



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Print Date: 12/17/21

Title: National HIV Behavioral Surveillance

Project Id: 0900f3eb81bae32c

Accession #: NCHHSTP-BST-8/4/20-ae32c

Project Contact: Dafna Kanny

Organization: NCHHSTP/DHP/BCSB/BST

Status: **Project In Progress : Amendment**

Intended Use: **Project Determination**

Estimated Start Date: 01/01/2022

Estimated Completion Date: 12/31/2022

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0920-0770 Exp. 01/31/2023

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(l)(2)</i>	12/17/21	Dodson_Janella R. (jhd7) CIO HSC
PRA: PRA Applies		8/7/20	Bonds_Constance (akj8) CTR OMB/PRA Coordinator

Description & Funding

Description

Priority: Urgent

Date Needed: 12/27/2021

Priority Justification: We need to share the updated protocol with project areas by the end of Dec 2021.

Determination Start Date: 12/16/21

Description:

This submission is to amend the protocol of the longstanding National HIV Behavioral Surveillance (NHBS), a non-research surveillance system (OMB #0920-0770, Exp. 01/31/2023), to incorporate new NHBS Cooperative Agreements awarded for 2022-2026 (see Supporting Info for Model Surveillance Protocol). NHBS is CDC's ongoing national HIV bio-behavioral surveillance system to monitor the prevalence of and trends in HIV infection and behaviors that lead to acquisition of HIV infection. The primary intent of NHBS is to collect data in an ongoing and systematic manner on HIV risk behaviors, HIV testing, exposure and access to HIV prevention programs, and HIV seroprevalence and incidence. This system provides the opportunity to capitalize on experience recruiting at-risk individuals from non-healthcare community settings using scientifically sound methodologies. The findings from NHBS will be used to develop local HIV prevention programs and to evaluate existing programs and services by assessing exposure to and use of prevention services over time, and determining gaps in provision of, access to or use of HIV prevention services. In particular, the extent of unrecognized HIV infection, measured through unawareness of HIV status among persons whose NHBS test result is positive, can be used to target testing services and evaluate testing guidelines. Combined with data from other HIV surveillance systems (such as case surveillance, incidence, and clinical surveillance) information obtained from NHBS will assist CDC and state/local health departments to understand and explain trends observed in HIV incidence, new HIV diagnoses and HIV prevalence in the population. NHBS is conducted in up to 25 Metropolitan Statistical Areas with high HIV prevalence.

IMS/CIO/Epi-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project: Not selected

Task Force Associated with the Response: Not selected

CIO Emergency Response Name: Not selected

Epi-Aid Name: Not selected

Assessment of Chemical Exposure Name: Not selected

Goals/Purpose

The goal of this project is to conduct an ongoing bio-behavioral surveillance system. This system provides the opportunity to capitalize on experience recruiting at-risk individuals from non-healthcare community settings using scientifically sound methodologies. Data from the bio-behavioral surveillance system will be used for HIV prevention program planning and evaluation at the national and local levels.

Objective: The objectives of this project are to conduct ongoing monitoring to ascertain the prevalence of and trends in HIV risk behaviors and HIV infection among groups at high risk for HIV infection for use in developing and directing national and local prevention services and programs; and to evaluate the impact of HIV prevention services. Specific objectives include the following: 1) To estimate the prevalence of HIV risk behaviors and HIV testing behaviors in persons at increased risk for acquiring HIV infection (men who have sex with men [MSM], persons who inject drugs [PWID], and heterosexually active adults at increased risk [HET]) in MSAs with high HIV prevalence. 2) To assess the exposure to and use of HIV prevention services among persons at high risk for HIV infection. 3) To measure trends in HIV seroprevalence, HIV incidence, and the prevalence of other sexually transmitted infections (STIs) among persons at high risk for HIV infection. 4) To use the data collected to target HIV prevention activities and evaluate HIV prevention programs locally. 5) To detect changes over time in HIV risk behaviors in groups at high risk for acquiring HIV infection. 6) To evaluate the surveillance system periodically to ensure that it is meeting its goals and to make recommendations for improving its methods, quality, efficiency, and usefulness.

Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?: No

Project does not incorporate elements of health equity science: Not Selected

Measuring Disparities: Yes

Studying Social Determinants of Health (SDOH): Not Selected

Assessing Impact: Not Selected

Methods to Improve Health Equity Research and Practice: Not Selected

Other: Not Selected

Activities or Tasks: New Collection of Information, Data, or Biospecimens

Target Populations to be Included/Represented: Other - MSM, PWID, heterosexually active persons at increased risk for HIV.

Tags/Keywords: MSM ; PWID ; Heterosexuals ; HIV ; bio-behavioral surveillance

CDC's Role: Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided

Method Categories: Survey

The overall strategy for NHBS is to conduct rotating annual cycles of surveillance in three populations at high risk for HIV: MSM, PWID, and HET. Surveillance activities during each cycle include formative assessment, surveys, and HIV testing. These surveillance activities will be conducted in MSAs with high HIV prevalence over time to provide information on trends in behaviors and use of prevention programs. Time-space sampling conducted in two stages when formative assessment is completed. In the first stage, staff construct monthly sampling frames of venues and day-time periods that meet criteria for sufficient attendance of the target population and feasibility of conducting the surveillance activities. From these frames, staff randomly select a set of venues and day-time periods in two stages and schedule these on monthly calendars. In the second stage, staff go to venues in accordance with the monthly calendar; at the venue and during the day-time period, staff count, systematically approach, screen, and recruit eligible men attending the venue. Respondent-driven sampling (RDS) starts with a limited number of #seeds,# who are

Methods:

chosen by referrals from people who know the local risk group well, or by staff doing outreach in areas identified through the formative assessment. These seeds complete an interview and are then asked to recruit up to 5 people they know who also meet the eligibility criteria for the cycle. Participants are provided an incentive for the interview and HIV testing, and for recruiting others. Recruiters and recruits are linked using coded coupons and tracked using a coupon manager software program. Under extreme circumstances, e.g. following a natural disaster or during a pandemic, NHBS sampling methods may be relaxed and approach convenience sampling to ensure the health and safety of NHBS staff and participants. Formative Assessment: For each behavioral surveillance cycle, grantee agencies will work with ethnographers and community-based organizations in their jurisdiction to conduct formative assessment. Within the context of NHBS, formative assessment allows grantees to gain insight into the context of HIV risk behavior within certain settings and among sub-populations of the specific groups at risk in their community. Formative assessment activities include a review of existing data on the population of interest specific to the MSA, qualitative data collection, garnering the support of community stakeholders, and development of questions that measure local prevention activities. Small stipends (\$25) or vouchers will be given to those interviewed and tested for HIV (\$25 for each). In cycles using RDS, additional rewards (\$10) are paid to those who successfully recruit others. Additional stipends or vouchers are generally provided for any additional tests (e.g., HBV or HCV, STI). Local project areas determine the exact amount for incentives deemed appropriate for the local populations being interviewed and tested. Evaluations of NHBS will be conducted on an ad hoc basis. These evaluations may include surveillance evaluations, program evaluations, and evaluation activities such as inclusion of different populations (e.g., transgender persons, sex partners of MSM, IDU, or HET) or different cities (e.g., Southern MSAs which are not eligible for NHBS but have a high prevalence of HIV among heterosexuals).

Collection of Info, Data or Biospecimen:

