

National HIV Surveillance System (NHSS)

Attachment 9
Project Determination - NHSS



Project Determination

National HIV Surveillance System (NHSS)

Project ID: 0900f3eb82570df0
Accession #: NCHHSTP-HSB-5/13/25-70df0
Project Contact: Nikiya Woodard
Organization: NCHHSTP/OD/OADS
Status: Pending Clearance
Intended Use: Project Determination
Estimated Start Date: 01/01/81
Estimated Completion Date: 05/31/29
CDC/ATSDR HRPO/IRB Protocol#:
OMB Control#:
End of Human Research Date:

Description

Priority

Standard

CDC Priority Area for this Project

Other CDC Priority - Infection disease surveillance

Determination Start Date

05/13/25

Description

The National HIV Surveillance System (NHSS) is a non-research surveillance system that supports non-research initiatives and is subject to the Paperwork Reduction Act (PRA). Data collection is approved by OMB number 0920-0573. Since 1981, the Centers for Disease Control and Prevention (CDC) has maintained national surveillance, initially for acquired immunodeficiency syndrome (AIDS) and later incorporating reports of diagnoses of human immunodeficiency virus (HIV). After the development of HIV antibody testing in 1985, states began adopting laws and regulations for reporting of confirmed diagnoses of HIV infection

and reporting those data to CDC. In December 1999, CDC published guidelines recommending that all states implement HIV case reporting and by April 2008 all jurisdictions had fully implemented confidential reporting of HIV infection using the same name-based methods for reporting as is used for AIDS. Currently, all 50 states, the District of Columbia, and 6 territories and freely associated states (American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, the Republic of Palau and the U.S. Virgin Islands) report HIV and AIDS cases to CDC. Health department programs collect longitudinal data on individuals diagnosed with HIV through various sources, including laboratories, healthcare providers, patient interviews, medical chart reviews, public health clinics, and vital statistics registries. Health Departments are responsible for maintaining the confidentiality and security of this data while voluntarily reporting information to the CDC without direct personally identifiable information. Community concerns about the confidentiality of HIV case reports have led to increased efforts to enhance the security and confidentiality of HIV surveillance data including data from case investigations and related studies. Since 1984, when the first Assurance of Confidentiality was established under Section 308 (d) of the Public Health Service Act (42 U.S.C. 242m), revisions and extensions of the Assurance have sought to ensure ongoing confidentiality and protection. The Division of HIV Prevention within the CDC supports Health Departments through federal funding and technical guidance to enhance HIV surveillance efforts. This includes assistance with standardized case definitions and data management tools. Although reporting to the CDC is voluntary for Health Departments, this support ensures local health departments can effectively monitor trends in HIV infections. The collected data provides essential insights into HIV infection trends, prevention and care efforts, informs resource allocation decisions, and aids in outbreak detection at federal, state, and local levels.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission

No

IMS Activation Name

Not selected

Submitted through IMS clearance matrix

Not selected

Primary Scientific Priority

Not selected

Secondary Scientific Priority (s)

Not selected

Task Force Responsible

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

Goals/Purpose

The National HIV Surveillance System is the primary source for monitoring HIV trends in the United States. Data collected as part of the National HIV Surveillance System and surveillance-related data projects are used widely to monitor patterns of HIV infection and infection with other infectious disease pathogens (e.g. sexually transmitted infections, hepatitis viruses), detect and respond to HIV transmission clusters, identify individuals in need of engagement of or re-engagement to care, describe behaviors and clinical outcomes of persons with HIV or at risk for HIV, and target HIV prevention and care efforts. HIV surveillance including adults/adolescent and pediatric case reports of persons diagnosed with HIV infection, together with behavioral, clinical and laboratory data provide information on the spectrum of HIV disease. HIV surveillance data including laboratory data on drug resistance and HIV-1 subtypes provide population-based data used to determine trends in transmission of drug resistance and the geographic distribution of subtypes in the U.S. HIV nucleotide sequence data are used for identifying recent and ongoing HIV transmission clusters to better focus prevention efforts. Surveillance data are also used to identify unusual or special cases requiring additional follow-up and to assess attributes of the performance of the surveillance system such as reporting completeness, timeliness, accuracy and validity. Supplemental data are also collected through related projects that extend and enhance the HIV case report data.

Objective

The main objectives are to: 1. Conduct HIV surveillance data collections and reporting; 2. Maintain surveillance data systems and conduct data management activities 3. Conduct HIV surveillance data analysis, dissemination and evaluation 4. Support HIV data for public health action 5. Maintain security and confidentiality of the HIV surveillance data.

Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?

Yes

Does your project investigate underlying contributors to health inequities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?

Yes

Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?

Yes

Activities or Tasks

Secondary Data or Specimen Analysis

Target Population to be Included/Represented

General US Population; Children; Pregnant Women; Prisoners; American Indian or Alaska Native; Asian; Black or African American; Hispanic or Latino; Native Hawaiian or Other Pacific Islander; White; Female; Male; Adult 18-24 years; Older adults > 64 years; Emancipated Minors; Farmers; Healthcare Provider; Impaired hearing or deaf; Impaired mental; Impaired physical; International; Immigrants or Refugees; Patient-

Tags/Keywords

HIV; Surveillance; Pre-Exposure Prophylaxis; Disease Transmission, Infectious; Cluster Analysis

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; CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens; CDC employees will provide substantial technical assistance or oversight; CDC provides technical assistance but does not specifically request or approve study design or data collection

Method Categories

Other - Technical guidance, program Implementation and evaluation

Methods

Data collection and reporting approaches include :

- Collect HIV surveillance data for all people with diagnosed HIV infection using active and passive surveillance methods
- Implement and maintain activities to ensure complete case and laboratory reporting using electronic methods
- Conduct death ascertainment activities to identify deaths among all people with HIV and HIV-related causes of death
- Conduct risk factor ascertainment for all cases of HIV infection, including prevalent cases
- Maintain date and place of residence of all people with diagnosed HIV infection
- Leverage available geocoding tools and geocode to the census tract level places of residence for persons with HIV infection diagnosed during the specified period and persons living with diagnosed HIV infection
- Conduct case surveillance activities for pregnant and post-partum persons with diagnosed HIV infection and their infants
- Conduct annual matching of people with diagnosed HIV reported to surveillance with the state birth registry and tribal birth registry and report to CDC. Incorporate a match process with syphilis surveillance. Maintain data systems and conduct data management activities include:
- Transfer HIV surveillance data to CDC and process acknowledgement in required format by required deadlines, this includes census tract information.
- Integrate HIV data sources and other relevant data sources and enhance data linkage capacity to ensure completeness and improve usability of data
- Use CDC recommended tools and systems (e.g., Soundex Match Application, Secure Data Sharing Tool to support de-duplication of cases), conduct intrastate de-duplication, routine interstate duplicate review (RIDR) and cumulative interstate duplicate review (CIDR) identification and resolution for all cases reported.
- Leverage existing electronic laboratory reporting (ELR) and electronic case reporting (eCR) infrastructure and processes to reduce duplication and manual efforts.
- Work towards a more flexible, efficient, and automated approach to exchanging data between electronic health records (EHRs) and public health, with a goal of automating data extraction for use in HIV surveillance. Conduct Data Analysis, Dissemination and Evaluation activities include:
- Develop annual HIV surveillance reports and a jurisdictional Epidemiologic Profile to inform program planning, implementation, and improvement
- Routinely assess and improve data quality and conduct annual evaluation of the HIV surveillance system to assess progress towards meeting the outcome and process standards. Support Data for Action and Special Activities include:
- Routinely analyze HIV surveillance data for public health action.
- Investigate cases of public health importance (COPHI).
- Identify people who are presumptively not in care and relink those truly out of care to HIV medical care and other needed services.
- Strengthen identification and investigation of acute/early HIV infection.
- Conduct molecular, time-space, and other relevant analysis to detect clusters for further prioritization, investigation, and response.

Collection of Info, Data, or Bio specimens

The HIV surveillance data will be collected, reported, analyzed, disseminated and evaluated in an accurate and timely manner per Technical Guidance for the HIV Surveillance Programs. CDC provides financial support, technical consultation, system platforms and analytic tools to state and local health departments for HIV surveillance activities. These activities include designing, implementing, maintaining, and evaluating HIV surveillance programs at the state and local levels as well as investigating unusual reports and clusters of HIV transmission, conducting surveillance-related activities that characterize behaviors and clinical outcomes among HIV-infected persons and behaviors among persons at risk for HIV infection in accordance with CDC guidelines and recommendations. More details on data collection activities are listed on the previous page under "Methods". The estimated burden for these data collection efforts for NHSS activities is approximately 1,035,569 responses representing 60,731hrs. All data collection activities are listed in the previous section. The information will be collected from persons living

with HIV. Any personally identifiable information collected to carryout necessary activities will not be transmitted ot the CDC and will stay with jurisdiction collecting the data.

