee. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process usually requires not more than five business days, and registration must be renewed annually. Additional information about registration procedures may be found at www.SAM.gov.

c. Grants.gov: The first step in submitting an application online is registering your organization through www.grants.gov, the official HHS E-grant website. Registration information is located at the "Get Registered" option at www.grants.gov.

All applicant organizations must register with www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants must start the registration process as early as possible.

2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC PGO staff at 770-488-2700 or e-mail PGO PGOTIM@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the FOA, it will not be processed. PGO personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by PGO.

a. Letter of Intent Deadline (must be emailed or postmarked by)

Due Date for Letter of Intent: **06/10/2015**

b. Application Deadline

Due Date for Applications: **08/03/2015**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

Date for Informational Conference Call: 06/17/2015

An informational conference call will be held on Wednesday June 17, 2015 from 1:30 - 3:00 PM EDT.

Dial in number: 1-866-742-9957

Passcode: 4052267

Questions may also be directed to nhbsquestions@cdc.gov

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at <http://www.cdc.gov/grants/interestedinapplying/applicationprocess.html>.

- Complete the applicable assurances and certifications on an annual basis, name the file "Assurances and Certifications" and upload it as a PDF file at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at [http://wwwn.cdc.gov/grantassurances/\(S\(mj444mxct51lnrv1hljjjmaa\)\)/Homepage.aspx](http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjjmaa))/Homepage.aspx)

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

A Letter of Intent (LOI) is **requested** from eligible applicants with **no previous experience conducting NHBS**.

The LOI must be sent via U.S. express mail, delivery service, or email to:

Melissa Cribbin Sharma, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
1600 Clifton Rd NE, MS E-46, Atlanta, GA 30329
Telephone: 404-639-2016
Email: nhbsquestions@cdc.gov

8. Table of Contents

(No page limit and not included in Project Narrative limit): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package.

Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and

upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

(Maximum 1 page)

A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative

(Maximum of 20 pages, single spaced, Calibri 12 point, 1-inch margins, number all pages. Content beyond 20 pages will not be considered. The 20 page limit includes the work plan. For a multi-component FOA, maximum page limit is 25.)

The Project Narrative must include all of the bolded headings shown in this section. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire project period as identified in the CDC Project Description section. Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at www.grants.gov.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the project period. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (e.g., increase, decrease, maintain). (See the logic model in the Approach section of the CDC Project Description.)

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the project period outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan, how these strategies will be evaluated over the course of the project period. (See CDC Project Description: Strategies and Activities section.)

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC.

Refer back to the CDC Project Description section – Approach: Collaborations.

Applicants must file letters of support, as appropriate, name the file "Letters of Support", and upload it as a PDF file at www.grants.gov.

2. Target Populations

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. Refer back to the CDC Project Description section – Approach: Target Population.

Include description of optional NHBS populations if choosing to apply.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an overall evaluation and performance measurement plan that is consistent with the CDC Evaluation and Performance Measurement Strategy section of the CDC Project Description of this FOA. Data collected must be used for ongoing monitoring of the award to evaluate its effectiveness, and for continuous program improvement.

The plan must:

- Affirm the ability to collect the performance measures and respond to the evaluation questions specified in the CDC strategy. (For guidance regarding the Paperwork Reduction Act, please visit <http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html>)
- Describe how key program partners will participate in the evaluation and performance measurement planning processes.
- Describe how evaluation findings will be used for continuous program quality improvement.

Where the applicant chooses to, or is expected to, take on specific evaluation studies:

- Describe the type of evaluation(s) (i.e., process, outcome, or both) to be conducted.
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information relevant to the evaluation (e.g., measures, data sources)

Awardees will be required to submit a more detailed evaluation and performance measurement plan within the first 6 months of the project, as outlined in the reporting section of the FOA.

d. Organizational Capacity of Applicants to Implement the Approach

Applicant must address the organizational capacity requirements as described in the CDC Project Description.

Applicants must name this file "CVs/Resumes" or "Organizational Charts" and upload it at www.grants.gov.

11. Work Plan

(Included in the Project Narrative's 20 page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the awardee plans to carry out achieving the project period outcomes, strategies and activities, evaluation and performance measurement.

Applicants must name this file "Work Plan" and upload it as a PDF file at www.grants.gov.

12. Budget Narrative

Applicants must submit an itemized budget narrative, which may be scored as part of the Organizational Capacity of Awardees to Execute the Approach. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits

- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs will not be reimbursed under grants to foreign organizations, international organizations, and foreign components of grants to domestic organizations (does not affect indirect cost reimbursement to the domestic entity for domestic activities). The CDC will not reimburse indirect costs unless the recipient has an indirect cost rate covering the applicable activities and period.

For guidance on completing a detailed budget, see Budget Preparation Guidelines at: <http://www.cdc.gov/grants/interestedinapplying/applicationresources.html> .

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this FOA to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: <http://www.phaboard.org>). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the FOA. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Applicants must name this file “Budget Narrative” and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Grantees under such a plan. Applicants must name this file “Indirect Cost Rate” and upload it at www.grants.gov.

Applicants must submit separate budget narratives to be considered for funding for Core NHBS (required), for each of the 2 optional NHBS activities (if applying), and for conducting NHBS with each of the 2 optional populations (if applying). Technical guidance is provided in Attachments A-F, available at: <http://www.cdc.gov/hiv/funding/announcements/ps16-1601/attachments.html>.

Applicants must submit a SUMMARY SF-424a showing the total funds requested for the entire project period. This SUMMARY SF-424a must include Required Core NHBS activities, the 2 optional testing activities (if applying) and the 2 optional NHBS populations (if applying). An example of a SUMMARY SF-424a is available at: <http://www.cdc.gov/hiv/funding/announcements/ps16-1601/attachments.html>.

In addition, applicants must submit the following:

For conducting required Core NHBS, applicants must submit:

- an itemized budget for the first year (12 month budget period, see Attachment A)
- a budget justification for the first year

For conducting optional anonymous hepatitis testing during NHBS-IDU, applicants must submit:

- an itemized budget for the NHBS-IDU cycle (12 month budget period, see Attachment B)
- a budget justification for the NHBS-IDU cycle

For conducting optional anonymous STI testing during NHBS-MSM, applicants must submit:

- an itemized budget for one NHBS-MSM cycle (12 month budget period, see Attachment C)
- a budget justification for one NHBS-MSM cycle

For conducting optional anonymous STI testing during NHBS-HET, applicants must submit:

- an itemized budget for one NHBS-HET cycle (12 month budget period, see Attachment D)
- a budget justification for one NHBS-HET cycle

For conducting optional NHBS among YMSM, applicants must submit:

- itemized budgets for 3 years (three, 12-month budget periods, see Attachment E)
- budget justifications for 3 years (three, 12-month budget periods)
- **a separate SF-424A for 3 years in addition to the summary SF-424a. An example of a SF-424a for the optional NHBS among YMSM is available at: <http://www.cdc.gov/hiv/funding/announcements/ps16-1601/attachments.html>**

For conducting optional NHBS among transgender women, applicants must submit:

- itemized budgets for 3 years (three, 12-month budget periods, see Attachment F)
- budget justifications for 3 years (three, 12-month budget periods)
- **a separate SF-424A for 3 years in addition to the summary SF-424a. An example of a SF-424a for the optional NHBS among transgender women is available at: <http://www.cdc.gov/hiv/funding/announcements/ps16-1601/attachments.html>.**

Central administrative costs incurred in the management and administration of required Core NHBS strategies and activities, optional NHBS activities, and NHBS among optional populations above those included in an indirect cost agreement will not be supported

13. Tobacco and Nutrition Policies

Awardees are encouraged to implement tobacco and nutrition policies.