In each cycle, participants will be recruited and administered an eligibility screener; those who are eligible and give consent will be interviewed about sex and drug use behaviors and their past HIV testing experiences using a standard questionnaire. The survey is administered by trained interviewers using computers; HIV testing is done by trained staff. Other tests, such as new HIV testing technologies or biological testing for STIs or hepatitis, may be performed in project areas that are funded to perform these activities. In project areas offering these other tests, consent for the other tests will be obtained along with consent for the survey and HIV test; blood will be drawn for these other tests at the time of the survey. A minimum of 500 eligible persons from each MSA will be interviewed during each cycle. All participants will be explicitly assured during the recruitment process of the anonymous nature of the data including the interview, HIV testing, and any additional testing offered. All participants will provide their informed consent to take part in the interview, HIV testing, and any additional testing. For participants' convenience or benefit, participants may have the option to provide contact information to project staff on a voluntary basis. Examples of participants providing contact information for convenience include but are not limited to: providing a phone number for phone text reminders of interview appointments; providing payment information so incentives can be provided electronically; providing an email address to facilitate video conference interviews; or providing an address to receive self-collection or self-testing kits via mail. Examples of participants providing contact information for participant benefit include but are not limited to: providing telephone contact information so that project staff can call participants when their HIV/additional test results are ready; providing contact information to help participants with linkage to HIV care or other services they may need. Provision of contact information will be optional. In all cases, participants also will be provided information and instructions for how to participate fully without providing contact information. This surveillance activity is funded through cooperative agreements with participating health departments. All data will be collected locally by grantee staff. No contact information will be sent to CDC. Project areas will keep contact information separately from all NHBS data and destroy contact information immediately upon completion of its intended use. Contact information will be stored securely in a separate document from any NHBS test result data, paper or electronic. In most cases, contact information will not be linkable to any NHBS data. In rare circumstance, contact information may need to be indirectly linkable to limited NHBS data, for example NHBS staff cannot return test results by phone without both a phone number and test result. A generated survey ID number will be used to link NHBS test results data or test kits for the purpose of returning test results to participants or contacting participants to ensure a test kit is completed and returned. Consent forms, questionnaires, lab forms, and other NHBS data collection forms will be maintained in confidential secure environments and any hard copies stored in locked filing cabinets. Only authorized persons will have access to NHBS files.

CDC will have principal responsibility for analyzing multi-site data, i.e., making comparisons across project areas. Each participating

health department will have principal responsibility for analyzing project area-specific data. Analysis of data collected using time-space sampling may be weighted in order to increase the generalizability of the findings. Analysis of data collected using RDS will be analyzed using the RDS Analysis Tool or other newly developed methods that result in weighted population estimates and standard errors, also to increase the generalizability of the findings. CDC will have principal responsibility for developing reports that utilize multi-site data, e.g., for making comparisons across project areas. CDC will publish NHBS data in surveillance reports and the MMWR, as well as peer-reviewed journals. CDC will provide formal or informal subject matter expertise on topics related to NHBS (e.g., methods, analysis, populations, HIV prevention, risk, etc.) to internal and external stakeholders as needed. Each participating health department will develop and publish reports that use project area-specific data. It is expected that local areas will disseminate the findings to the HIV prevention community planning groups to assist in the planning of local prevention activities. Health departments will use the data to evaluate the success of prevention programs by determining if the programs are reaching the high-risk groups targeted for these activities and if not identify barriers to using prevention services.

Expected Use of Findings/Results and their impact:

- Could Individuals potentially be identified based on Information Collected?** Yes
- Will PII be captured (including coded data)?** Yes
- Does CDC have access to the identifiers (including coded data)?:** No
- Is this project covered by an Assurance of Confidentiality?** Yes
- Assurances of Confidentiality associated with this project:** NCHHSTP - AIDS and HIV Surveillance
- Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?** No
- Is there a formal written agreement prohibiting the release of identifiers?** Yes, *see supporting info*

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	National HIV Behavioral Surveillance (NHBS)	PS22-2201	2022	5	

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children

Protocol Page #:

Population - Minors

Protocol Page #:

Population - Prisoners

Protocol Page #:

Population - Pregnant Women

Protocol Page #:

Population - Emancipated Minors

Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process wavers

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPPA Privacy Rule No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Consent process shown in an understandable language

Reading level has been estimated No Selection

Comprehension tool is provided No Selection
Short form is provided No Selection
Translation planned or performed No Selection
Certified translation / translator No Selection
Translation and back-translation to/from target language(s) No Selection
Other method No Selection