Expected Use of Findings/Results and their impact

Data collected as part of the National HIV Surveillance System and surveillance-related data projects are used widely to monitor patterns of HIV infection and infection with other infectious disease pathogens (e.g. sexually transmitted infections, hepatitis viruses), detect and respond to HIV transmission clusters, identify individuals in need of engagement of or re-engagement to care, describe behaviors and clinical outcomes of persons with HIV or at risk for HIV, and target HIV prevention and care efforts. HIV surveillance including adults/adolescent and pediatric case reports of persons diagnosed with HIV infection, together with behavioral, clinical and laboratory data provide information on the spectrum of HIV disease. HIV surveillance data including laboratory data on drug resistance and HIV-1 subtypes provide population-based data used to determine trends in transmission of drug resistance and the geographic distribution of subtypes in the U.S. HIV surveillance data in aggregate form is made available through publication of surveillance and supplemental surveillance reports, at national as well as jurisdictional levels. The data are also available via the NCHHSTP Atlas+

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)?

Yes

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

Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award	Budget Amount
CDC Cooperative Agreement	High-Impact HIV Prevention and Surveillance Programs for Health Departments	PS24-0047	2024	5	240358385.00
CDC Cooperative Agreement	Accelerating the Prevention and Control of HIV in the U.S. Affiliated Pacific Islands	PS23-2302	2023	5	608965.00
CDC Contract	EHARS maintenance and operations	200-2020-F-08494	2020	5	95113840.00
CDC Grant	Privacy Data Sharing Tool to Support De-duplication of Cases in the National HIV Surveillance System	PS24-0121	2024	5	2350000.00

HSC Review

Regulation and Policy

Do you anticipate this project will require review by a CDC IRB or HRPO?

No

Will you be working with an outside Organization or Institution? No

Institutions

Institution	FWA #	FWA Exp. Date	Funding	Funding Restriction Amount
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Institution	Funding Restriction Percentage	Funding Restriction Reason	Funding Restriction has been lifted
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Institution	Institution Role(s)	Institution Project Title	Institution Project Tracking #	Prime Institution
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Institution	Regulatory Coverage	IRB Review Status
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Institution	Registered IRB	IRB Registration Exp. Date	IRB Approval Status
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Institution	IRB Approval Date	IRB Approval Exp. Date	Relying Institution IRB
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Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Citi Good Laboratory Practice Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
Angela Hernandez	05/01/2027					Program Official	awh4@cdc.gov	404-639-8969	HIV SURVEILLANCE BRANCH

DMP

Proposed Data Collection Start Date	08/01/24
Proposed Data Collection End Date	05/31/29
Proposed Public Access Level	Public
Public Access justification	The data reported to CDC cannot be released to public in line listed form. This and other restrictions are imposed and governed by the assurance of confidentiality, and data use agreements between CDC and the jurisdictions. Data in aggregate form is available publicly, as described in sections below.
How Access Will Be Provided for Data	Data is released in compliance with data rerelease agreements with Health Departments. HIV surveillance data are publicly available in the NCHHSTP Atlas Plus available at https://www.cdc.gov/nchhstp/about/atlasplus.html . Data in the Atlas are provided in aggregate forms and available at the national, state, region, MSA and county level.in aggregate form and at national level can be released to public. Data at the sub-national level are made available publicly, to the extent allowed by data re-release agreements. Public use data is freely available and is not copyrighted. The data are made available routinely via publication of HIV surveillance reports, supplemental surveillance reports and the NCHHSTP Atlas+ (an online tool for data dissemination).
Plans for archival and long-term preservation of the data	Currently, HIV surveillance data collected from health departments are stored in a cumulative database at CDC and stored securely with limited access and retained according to HIV Surveillance Branch policies. Data are stored at: (https://www.cdc.gov/hiv-data/)and also a link to the ATLAS+

(<https://www.cdc.gov/nchhstp/about/atlasplus.html>). Health departments collecting surveillance data also collect cumulative data and follow local storage and retention policies in accordance with NCHHSTP Data Security and Confidentiality Guidelines. HIV prevention program monitoring and evaluation data collected from health departments are also stored in a cumulative database at CDC and stored securely with limited access and retained according to Translation and Evaluation Branch policies.

Spatiality (Geographic Location)

Country	State/Province	County/Region
United States		

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>	05/19/25	Dodson_Janella R. (jhd7) CIO HSC
PRA: PRA Applies		05/20/25	Cody_Aisha (xvt3) CTR OMB/PRA Coordinator