Unless otherwise explicitly permitted under the terms of a specific CDC award, no funds associated with this FOA may be used to implement the optional policies, and no applicants will be evaluated or scored on whether they choose to implement these optional policies.

CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following optional recommended evidence-based tobacco and nutrition policies within their own organizations. The tobacco policies build upon the current federal commitment to reduce exposure to secondhand smoke, specifically The Pro-Children Act, 20 U.S.C. 7181-7184, that prohibits smoking in certain facilities that receive federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

Tobacco Policies:

1. Tobacco-free indoors: Use of any tobacco products (including smokeless tobacco) or electronic cigarettes is not allowed in any indoor facilities under the control of the awardee.
2. Tobacco-free indoors and in adjacent outdoor areas: Use of any tobacco products or electronic

cigarettes is not allowed in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the awardee.

3. Tobacco-free campus: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities or anywhere on grounds or in outdoor space under the control of the awardee.

Nutrition Policies:

1. Healthy food-service guidelines must, at a minimum, align with HHS and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations. These guidelines apply to cafeterias, snack bars, and vending machines in any facility under the control of the awardee and in accordance with contractual obligations for these services (see: http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf).
2. Resources that provide guidance for healthy eating and tobacco-free workplaces are:

<http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm>

<http://www.thecommunityguide.org/tobacco/index.html>

<http://www.cdc.gov/obesity/strategies/food-serv-guide.html>

14. Health Insurance Marketplaces

A healthier country is one in which Americans are able to access the care they need to prevent the onset of disease and manage disease when it is present. The Affordable Care Act, the health care law of 2010, creates new Health Insurance Marketplaces, also known as Exchanges, to offer millions of Americans affordable health insurance coverage. In addition, the law helps make prevention affordable and accessible for Americans by requiring health plans to cover certain recommended preventive services without cost sharing. Outreach efforts will help families and communities understand these new options and provide eligible individuals the assistance they need to secure and retain coverage as smoothly as possible. For more information on the Marketplaces and the health care law, visit: www.HealthCare.gov.

15. Intergovernmental Review

Executive Order 12372 does not apply to this program.

16. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

17. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Awardees may not use funds for research.
- Awardees may not use funds for clinical care.
- Awardees may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, awardees may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs is not allowed.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
 - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
 - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations,

regulation, administrative action, or Executive order proposed or pending before any legislative body

- See http://www.cdc.gov/grants/additional_requirements/index.html#ar12 for detailed guidance on this prohibition and http://www.cdc.gov/grants/documents/Anti-Lobbying_Restrictions_for_CDC_Grantees_July_2012.pdf
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.
- Data collection initiated under this cooperative agreement has been approved by the Office of Management and Budget (OMB): "National HIV Behavioral Surveillance System, NHBS", OMB #0920-0770 Expires 03/31/2017. Any changes to the existing data collection will be subject to review and approval by OMB under the Paperwork Reduction Act.
- The HHS Policy on the Use of Appropriated Funds for Promotional Items prohibits the use of cooperative agreement funds to purchase promotional items except in rare circumstances that such items are deemed a necessary expense approved in advance by CDC that directly furthers the program's public health mission.

18. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically at www.grants.gov. The application package can be downloaded at www.grants.gov. Applicants can complete the application package off-line and submit the application by uploading it at www.grants.gov. All application attachments must be submitted using a PDF file format. Directions for creating PDF files can be found at www.grants.gov. File formats other than PDF may not be readable by PGO Technical Information Management Section (TIMS) staff.

Applications must be submitted electronically by using the forms and instructions posted for this funding opportunity at www.grants.gov.

If Internet access is not available or if the forms cannot be accessed online, applicants may contact the PGO TIMS staff at 770- 488-2700 or by e-mail at pgotim@cdc.gov, Monday through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are available to PGO TIMS staff for processing from www.grants.gov on the deadline date.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate

ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the FOA. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a “validation” e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the [Applicant User Guide](#), Version 1.1, page 102.

[http:// www.grants.gov /documents /19/18243 /Grantsgov ApplicantUserGuide .pdf /ce754626 -c2aa-44bc- b701 -30a75bf428c8](http://www.grants.gov/documents/19/18243/GrantsgovApplicantUserGuide.pdf/ce754626-c2aa-44bc-b701-30a75bf428c8)

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@www.grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@www.grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail or call CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.

An applicant’s request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be postmarked at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered. If a paper application is authorized, PGO will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases.

a. Phase I Review

All applications will be reviewed initially for completeness by CDC PGO staff and will be reviewed jointly for eligibility by the CDC NCHHSTP and PGO. Incomplete applications and applications that do not meet the eligibility criteria will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility or published submission requirements.

b. Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the criteria below.

- i. Approach
- ii. Evaluation and Performance Measurement
- iii. Applicant’s Organizational Capacity to Implement the Approach

i. Approach

Maximum Points: 45

The extent to which the applicant:

- Presents outputs and outcomes that are consistent with the project period outcomes described in the CDC Project Description and logic model.
- Describes plans for conducting all 5 required strategies for Core NHBS and activities for each strategy that are consistent with the CDC Project Description and logic model. Including:
 - Adequately describes plans to complete 500 surveys with eligible participants for each data collection cycle (NHBS-MSM, NHBS-IDU, NHBS-HET).
 - Adequately describes plans to offer anonymous blood-based HIV testing. If applicant does not propose rapid HIV testing, provides justification and plans for standard HIV testing. If applicant does not propose blood-based HIV testing, provides justification and plans for collecting oral specimens.
- If applying, adequately describes plans for conducting optional anonymous hepatitis testing during NHBS-IDU.
- If applying, adequately describes plans for conducting optional anonymous STI testing during NHBS-MSM and/or NHBS-HET.
- Demonstrates experience implementing recruitment strategies to reach MSM, IDU and heterosexuals at increased risk for HIV infection.
- Shows that the proposed use of funds is an efficient and effective way to implement the strategies and activities and attain the project period outputs and outcomes.
- Presents a detailed work plan for the first year of this award and a high level work plan for the entire five-year project period that are aligned with the strategies/activities, outputs, outcomes, and performance measures in the approach and are consistent with the content proposed by CDC. Presents a timeline and responsible party for each activity.

ii. Evaluation and Performance Management

Maximum Points: 25

The extent to which the applicant:

- Proposes an evaluation and performance measurement plan that is consistent with the work plan and the CDC Evaluation and Performance Measurement Strategy.
- Describes quality assurance activities consistent with the content proposed in the CDC Project Description.
- Describes clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities. Describes clear plans for monitoring recruitment and participation numbers for each data collection cycle.
- Describes how performance measurement and evaluation findings will be reported and used to demonstrate the outputs and outcomes of the FOA and for continuous program quality improvement.
- Describes how evaluation and performance measurement will contribute to improving NHBS strategies and methods.

iii. Applicant's Organizational Capacity to Implement the Approach

Maximum Points: 30

The extent to which the applicant:

- Demonstrates experience administrating public health surveillance.
- Demonstrates experience conducting community-level surveys.
- Demonstrates ability to conduct HIV testing anonymously.
 - Demonstrates ability to conduct hepatitis anonymously (if applying for this optional NHBS

activity).

