



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

Print Date: 7/7/22

Title: National HIV Behavioral Surveillance Brief HIV Biobehavioral Assessment project (NHBS-BHBA)

Project Id: 0900f3eb81f40989

Accession #: NCHHSTP-BST-5/17/22-29c49

Project Contact: Dafna Kanny

Organization: NCHHSTP/DHP/BCSB/BST

Status: **Pending Regulatory Clearance**

Intended Use: **Project Determination**

Estimated Start Date: 01/01/2022

Estimated Completion Date: 12/31/2026

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #:

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(1)(2)</i>	5/24/22	Dodson_Janella R. (jhd7) CIO HSC
PRA: PRA Applies		6/1/22	Bonds_Constance (akj8) CTR OMB/PRA Coordinator

Description & Funding

Description

Priority: Standard
Date Needed: 06/15/2022
Determination Start Date: 06/01/22

Description:

The National HIV Behavioral Surveillance system (NHBS) is a non-research surveillance system to monitor HIV prevention progress (OMB #0920-0770, Exp. 01/31/2023). However, with efforts underway to end the HIV epidemic in the U.S., CDC's Division of HIV Prevention (DHP) recognized the need for additional rapid assessment data to inform local prevention efforts, especially in geographic areas or populations which lack information on HIV risk behaviors. The National HIV Behavioral Surveillance system's Brief HIV Biobehavioral Assessment project (NHBS-BHBA) is designed to use mixed-methods assessments to meet this need. As part of a new Notice of Funding Opportunity CDC-RFA-PS22-2201 to fund NHBS project areas (OMB #0920-0770, Exp. 01/31/2023) (component 1), a new component (2) was awarded to 2 state health departments. An ICR packet has been submitted. Funded state health departments for NHBS-BHBA will work with local entities to conduct brief bio-behavioral assessments (BHBA) in priority populations throughout the state. Priority populations may include persons at highest risk for HIV: men who have sex with men (MSM), persons who inject drugs (PWID), and heterosexually active persons at increased risk for HIV infection (HET), and locally identified populations of interest (e.g., women who inject drugs and exchange sex, persons who use stimulants) or geographic areas of interest (e.g., non-urban areas experiencing increased HIV incidence). The BHBA process includes 1) identification of geographic areas/populations at risk, 2) formative assessment for operations, 3) brief mixed methods quantitative and qualitative data collection and HIV testing, and 4) data analysis and dissemination, and development of grantee-developed recommendations for state/local partners. NHBS-BHBA data may be used rapidly by public health officials and researchers to develop specific and timely recommendations for state/local partners, respond to ongoing and emerging HIV hotspots, identify HIV prevention and care needs, allocate prevention and treatment resources, and develop and improve prevention programs directed to the populations of interest and their communities. Data will be shared with community partners and inform grantee-developed recommendations for state and local public health partners.

IMS/CIO/Epi-Aid/Lab-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
Lab-Aid Name: Not selected
Assessment of Chemical Exposure Name: Not selected

The goal of this project is to conduct brief bio-behavioral surveillance using mixed-methods assessments among priority populations

Goals/Purpose

in specified geographic areas of interest across funded states. This surveillance system provides the opportunity to fill knowledge gaps about HIV prevention among populations in geographic areas where data are limited and capitalize on experience recruiting at-risk individuals from non-healthcare community settings using scientifically sound methodologies. Data from these brief bio-behavioral surveillance using mixed-methods assessments will be used for HIV prevention program planning and evaluation at the state and local levels.

Objective:

The objectives of NHBS-BHBA are to conduct ongoing monitoring to assess prevention and risk behaviors and HIV-associated health outcomes in populations at high-risk for HIV, especially in geographic areas and populations where behavioral data are limited. These data are critical for tracking the epidemic, planning effective responses, and monitoring and evaluating those responses. The specific objectives are as follows: 1) Identify geographic areas with populations at increased risk of HIV infection. 2) Assess the size of populations at risk for HIV infection. 3) Assess the prevalence of HIV infection. 4) Assess the prevalence of STI infection or viral hepatitis (where appropriate, if funding is available). 5) Assess the prevalence of risk behaviors and social determinants of health that increase the risk of HIV acquisition and transmission, including sexual risk behaviors and drug-use risk behaviors. 6) Describe utilization of HIV testing, linkage to care, and antiretroviral therapy. 7) Assess the access to and use of prevention services, including SSPs and PrEP. 8) Identify gaps in prevention services and missed opportunities for prevention interventions.

