# Request for Approval Under the Generic Clearance for Public Health/Public Safety Strategies to Reduce Drug Overdose Data Collection "PH/PS Strategies"

(OMB#: 0920-1419)

# **PH/PS Strategies Investigation Protocol Template**

# Request Title: Overdose prevention strategies for individuals experiencing homelessness

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## INTRODUCTION

Describe the need and circumstances of the PH/PS Strategies investigation.

Individuals who use drugs and experience homelessness are at heightened risk of overdose (Yamamoto et al. 2019; van Draanen et al. 2020; Austin et al. 2021; Barocas et al. 2023; Cano & Oh 2023). They are also dying of overdose at higher rates than in previous years. In Boston, for example, the overdose mortality rate among people experiencing homelessness more than doubled between 2004 and 2018 (Fine et al. 2022). In Los Angeles, overdose mortality among people experiencing homelessness increased suddenly from 2016 to 2019, making overdose the leading cause of death among this group in Los Angeles County in 2017 (Nicholas et al. 2021). As these data suggest, evidence-based approaches to preventing overdose, such as medications for opioid use disorder (MOUD) and naloxone distribution, are not reaching this population effectively. While emergent, more tailored services, such as low-threshold MOUD and distributing naloxone in homeless encampments and other housing settings, hold promise, little is known about their availability outside of large cities, how they operate, or how well they achieve

their goals (Bardwell et al. 2017; McLaughlin et al. 2021; Miler et al. 2021). How these services are experienced by people experiencing homelessness and perceived by law enforcement, who often have high contact with this population and can play a role in supporting overdose prevention, is also poorly understood.

The High Intensity Drug Trafficking Areas (HIDTA) program seeks CDC assistance to help the Overdose Response Strategy (ORS) with a rapid assessment to address these knowledge gaps (Attachment A). The goal of the rapid assessment is to understand how homelessness contributes to overdose risk, how overdose prevention strategies can be tailored to meet the unique needs of individuals experiencing homelessness, and how law enforcement can be equipped to better support prevention efforts. The specific strategies to be examined may include, but are not limited to: low-threshold MOUD (e.g., including mobile units and bridge clinics); co-located SUD treatment (i.e., integrated into shelters and syringe service programs); overdose prevention (e.g., naloxone distribution, drug-checking, response plans, response buttons, overdose detection sensors, harm reduction trainings, treatment referrals, peer-witnessed supervised injection) in different housing settings (e.g., encampments, shelters, hotels, motels, supportive housing) or places where individuals who experience homelessness frequent (e.g., food pantries, libraries); and housing first models. The ORS will use the findings to make actionable recommendations for improving and scaling up overdose prevention services tailored to people experiencing homelessness and enlisting law enforcement in overdose prevention efforts.

This request for OMB approval is for CDC to respond to this request. The ORS is comprised of Public Health Analysts (PHAs) and Drug Intelligence Officers (DIOs) located in all U.S. states and territories. These staff positions support public health-public safety collaborations at local, state, federal, and tribal levels to help reduce overdose through data sharing, information dissemination, and promotion of overdose prevention strategies involving public health and public safety.

Specify which circumstances justify the PH/PS Strategies investigation:

- Increased overdoses (e.g., increase in number of nonfatal or fatal overdoses or accelerating trends) among justice-involved populations, specifically people experiencing homelessness.
- Emergence of a new overdose prevention or response strategy or expansion of an existing PH/PS strategy, specifically overdose prevention strategies for people experiencing homelessness
- Indication that existing strategies (e.g., MOUD and naloxone distribution) are not reaching all populations equitably

# PURPOSE

Describe the objectives of the investigation, specify the state or local authority(ies) that requested the response and the type of CDC technical assistance requested. Describe the strategy(ies) to be investigated. Include and reference the letter of invitation

Objective 1: Describe and qualitatively examine firsthand accounts of overdose and experiences using overdose prevention services among people experiencing homelessness;

Objective 2: Identify and describe overdose prevention services tailored to people experiencing homelessness, including barriers, facilitators, and use of innovative and best practices; and,

Objective 3: Assess the ability and readiness of law enforcement to help reduce overdose risk among people experiencing homelessness.