- Demonstrates ability to conduct STI testing anonymously (if applying for this optional NHBS activity).

- Demonstrates ability to collaborate with public health or private laboratories.
- Demonstrates willingness and ability to collaborate with local organizations that work with populations at high risk for HIV infection. Describes plans for disseminating findings to local stakeholders.
- Demonstrates capacity to conduct analysis of bio-behavioral surveillance data and report findings.
- Provides a clear staffing plan and project management structure that will be sufficient to achieve the project outputs and outcomes and which include staff roles as described in the CDC Project Description. Provides an organizational chart.
- Demonstrates the capacity to adhere to HIV data security and confidentiality guidelines as described in the CDC Project Description.

iv. Budget (Reviewed but not scored):

Maximum Points: 0

The extent to which the budget is reasonable, clearly itemized and justified, consistent with the intended use of funds and demonstrates the capacity to support the required Core NHBS project activities (refer to Attachment A).

- If applying to conduct optional anonymous hepatitis testing during NHBS-IDU, the extent to which the budget is reasonable, clearly itemized and justified, consistent with the intended use of funds and demonstrates the capacity to support this optional activity (refer to Attachment B).
- If applying to conduct optional anonymous STI testing during NHBS-MSM, the extent to which the budget is reasonable, clearly itemized and justified, consistent with the intended use of funds and demonstrates the capacity to support this optional activity (refer to Attachment C).
- If applying to conduct optional anonymous STI testing during NHBS-HET, the extent to which the budget is reasonable, clearly itemized and justified, consistent with the intended use of funds and demonstrates the capacity to support this optional activity (refer to Attachment D).

Applications for conducting NHBS with each of the two additional, optional populations (NHBS among YMSM and/or NHBS among transgender women) will undergo an additional evaluation by the review panel and will be scored separately:

Optional population #1: Conduct NHBS among YMSM (NHBS-YMSM) (Reviewed and scored separately)

Maximum Points: 100

The review panel will evaluate complete, eligible applications for conducting optional NHBS among YMSM (NHBS-YMSM) in accordance with the additional criteria below.

The extent to which the applicant:

- Demonstrates previous experience with surveillance or research activities among YMSM (30 points).
- Demonstrates willingness and ability to maintain or develop partnerships with organizations or academic institutions who have worked with YMSM (30 points).
- Demonstrates ability to reach 300 YMSM based on local estimates of the population size (40 points).

The extent to which the budget (Reviewed but not scored):

- Is reasonable, clearly itemized and justified, consistent with the intended use of funds and demonstrates the capacity to support the project activities for conducting optional NHBS-YMSM (please refer to Attachment E).

- Addresses the 3 phases/ years for conducting NHBS among this optional population.

**Optional population #2: Conduct NHBS among transgender women
(Reviewed and scored separately)**

Maximum Points: 100

The review panel will evaluate complete, eligible applications for conducting optional NHBS among transgender women in accordance with the criteria below.

The extent to which the applicant:

- Demonstrates previous experience with surveillance or research activities among transgender women (30 points).
- Demonstrates willingness and ability to maintain or develop partnerships with organization or academic institutions who have worked with transgender women (30 points).
- Demonstrates ability to reach 200 transgender women based on local estimates of the population size (40 points).

The extent to which the budget (Reviewed but not scored):

- Is reasonable, clearly itemized and justified, consistent with the intended use of funds and demonstrates the capacity to support the project activities for conducting optional NHBS among transgender women (refer to Attachment F).
- Addresses the 3 phases/ years for conducting NHBS among this optional population.

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

c. Phase III Review

The following factors will affect the funding decisions:

For Required Core NHBS strategies and activities:

- Available fiscal year funding may limit the number of awards.
- Funding preference will be given to applicants with previous experience conducting NHBS. Applicants with previous experience will be funded over applicants with a higher HIV prevalence.
- Applicants with higher HIV prevalence will be funded over applicants with a higher rank score.

Awardees for the required Core NHBS strategies and activities who apply for one or both of the optional NHBS activities will be funded based on the following factors:

For conducting anonymous hepatitis testing during NHBS-IDU:

- Available funding may limit the number of awards.
- Applications will be funded in order of HIV prevalence.
- Applicants must provide documentation that anonymous hepatitis testing can be conducted in the MSA or Division.

For conducting anonymous STI testing during NHBS-MSM and NHBS-HET:

- Available funding may limit the number of awards.
- Applications will be funded in order of HIV prevalence.
- Applicants must provide documentation that anonymous STI testing can be conducted in the MSA or

Division.

Awardees for the required Core NHBS strategies and activities who apply to conduct NHBS among one or both of the optional populations will be funded based on the following factors:

For conducting NHBS among YMSM (NHBS-YMSM):

- Available funding may limit the number of awards.
- Applications will be funded in order by score and rank determined by the review panel.

For conducting NHBS among transgender women:

- Available funding may limit the number of awards.
- Applications will be funded in order by score and rank determined by the review panel.

2. Announcement and Anticipated Award Dates

CDC will notify selected awardees by phone call prior to distribution of official award notice. Anticipated award date is January 1, 2016.

F. Award Administration Information

1. Award Notices

Awardees will receive an electronic copy of the Notice of Award (NOA) from CDC PGO. The NOA shall be the only binding, authorizing document between the awardee and CDC. The NOA will be signed by an authorized GMO and emailed to the Awardee Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this FOA will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.

2. Administrative and National Policy Requirements

Awardees must comply with the administrative and public policy requirements outlined in 45 C.F.R. Part 74 or Part 92 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available

at <http://www.cdc.gov/grants/additionalrequirements/index.html>

The HHS Grants Policy Statement is available at <http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>.

