



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

Print Date: 9/14/21

Title: National HIV Behavioral Surveillance among Transgender Women (NHBS-Trans)
Project Id: 0900f3eb81dafa47
Accession #: NCHHSTP-BST-8/25/21-afa47
Project Contact: Dafna Kanny
Organization: NCHHSTP/DHAP/BCSB/BST
Status: **Project In Progress**
Intended Use: **Project Determination**
Estimated Start Date: 01/01/2022
Estimated Completion Date: 12/31/2026
CDC/ATSDR HRPO/IRB Protocol #: N/A
OMB Control #: 0920-1262 Exp. 04/30/2022

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> | 8/30/21 | Dodson_Janella R. (jhd7) CIO HSC |
| PRA: PRA Applies | | 8/31/21 | Bonds_Constance (akj8) CTR OMB/PRA Coordinator |

| | | | |
|----------------------|--|---------|-------------------------------------|
| HRPO: Concur | | 9/13/21 | Bass_Micah (zgi7) HRPO Reviewer |
| ICRO: PRA Applies | OMB Approval date: 4/24/19 OMB Expiration date: 4/30/21 | 8/31/21 | Zirger_Jeffrey (wtj5) ICRO Reviewer |

Description & Funding

Description

Priority: Standard

Date Needed: 09/10/2021

Determination Start Date: 08/25/21

Description:

The purpose of this request is to amend the original project determination (PD) which was approved on 09/29/2017 before STARS and is being entered into STARS for the first time. This project was approved by OMB (#0920-1262; exp date 4/30/2022). The original PD received an HSR determination that the activity is surveillance and not human subject research. CDC does not require project sites to submit NHBS-Trans to their local IRB(s) for review and approval. Nevertheless, sites must still adhere to their local policies for human subjects protection. These policies may require sites to submit NHBS-Trans to their local IRB(s) for a research determination or for an expedited or full review. The primary intent of NHBS-Trans 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 among transgender (trans) women. NHBS-Trans is a combined qualitative and quantitative project wherein project areas conduct formative assessment activities before implementing the NHBS survey for trans women, with qualitative data collection activities including professional and community key informant interviews, focus groups, and quantitative data collection activities including a behavioral assessment survey and optional HIV testing made available to those who consent to the survey and testing. NHBS-Trans conducted its first data collection cycle in 2019-20, an important public health contribution as data on trans women in the US are limited. NHBS-Trans uses a culturally appropriate survey instrument specifically designed for capturing and assessing the needs and HIV risk behaviors of trans women. Ongoing behavioral surveillance among trans women is needed for HIV prevention program planning and evaluation at the national and local levels. The findings from NHBS-Trans 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-Trans test result is positive, can be used to target testing services and evaluate testing guidelines. NHBS-Trans will be conducted in up to 10 Metropolitan Statistical Areas (MSA) 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 ongoing bio-behavioral surveillance among trans women. This surveillance 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 trans women 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 among trans women in MSAs with high HIV prevalence. 2) To assess the exposure to and use of HIV prevention services among trans women. 3) To measure trends in HIV seroprevalence, HIV incidence, and the prevalence of other sexually transmitted infections (STIs) among trans women. 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 among trans women. 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?: Yes

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: Not Selected

Before starting quantitative data collection, project areas will engage in a period of formative research. Project areas will work with ethnographers and community-based organizations in their jurisdiction to conduct formative assessment. Within the context of NHBS-Trans, formative assessment allows project areas to gain insight into the context of HIV risk behavior within certain settings

Other: 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.

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

Target Populations to be Included/Represented: Female ; Transgender

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

Methods: The overall strategy for NHBS-Trans is to conduct surveillance among trans women who may be at high risk for HIV acquisition or transmission. Surveillance activities include formative assessment, a behavioral assessment survey, 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. Formative Assessment (Qualitative) Project areas will work with ethnographers and community-based organizations in their jurisdiction to conduct formative assessment. Within the context of NHBS-Trans, formative assessment allows project areas 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 interviews with professional and community key informants, garnering the support of community stakeholders, and development of questions that measure local prevention activities. Each NHBS-Trans site should follow local requirements regarding informed consent for focus groups and key informant interviews. Three model consent forms are provided (Appendices A, B, and C in NHBS-Trans Model Protocol_August 2021) and are only modified to meet local IRB requirements. To protect the anonymity of those interviewed, consent to participate shall only be provided verbally by participants and no data collection activities will be video- or audio-taped. Please refer to approved NHBS core project determination (project ID: 0900f3eb81bae32c, OMB Control # 0920-0770) for more details on formative assessment activities. Behavioral Assessment Survey (Quantitative) Respondent-driven sampling (RDS) starts with a limited number of #seeds,# who are 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. After confirming eligibility and obtaining informed consent (Appendix E_Model Consent Form Trans), participants are asked to complete an interviewer-administered survey lasting approximately 40 minutes. Also, after eligibility and consent, participants will be asked if they wish to receive HIV testing in conjunction with the survey, which they may refuse with no effect on participation in the survey. However, HIV testing is only available through NHBS-Trans to persons who respond to the survey. Persons who do not consent to participate in the survey will be directed to other HIV testing resources upon request.