The High Intensity Drug Trafficking Areas (HIDTA) program is requesting CDC assistance with the rapid assessment (Attachment A). HIDTA is requesting that CDC assist with finalizing study objectives and developing data collection tools. CDC will obtain anonymous data for data analysis and the development of resources and tools in consultation with the ORS.

# METHODS

Describe the proposed data collection methods.

This is an exempt human research study; the protocol has been reviewed and approved by CDC IRB. A copy of the approval letter is provided (Attachment B). All persons working on the project will be required to protect confidentiality as stipulated in HHS regulations for the protection of human subjects in research (45 CFR 46), the Common Rule (45 CFR 46 Subpart A). Data will be kept private to the extend allow by law.

The CDC Office of the Chief Information Officer has determined that the Privacy Act does not apply, the Privacy Determination for this evaluation is attached (Attachment C). The study received a Certificate of Confidentiality (COC), the COC protects the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations. COCs are now automatically issued by HHS agencies to HHS funded projects to protect identifiable research information from forced disclosure.

To meet the objectives, the ORS will conduct primary data collection using in-person focus groups, semistructured interviews, and an online survey:

- 5 in-person focus groups with people experiencing homelessness who have a history of overdose (8-10 individuals per focus group)
- 60 in-person or virtual semi-structured interviews with providers of overdose prevention services for people experiencing homelessness
- 300 online surveys with law enforcement officials who work in counties with high rates of homelessness

Below, we describe each data collection method and discuss the use of the information collected.

#### Focus groups with people experiencing homelessness who have a history of overdose

The ORS will hold 5 in-person focus groups with people experiencing homelessness who have a history of overdose. Each focus group will include 10 participants. Each discussion will last approximately 90 minutes and be audio-recorded and transcribed. Focus groups will be facilitated by ORS PHAs following a focus group guide (Attachment D). DIOs will not facilitate focus groups (unless at the request of the host

organization) because their affiliation with law enforcement may cause unease among focus group participants or serve as a deterrent to participation.

## <u>Semi-structured interviews with providers of overdose prevention services for people experiencing</u> <u>homelessness.</u>

The ORS will conduct a total of 60 virtual or in-person interviews with providers of overdose prevention services for people experiencing homelessness. Examples of services include, but are not limited to: low-threshold MOUD (e.g., including mobile units and bridge clinics); co-located SUD treatment (i.e., integrated into shelters and syringe service programs); overdose prevention (e.g., naloxone, drug-checking, response plans, overdose detection sensors, overdose response buttons, harm reduction trainings, treatment referrals, peer-witnessed supervised injection) in different housing settings (encampments, shelters, hotels, motels, supportive housing) or places where individuals who experience homelessness frequent (e.g., food pantries, libraries). Each interview will last 90 minutes and be audio-recorded and transcribed. Interviews will be jointly conducted by ORS PHAs and DIOs following an interview guide (Attachment E).

#### Online survey with law enforcement

The ORS will disseminate an email with a link to an online survey to 1,000 law enforcement officials with an anticipated response rate of 30%. The survey (Attachment F & F1) will take approximately 10 minutes to complete. The survey link will be disseminated by police chiefs. ORS DIOs will conduct outreach to up to 175 police chiefs (2-3 police chiefs per DIO) to request assistance with survey dissemination.

All procedures have been developed, in accordance with federal, state, and local guidelines, to ensure that the rights and privacy of respondents will be protected and maintained.

## Types of participants:

The data collection activities will focus on three study populations:

- Adults (aged 18 and older) experiencing homelessness who have a history of overdose
- Providers of overdose prevention services for people experiencing homelessness
- Law enforcement officials working in counties that have high rates homelessness

#### Summary of Study Populations for Proposed Information Collection

Table 1 (below) summarizes, by data collection activity, the study populations and targeted respondents. No statistical sampling method will be used.

Data Collection Activity	Study Populations	Targeted Respondents
In-person focus groups	Adults (aged 18 and older) experiencing homelessness who have a history of overdose	50 individuals
Virtual or in-person semi- structured interviews	Providers of overdose prevention services for people experiencing homelessness	60 individuals
Online survey	Law enforcement officials working in counties that have high rates homelessness	300 individuals

## Data collection procedures:

No statistical methods will be used to draw the sample for the focus groups, interviews, or surveys. Procedures for the data collection are described below.