*Note that 2 CFR 200 will supersede the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

The following Administrative Requirements (AR) apply to this project:

- AR-4: HIV/AIDS Confidentiality Provisions
- AR-5: HIV Program Review Panel
- AR-6: Patient Care
- AR-9: Paperwork Reduction Act <http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html>

The Paperwork Reduction Act of 1995 (PRA): Applicant should be advised that any activities involving information collection (i.e., posing similar questions or requirements via surveys, questionnaires, telephonic requests, focus groups, etc.) from 10 or more non-Federal entities/persons, including States,

are subject to PRA requirements and may require CDC to coordinate an Office of Management and Budget (OMB) Information Collection Request clearance prior to the start of information collection activities. This would also include information sent to or obtained by CDC via forms, applications, reports, information systems, and any other means for requesting information from 10 or more persons; asking or requiring 10 or more entities/ persons to keep or retain records; or asking or requiring 10 or more entities/persons to disclose information to a third-party or the general public.

- [AR-10](#): Smoke-Free Workplace
- AR-11: Healthy People 2020
- AR-12: Lobbying Restrictions
- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-14: Accounting System Requirements
- AR-16: Security Clearance Requirement
- AR-21: Small, Minority, And Women-owned Business
- AR-24: Health Insurance Portability and Accountability Act
- AR-25: Release and Sharing of Data
- AR-27: Conference Disclaimer and Use of Logos
- AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving,” October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-33: Plain Writing Act of 2010
- AR-34: Patient Protection and Affordable Care Act (e.g., a tobacco-free campus policy and a lactation policy consistent with S4207)
- AR-35: Nutrition Policies

For more information on the C.F.R. visit <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>.

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that awardees encounter throughout the project period. Also, reporting is a requirement for awardees who want to apply for yearly continuation of funding. Reporting helps CDC and awardees because it:

- Helps target support to awardees;
- Provides CDC with periodic data to monitor awardee progress toward meeting the FOA outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the project period and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the FOA.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the “Agency Contacts” section of the FOA copying the CDC Project Officer.

Report	When?	Required?
Awardee Evaluation and Performance Measurement Plan	6 months into award	Yes
Annual Performance Report (APR)	120 days before end of budget period. Serves as yearly continuation application.	Yes

Data on Performance Measures	CDC program determines. Only if program wants more frequent performance measure reporting than annually in APR.	No
Federal Financial Reporting Forms	90 days after end of calendar quarter in which budget period ends	Yes
Final Performance and Financial Report	90 days after end of project period.	Yes

a. Awardee Evaluation and Performance Measurement Plan (required)

With support from CDC, awardees must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; awardees must submit the plan 6 months into the award.

This plan should provide additional detail on the following:

- The frequency that evaluation and performance data are to be collected.
- How data will be reported.
- How evaluation findings will be used for continuous quality and program improvement.
- How evaluation and performance measurement will yield findings to demonstrate the value of the FOA (e.g., improved public health outcomes, effectiveness of FOA, cost-effectiveness or cost benefit).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

b. Annual Performance Report (APR) (required)

The awardee must submit the APR via www.grants.gov 120 days before the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but weblinks are allowed.

This report must include the following:

- **Performance Measures:** Awardees must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Awardees must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Awardees must update work plan each budget period to reflect any changes in project period outcomes, activities, timeline, etc.
- **Successes**
 - Awardees must report progress on completing activities and progress towards achieving the project period outcomes described in the logic model and work plan.
 - Awardees must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
 - Awardees must describe success stories.
- **Challenges**
 - Awardees must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the project period outcomes.

- Awardees must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.

- **CDC Program Support to Awardees**

- Awardees must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving project period outcomes.

- **Administrative Reporting** (No page limit)

- SF-424A Budget Information-Non-Construction Programs.
- Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
- Indirect Cost Rate Agreement.

For year 2 and beyond of the award awardees may request that as much as 75% of their estimated unobligated funds be carried over into the next budget period.

The carryover request must:

- Express a bona fide need for permission to use an unobligated balance;
- Include a signed, dated, and accurate Federal Financial Report (FFR) for the budget period from which funds will be transferred (as much as 75% of unobligated balances);
- and Include a list of proposed activities, an itemized budget, and a narrative justification for those activities.

The awardee must submit the Annual Performance Report via www.grants.gov 120 days before the end of the budget period.

- **Data Uses**

- Awardees must report a list of all data uses, including from required Core NHBS populations, the 2 optional NHBS activities and the 2 optional NHBS populations. The list should include: all conference presentations (author(s), title, forum, date); presentations to health departments, CBOs, and other community partners (author(s), title, forum, date); citations for publications in journals and other reports (e.g. factsheets, epidemiologic profiles); policies, recommendations, programs, guidelines and other, that were developed as a result of NHBS findings; and media coverage that utilize NHBS data sources from the current and previous cycles.

c. Performance Measure Reporting (optional)

CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for awardees at the beginning of the award period.

d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted through eRA Commons 90 days after the end of the calendar quarter in which the budget period ends. The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, awardees are required to submit a letter of explanation to PGO and include the date by which the Grants Officer will receive

information.

e. Final Performance and Financial Report (required)

This report is due 90 days after the end of the project period. CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire project period and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Awardees must report final performance data for all process and outcome performance measures.
- Evaluation Results – Awardees must report final evaluation results for the project period for any evaluations conducted.
- Impact/Results/Success Stories – Awardees must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).
- Data Uses -Awardees must report a final list of all data uses, including from required Core NHBS populations, the 2 optional NHBS activities and the 2 optional NHBS populations. The list should include: all conference presentations (author(s), title, forum, date); presentations to health departments, CBOs, and other community partners (author(s), title, forum, date); citations for publications in journals and other reports (e.g. factsheets, epidemiologic profiles); policies, recommendations, programs, guidelines and other, that were developed as a result of NHBS findings; and media coverage that utilize NHBS data sources from the current and previous cycles

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

The FFATA and Public Law 109-282, which amends the FFATA, require full disclosure of all entities and organizations that receive federal funds including awards, contracts, loans, other assistance, and payments. This information must be submitted through the single, publicly accessible website, www.USASpending.gov.

Compliance with these mandates is primarily the responsibility of the federal agency. However, two elements of these mandates require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through SAM; and 2) similar information on all sub-awards, subcontracts, or consortiums for greater than \$25,000. For the full text of these requirements, see: <http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=BILLS>.

G. Agency Contacts

CDC encourages inquiries concerning this FOA.

Program Office Contact

For programmatic technical assistance, contact:

Melissa Cribbin Sharma, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
1600 Clifton Rd NE, MS E-46
Atlanta, GA 30329
Telephone: (404) 639-2016
Email: nhbsquestions@cdc.gov

Grants Staff Contact

For **financial, awards management, or budget assistance**, contact:

Gladys Gissentanna, Grants Management Specialist

Department of Health and Human Services

CDC Procurement and Grants Office

2920 Brandywine Road, MS-E15

Atlanta, GA 30341

Telephone: (770) 488-2741

Email: gcg4@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

For all other **submission** questions, contact:

Technical Information Management Section

Department of Health and Human Services

CDC Procurement and Grants Office

2920 Brandywine Road, MS E-14

Atlanta, GA 30341

Telephone: 770-488-2700

E-mail: pgotim@cdc.gov

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348.

H. Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- CDC Assurances and Certifications
- Table of Contents for Entire Submission

- Work plan
- Resumes/CVs
- Staffing plan
- Position descriptions
- Letters of Support
- Organizational Charts
- Indirect Cost Rate , if applicable
- Brief signed letter from a high-ranking authority in the applying health department affirming that anonymous HIV testing is permissible for NHBS
- Certification Statement with the “Security and Confidentiality Standards for Public Health Data and Designation of Overall Responsible Party (ORP)”
- **Bona Fide Agent status documentation, if applicable**

Additional information on NHBS is available at <http://www.cdc.gov/hiv/statistics/systems/nhbs/index.html>

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 74 and Part 92 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the FOA; awardees must comply with the ARs listed in the FOA. To view brief descriptions of relevant provisions, see http://www.cdc.gov/grants/additional_requirements/index.html. Note that 2 CFR 200 will supersede the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Catalog of Federal Domestic Assistance (CFDA): A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

CFDA Number: A unique number assigned to each program and FOA throughout its lifecycle that enables data and funding tracking and transparency.

CDC Assurances and Certifications: Standard government-wide grant application forms.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established project period (i.e., extends the “life” of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial

involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the awardees. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the awardee.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. [http:// www.cdc.gov /grants /additionalrequirements /index.html](http://www.cdc.gov/grants/additionalrequirements/index.html).

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at [http://fedgov.dnb.com/ webform/displayHomePage.do](http://fedgov.dnb.com/webform/displayHomePage.do).

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The FOA evaluation plan is used to describe how the awardee and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Healthy People 2020: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list: http://www.whitehouse.gov/omb/grants_spoc/.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending

legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Plain Writing Act of 2010: Requires federal agencies to communicate with the public in plain language to make information more accessible and understandable by intended users, especially people with limited health literacy skills or limited English proficiency. The Plain Writing Act is available

at www.plainlanguage.gov.

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Program Official: Person responsible for developing the FOA; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Project Period Outcome: An outcome that will occur by the end of the FOA's funding period.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation <http://www.phaboard.org>.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of project period outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

Overall Responsible Party (ORP): A high-ranking official identified to accept overall responsibility for implementing and enforcing data security, confidentiality and sharing standards. This official should have the authority to make decisions about program operations that might affect programs authorizing, accessing or using the data, and should serve as the contact for public health professionals regarding security and confidentiality policies and practices. If the required span of control is not under a single person's purview, several persons can serve in the capacity of ORP as an ORP panel.

AMENDMENT 1, dated 06/26/2015, adds the following information to this FOA:

1. FOA Questions and Answers from e-mails and the informational conference call with applicants (Attached at the end of

the FOA in Section J).

2. Clarification in Section A.2 that both gonorrhea and chlamydia testing should be offered for the Optional activity #2: Conduct anonymous STI testing during NHBS-MSM and NHBS-HET.
3. Clarification in Section D.12 of required forms 424a.
4. Clarification in Section E of the Phase III Review for Required Core NHBS strategies and activities.
5. Bona Fide Agent status documentation (if applicable) to the list of acceptable attachments in Section H.

J. Questions and Answers on FOA CDC-RFA-PS16-1601, National HIV Behavioral Surveillance (NHBS):

TOPIC: GENERAL

Q1: I understand that NHBS involves 3 rotating annual data collection cycles, including NHBS-MSM, NHBS-HET, and NHBS-IDU. I assume that all funded sites collect data from the same target population during any one calendar year?

I would like to confirm that the cycles under the NHBS FOA would be:

Year one – HET

Year two – MSM

Year three – IDU

Year four – HET

Year five – MSM

For the required core NHBS, a different population will be sampled each year. All awardees will conduct data collection with the same core population during the same calendar year. To reiterate, the data collection cycles under this FOA are:

Year one – HET

Year two – MSM

Year three – IDU

Year four – HET

Year five – MSM

Q2: Is it known when activities will start for the optional NHBS among YMSM and NHBS among transgender women? From reading the guidance, it appears as though special population activities are anticipated to occur in Years 2-4 of the FOA. Is this correct?

For conducting NHBS with each of the 2 optional populations, CDC will work with awardees to develop timelines and guidance documents. We do not anticipate that the start-up phase for either of these 2 optional populations will begin until year 2 (2017).

Q3: Would we collect data for each of these 2 optional populations during each of the required core NHBS data collection cycles, as a sub-component to the core NHBS populations (HET, MSM and IDU)?

Please refer to Section A.2 of the FOA under "Strategies and Activities", "Optional NHBS Populations" and Attachments E and F for information about conducting NHBS among the 2 optional populations (YMSM and transgender women). NHBS among these 2 optional populations are independent of required NHBS core activities and will be conducted in parallel with the NHBS core data collection cycles. The whole duration of conducting NHBS with each of these 2 optional populations is expected to be up to 3 years, including the start-up, extensive formative assessment and data collection phases. The proposed sample size for each of these optional populations would be achieved by the end of the 3 year period.

Q4: For the application itself, how much of the FOA language should follow the very specified format or should the application be more like an NIH proposal? The difference is the emphasis on the specified sections for the narrative (background, approach, outcomes, strategies, collaborations, populations, organizational capacity, work plan) vs. significance, innovation, approach, methods, statistical analysis, etc. This is crucial as if detailed methods are required it may take a lot of pages.

This FOA is for non-research and therefore, the application has a different format than NIH or other research applications. Please follow the application instructions in Section D of the FOA.

Q5: The zip file on the grants.gov website only seems to have the PDF of the published FOA and I'm unable to find the corresponding attachments. Is there another file that includes the attachments?

Under Section D.12 "Budget Narrative" there is a statement with a link to the attachments: "Applicants must submit separate budget narratives to be considered for funding for Core NHBS (required), for each of the 2 optional NHBS activities (if applying), and for conducting NHBS with each of the 2 optional populations (if applying). Technical and budgetary guidance is provided in Attachments A-F, available at: <http://www.cdc.gov/hiv/funding/announcements/ps16-1601/attachments.html>." Please refer to this cdc.gov link to access Attachments A-F which contain budgetary technical assistance information. These attachments are only available through this link and not the pdf FOA document or through grants.gov.

Q6: Is this considered a multi-component FOA? From the N/A on Item iv., Page 15 it would appear not to be.

This is not a multi-component FOA. However, this FOA contains two optional NHBS testing activities and two optional NHBS populations.

Q7: What is the page limit for this FOA? Is it 20 or 25 pages? Are there page limits for describing the optional activities and populations? Or are the optional activities and populations included in the 20 pages? It will be a challenge to address optional testing and optional populations in five extra pages. If there are any creative ways to approach this, we would appreciate further guidance. Twenty five pages is very tight.