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):

Yes

SDOH Economic Stability:

Yes

SDOH Education:

Yes

SDOH Health Care Access:

Yes

SDOH Neighborhood and Environment:

Yes

SDOH Social and Community Context:

Yes

SDOH Indices:

Not Selected

Other SDOH Topics:

Not Selected

Assessing Impact:

Not Selected

Methods to Improve Health Equity Research and Practice:

Yes

Other:

Not Selected

Activities or Tasks:

New Collection of Information, Data, or Biospecimens

Target Populations to be Included/Represented:

Other - Adults at high-risk for HIV in identified priority populations in specified geographic areas within

Tags/Keywords:

HIV ; bio-behavioral surveillance ; rapid assessments ; quantitative ; Qualitative Research ; mixed methods

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:

Focus Group; Individual Interviews (Qualitative); Prevalence (Cross-sectional) Surveys; Other - HIV Testing/collection of bio-specimens

Methods:

NHBS-BHBAs are brief mixed-methods bio-behavioral HIV assessments conducted in priority populations in specified geographic areas of interest (BHBA populations). The process includes 1) identification of geographic areas/populations at risk, 2) formative assessment for operations, 3) quantitative and qualitative data collection and HIV testing, and 4) data analysis and dissemination. State needs assessment activities include examining a comprehensive list of existing data sources to assess HIV prevention priorities and develop a process to prioritize at least two populations to conduct HBHAs for each year of data collection. Project staff will also establish community partnerships to support the project at the state and local levels. Project areas will conduct formative assessment for each BHBA to identify appropriate recruitment methods and develop operational procedures in the project area. Project areas will also garner the support of the local community and identify questions of local interest for HIV prevention. Formative assessment will precede data collection. NHBS-BHBAs will be conducted through mixed-methods quantitative and qualitative data collection. Project areas will implement recruitment strategies that may include venue based, time-space sampling (VBS), respondent-driven sampling (RDS), and other CDC-approved methods to recruit populations at high-risk for HIV infection. Project areas will conduct brief standardized quantitative interviews with eligible participants to meet the target sample size (n=500) total participants from at least two HBHAs per year in funding years 2-5. Project areas will offer usually anonymous HIV blood-based rapid testing and supplemental testing to those who participate in quantitative interviews to assess HIV seroprevalence. HIV screening results will be made available to participants, and those with preliminary positive test results will be linked to HIV care. Pending funding availability, HIV testing may include the collection of dried blood spot specimens for long term storage to conduct additional testing, e.g., testing for recent HIV infection, HIV viral load, presence of antiretroviral drugs or pre-exposure prophylaxis, or drug resistance. Other biological specimens may be collected and tested (e.g., viral hepatitis, sexually transmitted infections (STI)) when funds are available. NHBS-BHBA rapid qualitative data collection include at least two forms of primary data collections, including observations, key informant interviews with community members and professionals familiar with the population, focus groups and other activities to interpret standardized quantitative findings and inform grantee-developed recommendations for state /local public health partners. Small stipends or vouchers will be given to those interviewed and tested for HIV (approximately \$25 for each). In cycles using RDS, additional incentives (approximately \$10) are paid to those who successfully recruit others. Funded states will analyze and triangulate BHBA data to identify emerging key themes and recommendations and share preliminary findings with their core and local advisory group comprised of community organizations and institutions that serve populations at high-risk of HIV infection. They will develop a summary report for each BHBA with integrated findings from quantitative and qualitative data and recommendations for state/local partners to inform HIV treatment and prevention.

Participants will be 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 quantitative survey is administered by trained interviewers using computers; HIV testing is done by trained staff. Other tests (e.g., new HIV testing technologies, biological testing for STIs or hepatitis) may be performed in states that are funded to perform these activities. All participants will provide their informed consent to take part in the interview, HIV testing, and any additional testing. 500 eligible persons from each NHBS-BHBA funded state will be interviewed each year. The qualitative survey is administered by trained interviewers and a minimum of 20 participants per BHBA population is expected. All participants will be informed during the recruitment process of the anonymous nature of the data including the interview, HIV testing, and any additional testing offered. For participants# convenience or benefit, participants may have the option to provide contact information to project staff on a voluntary basis. Examples of participant convenience include but are not limited to: providing a phone number for phone text reminders of 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 participant benefit include but are not limited to: providing a phone number so that project staff can call participants when their HIV/additional test results are

Collection of Info, Data or Biospecimen:

ready; providing contact information to help participants with linkage to HIV care or other services they may need. In all cases, participants will be provided information and instructions for how to participate without providing contact information. This surveillance activity is funded through cooperative agreements with participating health departments. All data will be collected locally by grantees. No contact information will be sent to CDC. Project areas will keep contact information separately from all NHBS-BHBA 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-BHBA test result data, paper or electronic. In most cases, contact information will not be linkable to any NHBS-BHBA data. In rare circumstance, contact information may need to be indirectly linkable to limited NHBS-BHBA data, for example NHBS-BHBA project area 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 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-BHBA 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-BHBA files. Audio recordings of qualitative interviews and focus groups will be kept in a secure location that only authorized project staff can access and will be destroyed once the information is transcribed and checked. Audio files will not be submitted to CDC.