#### **Focus Groups**

Focus group discussions will take place at the harm reduction organizations, such as syringe service programs, that will be identified to assist with recruitment. On the day of the focus groups, all participants will ask for their consent prior to engaging in the discussion; the consent will be read aloud and is part of the focus group guide (Attachment D). The consent section provides an overview of the project; it clearly notes that participation is voluntary and participants can discontinue their participation at any time; it informs participants that the discussion will be recorded with their consent; it explains how the team will keep their information confidential (i.e., there will be no link between names and comments, participants will be asked to not share what is discussed). Each participant will be recorded. The focus group facilitator (e.g., the ORS PHA) will then ask the questions outlined in the Focus Group Guide. Harm reduction staff will be present during focus group discussions to provide direct guidance in addressing any situation in which a participant becomes distressed. Harm reduction staff will also be asked to review the focus group guide in advance and suggest any changes to the wording of questions may change, the content of the focus group guide will not.

Only verbal consent will be collected for the focus groups because this study is low risk and because a signed consent form would be the only record linking back to the participant's identity.

#### In-person or virtual semi-structured interviews

Semi-structured interviews will take place virtually via a video conference platform (e.g., Zoom) or at a facility in the community that the ORS team has previously identified and secured. On the day of the focus groups, all participants will ask for their consent prior to engaging in the discussion; the consent will be read aloud and is part of the Semi-structured Interview Guide (Attachment E). The consent section provides an overview of the project; it clearly notes that participants is voluntary and participants can discontinue their participation at any time; it informs participants that the discussion

will be recorded with their consent; it explains how the team will keep their information confidential (i.e., there will be no link between names and comments, participants will be asked to not share what is discussed). Each participant will be asked to verbally confirm their understanding and consent to participate. That confirmation will be recorded. The interviewers (e.g., ORS team) will then ask the questions in the Semi-structured Interview Guide.

Only verbal consent will be collected for the interviews because this study is low risk and because a signed consent form would be the only record linking back to the participant's identity.

#### Surveys

Survey invitations (Attachment G) will be sent by email to law enforcement officials by the police chiefs that will be identified to assist with recruitment. The body of the email will include a summary of the project, an invitation to participate, and a survey link. Once opened, the survey link will display the consent form, which respondents will be asked to read and check a box indicating that they agree or do not agree to participate. The consent form will be available for download. The consent form provides an overview of the project and what participants will be asked to do; it clearly notes participation is voluntary and participants can discontinue their participation at any time; it informs participants that the survey will take up to 10 minutes to complete; it explains how the team will keep their information confidential (i.e., there will be no link between names and comments). The consent form also explains how information collected during the conversation might be used in the future. Only those individuals that check the "I agree" option on the consent form will advance to the survey questions (Attachment F & F1).

## Variables and measures to be collected:

The 90-minute focus group discussions will collect information about:

- Personal or witnessed overdose events among people experiencing homelessness
- Perspectives on how homelessness, including laws, policies, and law enforcement actions that seek to address homelessness, may contribute to overdose risk or serve as a barrier to effective overdose response
- How individuals and communities practice overdose prevention for themselves and each other
- Experiences with or perceptions of overdose prevention services, including those specifically tailored to people experiencing homelessness
- Recommendations for improving overdose prevention services
- Interactions with law enforcement, including experiences with or perceptions of encampment sweeps and other quality-of-life ordinances
- Recommendations for what roles public safety should play when engaging with people experiencing homelessness how have a history of overdose.