If applying for the required core NHBS activities ONLY, the page limit is 20. If applying for the required core NHBS activities AND one or more of the optional activities or optional NHBS populations, then the page limit is 25 to address both the core activities and the options. As stated in Section E.1 of the FOA, the optional NHBS among YMSM and the optional NHBS among transgender women will be funded in order by score and rank determined by the review panel. Therefore, if applying for one or both of the optional NHBS populations, you may want to allocate enough pages of the project narrative (within the 25 page limit) detailing activities for these optional populations.

Q8: Should the narrative for each of the 2 optional populations be a totally free-standing component or should it be incorporated into the core NHBS narrative?

If applying for one or both of the optional populations, begin the narrative with the required core NHBS activities and then address each of the optional populations subsequently in the same narrative.

Q9: For the Work Plan that is specified as part of the 20 page application limit, is it to be for all 5 years or just year 1? Does the 5 year work plan include the optional activities? Do we need to do a

different work plan for the optional populations? Do you want a work plan for all core activities and then at the end of the core, a separate work plan for the optional activities and for the optional populations?

Please refer to the FOA, Section A2 under "Work Plan". A detailed work plan must be provided for year one of the award. Year 1 includes the NHBS-HET cycle plus the optional STI testing during NHBS-HET, if applicable. Please also provide a high-level work plan to address the 5 years of NHBS. The high-level work plan should include the 2 optional NHBS testing activities and conducting NHBS with each of the 2 optional populations, if applicable. Separate work plans are NOT required if applying for the 2 optional populations.

Q10: On page 20 it is stated under c. "Organizational Capacity" that "Applicants shall have a clear staffing plan and project management structure." On page 30, it is stated that the work plan is part of the 20-page narrative. However, on page 44 the work and staffing plans are listed as separate attachments. Should we submit additional work and staffing plans as attachments in addition to those included in the narrative?

Under Section D.11 of the FOA, it states that the work plan is included in the project narrative page limit. However, it also states that "Applicants must name this file "Work Plan" and upload it as a PDF file at www.grants.gov." Therefore, the work plan as well as the staffing plan are listed as acceptable attachments in Section H.

Q11: It seems the organizational capacity statement is a separate file that does not count towards the page limit. Is that true? The organizational capacity statement specifies attaching CVs. Some individual CVs maybe 20 pages in themselves

*The organizational capacity statement counts toward the page limit; however, CVs can be attached as pdfs and do not count toward the page limit. **Please see Section H of the FOA for a list of acceptable attachments.***

Q12: Is there a preferred format for the CV, e.g. the new NIH biosketch? In past years, applicants included a "Biosketch" form in addition to staff CVs. Is that form still required? If so, does every staff member and contract employee need to submit one?

There is no preferred format for the CV but it must include the relevant capacity and experience as described in Section A.2 under "Organizational Capacity of Awardees to Execute the Approach". As stated in this section, "Please include CVs for key staff or note whether hiring new staff will be required."

Q13: Is determining whether to submit for IRB clearance at the discretion of each individual awardee?

Submission to IRBs are based on local regulations; therefore, each applicant should determine the approval process and the need for IRB review.

Q14: I just wanted to confirm that letters of support are mandatory for all sites applying regardless of whether or not they've done NHBS in the past.

Yes, letters of support are required from all applicants regardless of previous experience.

Q15: Are general letters of support ok from area agencies that are willing to collaborate on the project, as this would be a new project for us and we do not have established contracts?

Yes.

Q16: In the logic model table on page 5, one of the two key short-term outcomes is, "improved NHBS strategies and methods to reach populations at high risk for HIV infection" but on page six it is not identified as an expectation, please clarify.

It is anticipated that the strategies, activities and outputs will lead to the short-term outcome "Improved NHBS strategies and methods to reach populations at high risk for HIV infection." However, awardees are not required to demonstrate accomplishment of this outcome by the end of the five-year project period.

Q17: Can you clarify the structure of the narrative with respect to optional activities and optional populations? You said to address subsequently in the same narrative- do you mean address it in the section that it would fall (e.g. in Background, expand that section to include the optional activities and populations) or at the end of the narrative so that each optional activity and population would be addressed separately?

For the project narrative, first address all bolded headings for the Required Core NHBS activities and include the optional testing activities (if applying). Then continue the narrative and address all bolded headings for optional population #1 (YMSM), if applying. Then continue the narrative and address all bolded headings for optional population #2 (transgender women). As funding for the optional populations will be in order of score and rank determined by the review panel, applicants may want to allocate enough pages of the project narrative (within the 25 page limit) detailing activities for these optional populations.

Q18: Are you sure we should write the narrative for core NHBS and optional testing activities and THEN repeat the narrative for the optional populations? It seems like there would be a lot of duplicated sections and it seems the FOA suggests adding the optional populations to the body of the core narrative.

Although information for the Required Core NHBS and the optional populations are included in the same sections of the FOA, they should be addressed separately in the project narrative

Q19: Could you provide guidance of what is expected of the state health department if they subcontract with another agency to perform the activities?

Flow-down of Requirements for Contracts under Grants/Cooperative Agreement: The contractual agreement is between the primary awardee (Recipient) and their contractor. The terms and conditions in the HHS GPS apply directly to the recipient of HHS funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the Notice of Award (NoA). In general, the requirements that apply to the recipient, including public policy requirements, also apply to the contractors under grants/Cooperative Agreement.

TOPIC: BUDGET

Q20: How should the budget for optional activities be shown on the 424A form or on a separate 424-A? How should the 424-A be completed for the 3 year period for each of the 2 optional populations ? Should the columns be used and labelled Year 1, 2, and 3? In the revised FOA or

questions summary, it would be most helpful if detailed and specific instructions or a template, could be provided on completing the SF424A.

Sample 424a forms with labels can be found at: <http://www.cdc.gov/hiv/funding/announcements/ps16-1601/attachments.html>

A SUMMARY SF-424a should be submitted with your application showing the total funds requested for the entire project period. This SUMMARY SF-424a will include core NHBS activities, any optional testing activities and the 2 optional populations, if applying.

SECTION A contains information for Year 01. In the rows of SECTION A, you will list the activities you are applying for. Row 1 would be core NHBS plus optional testing (if applying). Rows 2 and 3 should list NHBS among Young MSM and/or NHBS among transgender women, if applying. Because this section only contains requested funds for Year 01 and the optional populations will not begin until Year 02, you will list \$0 requested dollars for Year 01 for these optional populations.

SECTION B is also only for Year 01. You should list the object class categories for the first year. In Year 01, the only activities occurring will be the NHBS-HET cycle and the optional STI testing for that cycle (if applying). For this SUMMARY SF-424a, you should combine funds for the core NHBS activities with the optional testing activities, so you would only use ONE column in SECTION B.

SECTION E includes estimates of funds you will need for the remainder of the project period. So these columns represent the 2nd, 3rd, 4th, and 5th budget periods. In the rows, you should again list core NHBS plus optional testing for that year if applying, NHBS among YMSM and/or NHBS among transgender women if applicable. You will project the funding needed in each year for the remaining 4 years of the project period.