The project#s target population is trans women within racial and ethnic minority populations. Eligibility for NHBS-Trans will be limited to trans women as assessed by the #two-step# approach measure of gender identity recommended by GenIUSS Group report: #Best Practices for Asking Questions to Identify Transgender and Other Gender Minority Respondents on Population-Based Surveys# (<http://williamsinstitute.law.ucla.edu/wp-content/uploads/geniuss-report-sep-2014.pdf>). To be eligible for the NHBS-Trans behavioral assessment survey, participants must report an assigned male sex at birth AND their gender as #woman# or #transgender woman.# Additionally, eligibility will be limited using the standard NHBS eligibility criteria (age ?18 years, resident of participating city, and ability to complete interview in English or Spanish). 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 portable computers; HIV

Collection of Info, Data or Biospecimen:

testing is done by trained staff. A minimum of 300 eligible persons from each site will be interviewed during NHBS-Trans. 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 and HIV 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. Please refer to approved NHBS core project determination (project ID: 0900f3eb81bae32c, OMB Control # 0920-0770) for more details on collection of contact information.

Expected Use of Findings/Results:

CDC will have principal responsibility for analyzing and disseminating multi-site survey data. CDC will also have principal responsibility for analyzing multi-site data on HIV prevalence. The CDC analyses will focus primarily on questions related to the objectives of this project described above (Objective). To examine the key behavioral outcomes, data will be weighted when possible to account for the complex sampling design. NHBS-Trans project areas are required to 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. Project areas are encouraged to establish Community Advisory Boards (CABs) or other organizations to transmit project findings to the community and stakeholders within the community. CDC will disseminate the information through: 1) DHAP surveillance reports, presentations, and publications and 2) providing assistance to project areas for their local dissemination efforts. NHBS-Trans collaborators will disseminate findings from project activities through presentations, reports, and publications to community, public health, and scientific partners at local and national levels.

| | |
|---|---------------------------------|
| 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? | No |
| Is this project covered by an Assurance of Confidentiality? | Yes |
| 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, <i>see supporting info</i> |

Funding

| Funding Type | Funding Title | Funding # | Original Budget Yr | # Years Award | Budget Amount |
|--------------|---------------|-----------|--------------------|---------------|---------------|
|--------------|---------------|-----------|--------------------|---------------|---------------|

| | | | | | |
|---------------------------|--|-------------------|------|---|------|
| CDC Cooperative Agreement | NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STDS AND TB PREVENTION National HIV Behavioral Surveillance (NHBS) | CDC-RFA-PS22-2201 | 2022 | 5 | 0.00 |
|---------------------------|--|-------------------|------|---|------|

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

Population - Minors

Population - Prisoners

Population - Pregnant Women

Population - Emancipated Minors

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

Institutions yet to be added

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 |
|------------------|----------------|---------------------------|------------------------------------|---------------------------------------|------------------------|--------------|--------------|---|
| Catlainn Sionean | 12/14 /2021 | | | | Program Official | ziq9@cdc.gov | 404-639-2 | BEHAVIORAL SURVEILLANCE TEAM |
| Cyprian Wejnert | 03/25 /2022 | | 02/07/2021 | | Principal Investigator | dwy7@cdc.gov | 404-639-6055 | BEHAVIORAL AND CLINICAL SURVEILLANCE BRANCH |
| Dafna Kanny | 04/26 /2024 | | 09/13/2021 | | Data Use Contact | dkk3@cdc.gov | 770-488-5411 | BEHAVIORAL SURVEILLANCE TEAM |
| Dita Broz | 08/11 /2023 | | | | Program Official | iga4@cdc.gov | 404-639-5258 | BEHAVIORAL SURVEILLANCE TEAM |
| Kathryn Lee | 08/10 /2023 | | | | Co-Investigator | hgi2@cdc.gov | 404-639-6110 | BEHAVIORAL SURVEILLANCE TEAM |
| Teresa Finlayson | 01/03 /2023 | | | | Statistician | taj4@cdc.gov | 404-639-2083 | BEHAVIORAL SURVEILLANCE TEAM |

Data

DMP

Proposed Data Collection Start Date: 1/1/22
Proposed Data Collection End Date: 12/31/23
Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement
Data Use Type URL: <https://www.cdc.gov/hiv/statistics/systems/nhbs/index.html>
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 is housed at CDC. 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-Trans data are described in the NHBS Multi-site Data Sharing Guidance document (Attached). The purpose of this guidance is to ensure that the data collected by NHBS are used and disseminated widely and that NHBS investigators can fairly participate in the process of publishing multi-site findings. In accordance with the Data Security and Confidentiality Guidelines, multi-site analysis of NHBS data may only be conducted on CDC premises. This current policy limits the ability of NHBS investigators outside of CDC to lead multi-site publications. This data sharing guidance outlines procedures for health departments to conduct NHBS multi-site data analyses off-CDC premises utilizing NHBS restricted use datasets.

Plans for Archival and Long Term Preservation:

Spatiality

| Country | State/Province | County/Region |
|---------------|----------------|---------------|
| United States | | |

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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