Dissemination of findings is critical to the success of the project and funded states should use the data to inform and improve local program efforts. Both quantitative and qualitative data should be analyzed, and findings, along with grantee-developed recommendations, should be disseminated to local partners with the support of the core and local advisory groups. Funded states will create a dissemination plan for each BHBA, including at least one data product or report and at least one presentation to community partners. Funded states will have principal responsibility for analyzing their local quantitative and qualitative data and developing tailored recommendations. NHBS-BHBA project areas and CDC may collaborate on articles and reports when appropriate. Funded states will contribute to national reporting of data collection outcomes such as surveillance reports and other publications by reviewing analysis notifications, concept proposals, table shells and manuscript drafts within specified timelines and participating in discussions during monthly conference calls and annual meetings. CDC may disseminate reports, e.g., CDC HIV Surveillance Special Reports and other CDC reports, the Morbidity and Mortality Weekly Report (MMWR), and peer-reviewed journals. CDC may also present results at national conferences and meetings.

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 #
Florida Department of Health					PS22-2201
Massachusetts Department of Public Health	FWA00000786	03/04/25			PS22-2201

Staff

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	12/27/2024		09/06/2021		Statistician		404-639-1956	BEHAVIORAL SURVEILLANCE TEAM
Catlainn Sionean	09/20/2024				Program Official		404-639-2	BEHAVIORAL SURVEILLANCE TEAM
Christine Agnew Brune	06/05/2023				Project Officer		404-718-5478	BEHAVIORAL SURVEILLANCE TEAM
Cyprian Wejnert	02/22/2025		02/07/2021		Program Lead		404-639-6055	BEHAVIORAL AND CLINICAL SURVEILLANCE BRANCH
Dita Broz	08/11/2023				Program Official		404-639-5258	BEHAVIORAL SURVEILLANCE TEAM
Ebony Symone Townsend	01/12/2024				Project Officer		404-498-4180	BEHAVIORAL SURVEILLANCE TEAM
	12/07				Project		404-718-	

Elana Morris	/2024				Officer	8193	BEHAVIORAL SURVEILLANCE TEAM
Janet Burnett	06/08 /2023		12/18/2018		Project Officer	404-639- 0086	BEHAVIORAL SURVEILLANCE TEAM
Jeffery Todd	02/28 /2023				Project Officer	404-718- 5389	BEHAVIORAL SURVEILLANCE TEAM
Johanna Chapin- Bardales	08/04 /2023				Statistician	404-718- 5879	BEHAVIORAL SURVEILLANCE TEAM
Kathryn Lee	08/10 /2023				Program Official	404-639- 6110	BEHAVIORAL SURVEILLANCE TEAM
Lyssa Faucher	06/08 /2024				Project Officer	404-718- 2086	BEHAVIORAL SURVEILLANCE TEAM
Paul Denning	08/11 /2023				Project Officer	404-639- 3	BEHAVIORAL SURVEILLANCE TEAM
Rashunda Lewis	03/20 /2023				Program Official	404-639- 2981	BEHAVIORAL SURVEILLANCE TEAM
Susan Cha	12/30 /2024		08/16/2019		Project Officer	404-718- 5486	BEHAVIORAL SURVEILLANCE TEAM
Taylor Robbins	06/14 /2023				Project Officer	404-639- 0016	BEHAVIORAL SURVEILLANCE TEAM
Teresa Finlayson	01/03 /2023				Program Official	404-639- 2083	BEHAVIORAL SURVEILLANCE TEAM

Data

DMP

Proposed Data Collection Start Date: 1/1/23
Proposed Data Collection End Date: 12/31/26
Proposed Public Access Level: Restricted

Restricted Details:

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
Current	Kanny_Dafna (dkk3) Project Contact	05/17/2022	NHSS Assurance packet, including a non-disclosure agreement and an agreement to abide by restrictions of data release	Non Disclosure Agreement	NHSS_FTE-Packet_FinJuly2020-508_compliant.pdf
Current	Kanny_Dafna (dkk3) Project Contact	05/17/2022	NCHHSTP_PRA Determination Form BHBA	Paperwork Reduction Act Form	NCHHSTP_PRA Determination Form BHBA_final.doc
Current	Kanny_Dafna (dkk3) Project Contact	05/17/2022	Model Qualitative FG Consent Form	Consent Form	Appendix G Model Qualitative FG Consent Form-final.docx
Current	Kanny_Dafna (dkk3) Project Contact	05/17/2022	Model Qualitative PKI Consent Form	Consent Form	Appendix E Model Qualitative PKI Consent Form-final.docx
Current	Kanny_Dafna (dkk3) Project Contact	05/17/2022	NHBS-BHBA Protocol	Protocol	Protocol_Full_20220517_STARS submit.docx
Current	Kanny_Dafna (dkk3) Project Contact	05/17/2022	Model Survey Consent Form	Consent Form	Appendix I Model Survey Consent Form-final.docx
Current	Kanny_Dafna (dkk3) Project Contact	05/17/2022	Model Qualitative CKI Consent Form	Consent Form	Appendix F Model Qualitative CKI Consent Form-final.docx
Current	Kanny_Dafna (dkk3) Project Contact	05/17/2022	NHBS Multi-site Data Sharing Guidance	Data Use Agreement	NHBS Multi-site Data Sharing Guidance 04122022.pdf