If you plan to apply for either NHBS among YMSM or NHBS among transgender women, you will need to submit an additional SF-424a for each of these optional populations. These will follow a similar format as the SUMMARY SF-424a. Activities for both of these optional populations will begin in 2017, so that will be regarded as Year 01 for these 424a forms. In SECTION A, you will list EITHER NHBS-YMSM or NHBS-Transgender in a single row and the amount requested for the first year of this activity. In SECTION B, you will list the object class categories for the first year of this activity. In SECTION E, you will list the 2nd and 3rd years of these activities and the estimates of funds needed.

Q21: What is the approximate anticipated annual budget for the optional population activities? Should a separate budget be developed for each of the 3 years, or should the budget for all 3 years be combined into a single, budget for the total period ?

Activities for each of the 2 optional populations should include a start-up phase, in-depth formative work and data collection. We estimate that these three phases will be completed in three years. A separate 12-month budget should be prepared for each of the 3 phases or years.

Q22: If a site applies for the two optional populations, what is the award ceiling?

There is a combined ceiling \$6,500,000 per project period for applying for core NHBS activities and any or all optional activities and optional populations; this ceiling is listed in Section B.9. and Section C.2. A ceiling is not specifically designated for each optional activity or population. However, example budgets are listed in Attachments A-F that are available at: <http://www.cdc.gov/hiv/funding/announcements/ps16-1601/attachments.html>. Applicants should request everything they need to conduct all activities when preparing budgets.

Q23: Regarding the optional STI testing during the HET cycle—if you conduct STI testing in Year 1, is there any expectation that you would also conduct testing in Year 4? This would be the same question for any of the optional testing activities that might occur twice during the project period. So if applying, should we add the funding for the possible years in our total request?

All funding for these optional activities is based on availability of funds. Optional STI testing during NHBS-HET will potentially occur in year one and year four. Optional STI testing during NHBS-MSM will potentially occur in year two and year five. Optional STI testing (if applying) should be included in all years of interest in the total budget request.

Q24: We would like to know if we can request funding in the 2016 budget for a vehicle; we cannot conduct sampling without a vehicle.

The FOA does not have restrictions for purchase of equipment. Applicants should request the resources that are needed to complete program activities. Applicants may refer to Attachments A-F for further budgetary technical assistance.

Q25: Please provide explanation needed regarding staffing for the supplemental analysis, or if this is left to the discretion of the project site/team?

The FOA does not address supplemental analysis. However, please refer to Section A.2 "Organizational Capacity of Awardees to Execute the Approach" for requirements for a staffing plan and Attachments A-F. However, applicants should use their discretion for staffing plans needed for local implementation of the activities.

Q26: If items like QDS 2.6 are not specified in the budget but rather mentioned in the narrative, will that suffice as evidence for the reviewers that we will use QDS 2.6?

Yes, a response in the narrative is sufficient.

Q27: In the optional activity, “Conducting NHBS among Transgender Women,” year two budget guidance (Attachment F), there is a line item for “Staff Identification.” Does this refer to badges?

Staff identification refers to badges, staff shirts, or other items deemed locally necessary for the identification of project staff.

Q28. In regards to allowable expenses, is it allowable to request funding to attend conferences? Also, is it allowable for either core or optional activities to request funding for syphilis testing? If not, why not?

Funding for travel to conferences will be based on the availability of funds. Applicants should request what they need. Syphilis testing is not included in this FOA, so funds cannot be used for that purpose.

TOPIC: ELIGIBILITY

Q29: It is noted that to be eligible, applicants must provide a brief signed letter from a high-ranking authority in the applying health department affirming that anonymous HIV testing is permissible for NHBS. What is CDC’s rationale for anonymous HIV testing with NHBS?

Since its inception in 2003, participation in NHBS, including HIV testing, has been anonymous. CDC has determined that for this FOA, anonymous testing is required to meet program outcomes.

Q30: Is such a letter required from current NHBS sites?

ALL APPLICANTS, regardless of previous experience with NHBS, must supply this letter documenting that anonymous testing is permissible for NHBS.

Q31: Why must applicants obtain a letter stating that anonymous testing will be allowed?

*Please refer to the FOA, Section C.2 "Information on Eligibility". It reads: "Additionally, to be eligible, applicants must provide a brief signed letter from a high-ranking authority in the applying health department affirming that anonymous HIV testing is permissible for NHBS." **To reiterate: to be eligible for this FOA, applicants are required to submit this letter stating that HIV testing is permissible for NHBS.***

Q32. Could you kindly confirm which geographic areas are eligible for this grant?

Please refer to the FOA, Section C.2 "Information on Eligibility"; the eligible applicants and metropolitan statistical areas are listed. Please also refer to Section C.3 "Justification for Less than Maximum Competition"; Table 1 lists the eligible metropolitan statistical areas or divisions in rank order of HIV prevalence.

Q33: On page 24 of the RFA, eligible applicants are listed as State and Territorial Health Departments or their Bona Fide Agents containing the following MSAs or specified Divisions. Would a political subdivision of the state be eligible to respond to this RFA directly? With regards to local health departments that are not directly funded, can we directly apply or do we have to go through the state health department?

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. CDC cannot determine the bona fide agent status of an organization or agency. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. The eligible applicants are those that are listed on the FOA. If your entity is not listed on the FOA, then you would have to consult with the state about applying as a Bona Fide Agent.

Q34: If we do not apply directly but rather through a Bona Fide Agent, can the letter agreeing to anonymous testing come from an authority at the Bona Fide Agent or does it need to come from the department of health?

Yes, the letter can come from the health department that is being represented by a Bona Fide Agent.

TOPIC: STAFFING

Q35: What staff and program(s) should be included in the organizational chart that is required/suggested in the Organizational Capacity section?

The organizational chart should depict where in the organization core NHBS and the optional activities and populations (if applicable) will fit. The organizational chart should include the principal Investigator, project coordinator, field supervisor, data manager/analyst, and field staff, including if a subcontractor is used.

Q36: Principal Investigator (PI) effort is specified at 20% or less. Is that just for the required core NHBS activities? Would additional effort be acceptable if additional optional population activities are applied for?

Applicants should request the level of effort that is needed to complete proposed activities.

Q37: May providers of state grantees contracted to conduct NHBS activities subcontract with providers to conduct any NHBS-related activities associated with this new RFA? Specifically for activities associated with optional NHBS populations e.g., YMSM, transgender? If so, are there restrictions on any specific activities? Funding ceilings for these subcontracts?

Awardees should determine how to best administer the activities, including subcontracts. CDC cannot determine funding ceiling for subcontracts.

TOPIC: REQUIRED CORE NHBS

Q38: Has the participation eligibility criteria for any of the required core NHBS populations changed?

As stated in the FOA, CDC will provide guidance documents to awardees. However, we are not anticipating the participation or analysis eligibility criteria to change for this announcement.

Q39: Is there any reason why Respondent Driven Sampling cannot be used for the MSM cycle?

