



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

Print Date: 1/17/24

Title: OD2A-Local Component C - Linkage to and Retention in Care Surveillance

Project Id: 0900f3eb8222fe30

Accession #: NCIPC-ESB-9/18/23-199cc

Project Contact: Seung Hee Lee

Organization: NCIPC/DOP/ESB

Status: Pending Regulatory Clearance

Intended Use: Project Determination

Estimated Start Date: 09/01/2023

Estimated Completion Date: 08/31/2028

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(l)(2)</i>	10/2/23	Duncan_Elizabeth (slz5) CIO HSC
PRA: PRA Applies		10/2/23	Angel_Karen C. (idy6) OMB / PRA

Description & Funding

Description

Priority: Standard

Date Needed: 10/12/2023

Determination Start Date: 10/02/23

Description: Twelve local health departments funded through the OD2A: LOCAL (Overdose Data to Action: Limiting Overdose through Collaborative Actions in Localities) cooperative agreement have also been funded to implement a surveillance system to collect standardized indicators on linkage to and retention in care surveillance. Recipients will submit aggregate data to CDC every 6 months beginning December 2024.

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

Goals/Purpose Monitor linkage to and retention in care among individuals with opioid use disorder and/or stimulant use disorder in a subset of county/local health departments funded through OD2A: LOCAL. This goal will be accomplished by standardizing methods and indicators used by local health departments to collect data on linkage to and retention in care for substance use disorder (SUD). This is a formative project among 12 funded county/local health departments. Lessons learned will be used to expand the program into a more comprehensive surveillance system in the future, potentially expanding to states. The project will also provide actionable data that localities can use to plan prevention activities. Funded health departments will collect standardized indicators of linkage to care for SUD and submit aggregate data to CDC on a 6-month basis via Partner#s Portal. There will be a 12-month planning period (Sept 2023 # Aug 2024). Funded jurisdictions begin submitting data to CDC on September 2024. This project will be PRA applicable, and we are in the process of developing an ICR.

Objective: Component C funds 12 local health departments to track the extent to which individuals misusing drugs or with substance use disorder are linked to evidence-based treatment, harm reduction services, and supports through the Cascade of Care (CoC) for Opioid Use Disorder and/or Stimulant Use Disorder. Program success hinges on generating actionable data that jurisdictions can leverage to enhance and fine-tune their linkage to and retention in care programs. Component C will also foster a robust foundation for deriving insights into disparities, unmet needs, and optimal practices across the CoC. Finally, data must be shared with CDC to inform and enhance regional and national linkage to care efforts.

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:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	General US Population ; Prisoners ; American Indian or Alaska Native ; Asian ; Black or African American ; Hispanic or Latino ; Native Hawaiian or Other Pacific Islander - Persons with an opioid use disorder or stimulant use disorder ; White ; Female ; Male ; Adult 18-24 years ; Older adults > 64 years ; Patient ; Other - Persons with an opioid use disorder or stimulant use disorder
Tags/Keywords:	Linkage to care ; Drug Overdose ; health disparities ; Retention in care
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 will provide substantial technical assistance or oversight ; CDC is providing funding
Method Categories:	Surveillance Support
Methods:	CDC will provide TA on how to create a surveillance system for collection of standardized data for Linkage to and Retention in Care strategy.
Collection of Info, Data or Biospecimen:	Twelve local health departments were funded by CDC in September 2023 to collect programmatic data on linkage to care among individuals with SUD identified via key entry points to care and leverage other existing data sources. Funded health departments will use the OD2A: LOCAL Linkage to Care Data Submission Template, an Excel data template, to collect standardized indicators of linkage to care for opioid and stimulant use disorders and aggregate data will be submitted to CDC on a 6-month basis via Partner#s Portal. A Privacy Impact Assessment was already done on the system. Some indicators will be required, and some will be optional.
Expected Use of Findings/Results and their impact:	CDC plans to disseminate results widely and publicly. In coordination with funded jurisdictions, CDC may share analyses and results to highlight progress in establishing standardized linkage to care surveillance. Data will be used by CDC and jurisdictions to enhance and fine-tune linkage to and retention in care programs and also provide insights in disparities, unmet needs, and optimal practices across the Continuum of Care for opioid and stimulant use disorders.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	No
Is this project covered by an Assurance of Confidentiality?	No
Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No

Is there a formal written agreement prohibiting the release of identifiers? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Overdose Data to Action Limiting Overdose through Collaborative Actions in Localities (OD2A LOCAL)	CDC-RFA-CE-23-0003	2023	5	

HSC Review

HSC Attributes

Other - Public Health Surveillance with local health authorities. Yes

Additional Ethical Considerations

New collection of data and potential access to identifiers are both OK under public health surveillance. The public health surveillance exclusion is for the collection/use of information and/or biospecimens to improve public health /inform public health action. It must be conducted, supported, requested, ordered, required or authorized by a public health authority, and it must be limited to activities necessary to allow a public health authority to identify, monitor, asses, or investigates potential public health signals, onsets of disease outbreaks, or conditions of public health importance.

Regulation and Policy

Do you anticipate this project will need IRB review by the CDC IRB, NIOSH IRB, or through reliance on an external IRB?

No

Estimated number of study participants

Population - Children

N/A

Protocol Page #:

Population - Minors

N/A

Protocol Page #:

Population - Prisoners

N/A

Protocol Page #:

Population - Pregnant Women

N/A

Protocol Page #:

Population - Emancipated Minors

N/A

Protocol Page #:

Suggested level of risk to subjects

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

Requested consent process waviers

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

Will you be working with an outside Organization or Institution? Yes

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
Emily Neusel Ussery	03/29/2026		10/29/2024		Program Lead	yzv4@cdc.gov	770-488-3766	EPIDEMIOLOGY AND SURVEILLANCE BRANCH
Sarah Konefal	08/22/2026				Program Lead	urt2@cdc.gov	- -	OVERDOSE MORBIDITY TEAM
Seung Hee Lee	06/20/2026				Program Lead	xde5@cdc.gov	770-488-6020	EPIDEMIOLOGY AND SURVEILLANCE BRANCH

Data

DMP

Proposed Data Collection Start Date: 9/1/24

Proposed Data Collection End Date: 8/31/28

Proposed Public Access Level: Public

Public Access Justification: CDC recognizes the critical importance of maintaining standards of data quality, upholding individual and institutional privacy and confidentiality, and ensuring impartiality in the sharing of public health data. CDC stores all data received by recipients in an access-controlled share folder, which resides on the CDC Network. The CDC Network follows all National Institute of Standards and Technology (NIST) requirements for data security.

How Access Will Be Provided for Data: OThe current plan is to publicly share aggregate data on standardized indicators that are validated during the planning year (9/2023 # 8/2024) and during the first year of data collection (9/2024 # 8/2025). These indicators will be shared in a #Downloadable CSV files from a CDC website#. Data may only be shared at the US regional level due to the sensitivity of the data. This plan will be revised on 9/2024 after the planning year.

Plans for Archival and Long Term Preservation: The data collected for Linkage to and Retention in Care (LTC) Surveillance will be handled and stored in compliance with the Federal Records Act. This ensures that all data, records, and related documentation will be appropriately archived and preserved for the required retention periods in accordance with federal regulations and guidelines.

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...									

Supporting Info

No Supporting Info



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