Clinical Trial

Involves human participants No Selection
Assigned to an intervention No Selection
Evaluate the effect of the intervention No Selection
Evaluation of a health related biomedical or behavioral outcome No Selection
Registerable clinical trial No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus No Selection
Human genetic testing is planned now or in the future No Selection
Involves long-term storage of identifiable biological specimens No Selection
Involves a drug, biologic, or device No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Amy Baugher	03/25/2022		09/06/2021		Statistician	yda1@cdc.gov	404-639-1956	BEHAVIORAL SURVEILLANCE TEAM
Catlainn Sionean	09/20/2024				Program Official	ziq9@cdc.gov	404-639-2	BEHAVIORAL SURVEILLANCE TEAM
Christine Agnew Brune	06/05/2023				Project Officer	lwz5@cdc.gov	404-718-5478	BEHAVIORAL SURVEILLANCE TEAM
Cyprian Wejnert	03/25/2022		02/07/2021		Program Lead	dwy7@cdc.gov	404-639-6055	BEHAVIORAL AND CLINICAL SURVEILLANCE BRANCH
Dita Broz	08/11/2023				Program Official	iga4@cdc.gov	404-639-5258	BEHAVIORAL SURVEILLANCE TEAM
Ebony Symone Townsend	01/12/2024				Project Officer	wnk5@cdc.gov	404-718-8569	BEHAVIORAL SURVEILLANCE TEAM
Elana Morris	12/07/2024				Project Officer	efm9@cdc.gov	404-718-8193	BEHAVIORAL SURVEILLANCE TEAM
Janet Burnett	06/08/2023		12/18/2018		Project Officer	iyn6@cdc.gov	404-639-0086	BEHAVIORAL SURVEILLANCE TEAM
Jeffery Todd	02/28/2023				Project Officer		404-718-5389	BEHAVIORAL AND CLINICAL SURVEILLANCE BRANCH
Johanna Chapin-Bardales	08/04/2023				Statistician	wif3@cdc.gov	404-718-5879	BEHAVIORAL SURVEILLANCE TEAM
Kathryn Lee	08/10/2023				Program Official	hgi2@cdc.gov	404-639-6110	BEHAVIORAL SURVEILLANCE TEAM
Lyssa Faucher	06/08/2024				Project Officer	qkm5@cdc.gov	404-718-2086	BEHAVIORAL SURVEILLANCE TEAM

Monica Adams	05/21 /2024		10/29/2017		Project Officer	ydy7@cdc. gov	404- 718- 5092	BEHAVIORAL SURVEILLANCE TEAM
Paul Denning	08/11 /2023				Project Officer	pbd0@cdc. gov	404- 639-3	BEHAVIORAL SURVEILLANCE TEAM
Rashunda Lewis	03/20 /2023				Program Official	xek5@cdc. gov	404- 639- 2981	BEHAVIORAL SURVEILLANCE TEAM
Susan Cha	03/25 /2022		08/16/2019		Project Officer	lxi3@cdc. gov	404- 718- 5486	BEHAVIORAL SURVEILLANCE TEAM
Taylor Robbins	06/14 /2023				Project Officer	kyn4@cdc. gov	404- 639- 0016	BEHAVIORAL SURVEILLANCE TEAM
Teresa Finlayson	01/03 /2023				Program Official	taj4@cdc. gov	404- 639- 2083	BEHAVIORAL SURVEILLANCE TEAM

Data

DMP

Proposed Data Collection Start Date: 8/1/20

Proposed Data Collection End Date: 12/31/26

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL:

Data Use Contact: nhbs@cdc.gov

Public Access Justification: As a component of HIV/AIDS surveillance, NHBS data are protected by the Assurance of Confidentiality (Section 308(d) of the Public Health Service Act, 42 U.S.C. 242 m(d)). This assurance prohibits the disclosure of any information that could be used to directly or indirectly identify individuals. HIV and hepatitis surveillance data require additional protection. Therefore, data collection, management and analysis for this project will be conducted in compliance with 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>

How Access Will Be Provided for Data:

Processes for accessing NHBS data are described in the NHBS Multi-site Data Sharing Guidance document (Attached).

Plans for Archival and Long Term Preservation:

Spatiality

Spatiality (Geographic Locations) yet to be added

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									



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