The 90-minute semi-structured interviews will collect information about:

- Implementing the strategy
- Barriers, facilitators, challenges, and successes associated with implementation
- Innovative and best practices for addressing circumstances surrounding homelessness that may contribute to overdose risk or serve as barriers to accessing treatment and services
- Recommendations for improving the strategy
- Current or planned partnerships with law enforcement and other referring providers to increase access to the strategy

- Perspectives on how law enforcement actions in response to homelessness may contribute to overdose risk or barriers to effective overdose response
- Perspectives on how law enforcement can help promote overdose prevention among people experiencing homelessness

Prior to the interview, interviewers will ask participants a few short questions to capture programmatic details listed below. These questions will not be a separate form and they will not be shared in advance:

- Location
- Type of overdose prevention service provided
- Population of focus (e.g., people who use drugs, people who experience homelessness)
- Number of individuals reached by overdose prevention service
- Percentage of organization's target population that is experiencing homelessness

The ten-minute survey will collect information about:

- Frequency with which law enforcement interact with people experiencing homelessness who use drugs
- Departmental policies and services regarding people experiencing homelessness who use drugs
- Knowledge of how homelessness, including laws, policies, and law enforcement actions that seek to address homelessness, may contribute to overdose risk or serve as a barrier to effective overdose response
- Perspectives on the usefulness of encampment sweeps and other quality of life ordinances.
- Degree to which law enforcement feel prepared to respond to treatment and social service needs of people experiencing homelessness who use drugs
- Attitudes toward people experiencing homelessness who use drugs
- Knowledge of and attitudes toward overdose prevention services that are tailored to people who experience homelessness. Examples of services include, but are not limited to: low-threshold medications for opioid use disorder (e.g., including mobile units and bridge clinics); co-located SUD treatment (i.e., integrated into shelters and syringe service programs); overdose prevention (e.g., naloxone, drug-checking, response plans, overdose detection sensors, overdose response buttons, harm reduction trainings, treatment referrals, peer-witnessed supervised injection) in different housing settings (encampments, shelters, hotels, motels, supportive housing) or places where individuals who experience homelessness frequent (e.g., food pantries, libraries).
- Ability and readiness to help people experiencing homelessness reduce overdose risk, for example, by minimizing law enforcement actions that could exacerbate risk, linking individuals to tailored overdose prevention services, or other means.
  - 0 Degree to which patrol officers already engage in these activities.

# Anticipated burden hours (see table below): 286

# Data analysis plan:

For the focus group and interview data, separate codebooks will be developed. The codebooks will include topical codes based on the guides and interpretive codes based on a preliminary review of the data. Two analysists will conduct coding. They will both code one focus group transcript and two

interview transcripts and review the coding line-by-line to compare how codes are applied. The codebooks will then be refined to ensure codes are applied in the same way across analysts and to incorporate newly identified themes. Once the codebooks are finalized, each analyst will code the reminder of the transcripts independently. Relevant codes will be summarized to identify patterns, themes, and anomalies that inform objectives 1 and 2. For the survey data, descriptive analysis will be conducted to examine the range, mean, median, and mode of each continuous variable and the range and frequency distribution of discrete variables. Bivariable analysis will be conducted to analyze relationships between variables to inform objective 3.

# RESULTS

Describe how results will be synthesized and reported to the requesting state or local health authority. Describe how results will be used.

The findings from this study will be used to support the following outcomes:

- 1. Increased and improved implementation of overdose prevention services tailored to people experiencing homelessness;
- 2. Improved ability and readiness of law enforcement to support overdose prevention for people experiencing homelessness;
- 3. Increased understanding of the role of homelessness, including quality-of-life ordinances, in overdose risk; and,
- 4. Increased awareness among public health and public safety audiences of the intersection between overdose risk and homelessness

CDC will share the findings through a report back to the ORS for local internal use and broader dissemination with ORS approval. We anticipate findings to be shared in conference abstracts and to be published in peer-reviewed journals. CDC will not publish or present the data without prior ORS approval.

# **BURDEN ESTIMATE**

						Total Burden
Data Collection Instrument Name	Type of Participant	Data Collection Mode	No. Respondents (A)	No. Responses per Participant (B)	Burden per Response in Hours (C)	in Hours (A x B x C)
Focus group (Att. D)	People experiencing homelessnes s who have a history of overdose	Focus group	50	1	1 30/60	75

Semi- structured interview (Att. E)	Providers of overdose prevention services for people experiencing homelessnes s	Semi- structured interview	52	1	1 30/60	78
Survey (Att. F)	Law enforcement	Survey	300	1	10/60	50
Email Invitation (Att. G)	Law enforcement	Email	1000	1	5/60	83
					Total	286

## **INVESTIGATIVE TEAM**

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