CDC has determined the sampling strategies for this FOA and they will remain consistent for the required core NHBS populations. Section A.1 under "Relevant Work" provides more information on past NHBS FOAs.

Q40: Will expectations and timelines for data collection vary between newly funded sites and previously funded sites in year one?

The timelines for data collection will be the same for all awardees, regardless of experience.

Q41: Can you offer a suggested or preferred timeline for completion of preparation activities and beginning of recruitment in year one for newly funded sites?

All awardees regardless of experience should complete preparation and other activities per the timelines specified in Section A.2 of the FOA.

Q42: Has any consideration been given to reducing the number of persons sampled in lower prevalence areas?

No the sample size requirements must be met.

TOPIC: OPTIONAL NHBS POPULATIONS

Q43: Based on formative activities that have already occurred, can start-up activities and extensive formative assessment be condensed so that data collection takes place during the first year of activity?

As stated previously, CDC will work with awardees to develop timelines and guidance documents. Therefore, it is unlikely that data collection would begin in the first year.

Q44: Can there be more information provided for the consent process for under 18 individuals for conducting NHBS among YMSM and the possible complications with these individuals being considered minors?

As stated in Section A.2 of the FOA, awardees for the optional NHBS among YMSM must apply for any locally required regulatory approvals, including IRB determinations and consent.

Q45: Why are young MSM given a different sampling strategy over the regular MSM participants which are being venue-based sampled?

For newer NHBS populations, CDC is assessing the optimal recruitment strategy to reach them and will provide the needed guidance documents to awardees for this optional population.

TOPIC: OPTIONAL NHBS TESTING ACTIVITIES

Q46: How many optional activities can we choose?

Eligible applicants for this FOA are not limited to the number of optional activities and/or optional populations for which they can apply.

Q47: What type of characteristics are used in deciding whether or not an applicant will be given funding for HBV and HCV testing rather than just one or the other? The RFA states that awardees may be funded to conduct HBV, HCV, or both.

Please refer to Section A.2 of the FOA under "Strategies and Activities", "Optional NHBS Activities" and Attachment B for information about conducting the optional anonymous hepatitis testing activity during NHBS-IDU. Based on availability of funding, awardees may be funded to conduct hepatitis B testing, hepatitis C testing or both.

Q48: What are the specific required Hepatitis B & C panels for sites proposing to conduct this activity? E.g., core, surface, antigen, antibody, etc. Considering the difficulties sometimes faced with venipuncture in the IDU population will finger stick or other tests be considered?

Although finger stick can be used for the rapid test for Hepatitis C, venipuncture will be required to collect a blood specimen for hepatitis B core antibody, hepatitis B surface antigen and antibody, and hepatitis C confirmatory tests. Please refer to Attachment B for more information.

Q49: Will serum for Hepatitis testing need to be sent to CDC lab?

Please refer to Section A.2 of the FOA under "Strategies and Activities", "Optional NHBS Activities" which states: "Prepare frequent shipments of specimens to local and CDC laboratories in compliance with CDC-approved guidelines and timelines". Please also refer to Attachment B.

Q50: For the optional hepatitis testing, HCV rapid testing, does it matter what kits you use?

The OraSure® HCV Rapid Antibody Test is the only FDA approved rapid test for Hepatitis C virus (HCV).

Q51: For the optional STI testing activity, are we required to perform both gonorrhea and chlamydia testing for the HET and/or MSM cycles if we are awarded this additional grant funding? Will some

sites be given the option to only test one of the two STIs?

Please refer to Section A.2 of the FOA under "Strategies and Activities", "Optional NHBS Activities" and Attachment C for information about conducting the optional anonymous STI testing activity during NHBS-MSM and Attachment D for information about conducting the optional anonymous STI testing activity during NHBS-HET. As stated in the FOA, applicants will have to perform BOTH gonorrhea and chlamydia testing for this optional activity. However, applicants can apply to conduct STI testing for either the HET cycles, MSM cycles or both populations.

Q52: Should MSM participants be offered both rectal and pharyngeal swabs for gonorrhea and rectal and pharyngeal swabs for chlamydia?

Please refer to Section A.2 of the FOA under "Strategies and Activities", "Optional NHBS Activities" and Attachment C for information about conducting the optional anonymous STI testing activity during NHBS-MSM. Yes, awardees for the optional anonymous STI testing during NHBS-MSM should offer both the gonorrhea and chlamydia test using the rectal and pharyngeal swabs. The FOA will be revised to state that both gonorrhea and chlamydia tests shall be offered.

Q53: What are the specific required assays for gonorrhea and chlamydia for sites proposing to conduct this activity?

The required assay for gonorrhea and chlamydia is PCR (polymerase chain reaction).

Q54: Will specimens collected for STI activities need to be sent to CDC lab? Can testing be done locally?

Please refer to Section A.2 of the FOA under "Strategies and Activities", "Optional NHBS Activities" which states: "Prepare frequent shipments of specimens to local and CDC laboratories in compliance with CDC-approved guidelines and timelines." Please also refer to Attachments C and D. Awardees may conduct the testing using local laboratories as long as the anonymous test results are included in the NHBS data submission to CDC. If awardees do not have this capacity locally, they may send the specimens to the CDC laboratory.

Q55: For the optional STI testing during NHBS-HET, why are females in the testing sample restricted to less than 30 years of age?

CDC has determined this based on available epidemiological data that show that disease burden is higher among younger women and based on screening guidelines which target this population group.

Q56: For the STI testing during NHBS-HET, why are only vaginal swabs included in the supplies for STI testing in the HET cycle? Will we not be conducting STI testing with men?

The optional STI testing in the NHBS-HET cycle is limited to women under the age of 30; refer to Attachment D for the supplies recommended. Attachment C lists the supplies and other recommended resources that may be needed for conducting the optional STI testing during NHBS-MSM. As a reminder, applicants can choose to apply to conduct the optional STI testing either during NHBS-HET, during NHBS-MSM or during both cycles.

Q57: May applicants proposing to conduct Hepatitis and/or STI activities separately incentivize for

participants? If so, are there dollar amount limits?

Applicants may propose to incentivize the optional hepatitis and STI testing activities. Please refer to Attachments B-D for example amounts for incentives. However, the amount proposed by applicants should be based on local procedures and regulations.

Q58: Will grantees face financial remedy if they fail to meet the minimum sample size (90%) for hepatitis and/or STI testing?

As stated in the FOA: "Awardees performing at a less than sufficient levels to achieve program activities and outputs within stated timeframes will be placed on a time-phased Corrective Action Plan (CAP) developed by CDC in collaboration with the awardee. The CAP is a comprehensive tool used to assist awardees to improve program performance through identifying factors contributing to less than sufficient performance and developing specific action steps to address areas in need of improvement."

Q59: If we are not funded for optional activities (STI and hepatitis testing), would we be able to conduct these testing activities through confidential rather than anonymous testing using the NHBS sample?

No, NHBS is anonymous.