SUPPORTING STATEMENT: PART A

Drug Overdose Response Investigation (DORI) Data Collection

OMB# 0920-1054

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Drug Overdose Response Investigations (DORI) Data Collections

A. Justification

Summary Table

- Goal of the study: Revision of OMB control number 0920–1054. The goal of Drug Overdose Response Investigations (DORI) is to collect data in response to an urgent request from a state or local public agency to inform responses to control a local drug overdose epidemic. When a data collection meets criteria for review and approval under the Paperwork Reduction Act, approval will be sought for the data collection through this generic Information Collection Request (ICR). The National Center for Injury Prevention and Control (NCIPC) anticipates that information will need to be collected to (a) understand sudden increases in drug use and misuse associated with fatal and nonfatal overdoses (e.g., collect data on type of drug, number of cases, time of increasing trend, morbidity and mortality), (b) understand the drivers and risk factors associated with those trends (e.g., collect data on circumstances surrounding overdose), and (c) identify the groups most affected.

- Intended use of the resulting data: The resulting data about drug use and misuse and associated fatal and nonfatal overdoses will be used to identify actions that can be taken to control a local drug overdose epidemic.

- Methods to be used to collect: The jurisdiction requesting assistance determines the specific data collection needs that CDC can fulfill. CDC staff may provide technical assistance with developing questionnaires and a data collection and analysis plan or may be deployed to the field to assist in operations of the investigation. Examples of data collection modes that could be employed during DORIs include: archival record abstraction and review, face-to-face interview, telephone interview, web-based questionnaire, or self-administered questionnaire. Multiple data collection modes may be employed in a single investigation. Data collection instruments and methods will be rapidly created and implemented to meet the unique needs of the situation and the agency requesting assistance, often immediately before deployment. Revisions will often be required when investigators are in the field.

- The subpopulation to be studied: Likely respondents include: public health authorities, law enforcement authorities, other public safety authorities, medical examiners, participants of overdose prevention and response services, individuals who have experienced nonfatal overdose, families and friends of individuals who have experienced drug overdose, members of the general public, individuals who are at higher risk for overdose (e.g., those with opioid use disorder), health care providers/pharmacists, dispensers of prescription medication, and representatives of community organizations (e.g., substance use service providers)

- How data will be analyzed: Data analysis will depend on the method of collection and content, but it is anticipated that most DORIs will involve computing basic descriptive statistics to characterize the population experiencing overdoses (e.g. the number and rate of fatal and/or non-fatal overdose cases, along with demographic characteristics); the creation an epidemic curve to graphically display the numbers of incident fatal or non-fatal overdose cases, plotted over time; potentially a bivariate exploration of risk and protective factors associated with overdose between cases and controls; and qualitative or quantitative summaries to describe overdose events.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC) seeks OMB approval for the Reinstatement with Change of this generic clearance (OMB control number 0920–1054, Expiration 03/31/2021) for a 3-year period, to conduct investigations of drug use and misuse and associated fatal and nonfatal overdose (hereafter referred to as "Drug Overdose Response Investigations (DORIs)." In this context, drug overdose refers to overdose from prescription drugs (with a special interest in opioid analgesics such as oxycodone or methadone; benzodiazepines such as alprazolam; psychostimulants such as dextroamphetamine) and/or illicit drugs (e.g., heroin, illicitly manufactured fentanyl, cocaine, methamphetamines).

Although in past years the DORI generic mechanism has not been used, the need to use this generic mechanism is expected to increase as the drug overdose epidemic continues to pose a serious threat. In October 2020, the declaration of a national public health emergency as a result of the opioid crisis was renewed yet again, and eight states (Alaska, Arizona, Florida, Maryland, Massachusetts, Pennsylvania, South Carolina, Virginia) have now declared state emergencies. Further, provisional data from CDC's State Unintentional Drug Overdose Reporting System suggest that overdose deaths increased from 2019 to early 2020 (the most recent data available to us), after a slight decrease from 2017 to 2018. More recent data from the Overdose Detection Mapping Application Program indicate yet another uptick in suspected overdose events since the start of the COVID-19 pandemic. Adding to this challenge, drug and overdose trends are rapidly changing, shaped by the westward expansion of fentanyl, the eastward expansion of methamphetamines, and increasing polysubstance overdose.

As of September 2020, CDC now funds enhanced surveillance and prevention of fatal and nonfatal opioid overdoses in 47 states, 16 localities, Puerto Rico, North Mariana Islands, and the District of Columbia. In addition, by June 2021, CDC will be funding public health analyst positions in 30 states to support the work of the Overdose Response Strategy, a unique collaboration between public health and public safety created to help local communities reduce drug overdose and save lives. Finally, CDC recently launched the Overdose Rapid Response Program, which leverages CDC's partnerships with the HHS Office of Inspector General and Public Health Service Commissioned Corps, to swiftly deploy staff to help jurisdictions prevent overdose deaths during an overdose spike or following the closure of an opioid clinic where patients are prescribed opioid therapy. During the past years the DORI generic mechanism has not been used, but the enhanced surveillance and prevention efforts mentioned may lead to an increase in the need for the use of DORI. While states continue to develop their capacity to respond to increases in drug overdose, some still require substantial technical assistance in order to identify actions that take into account: associated fatal and nonfatal overdoses, overdose drivers and risk factors, and the populations most affected. Because the epidemiology of drug overdoses varies in terms of which populations are affected and which drugs are fueling the overdoses, it is important that CDC preserve the ability to rapidly provide a catered response to protect the public's health.

CDC is anticipating the annual number of DORIs to increase to 53 to accommodate the new requests NCIPC expects to receive from not only public safety agencies but also the other authorities funded through its other enhanced surveillance and prevention activities. However, there is no change in the burden hours.

Background

DORIs are data collections conducted in response to urgent requests from state and local authorities. Traditionally, these data collections are conducted in the context of an Epi-Aid; however, DORIs may also be conducted in response to a direct request from state or local public agencies (e.g. health departments, law enforcement agencies) to NCIPC. The Epi-Aid mechanism is enacted to support a field response and provides CDC with the agility to respond rapidly to serious and urgent public health crises. Epi-Aids are used to provide epidemiological information, as quickly as possible, to inform the selection of interventions to lessen or prevent illness, injury, or death. Epi-Aids may or may not include data collection. The goal of DORIs is to collect data to inform responses that can be taken to control a local drug overdose epidemic. When a DORI data collection is conducted in response to an urgent request from a state or local public agency, and the data collection meets criteria for review and approval under the Paperwork Reduction Act, approval will be sought for the data collection through this ICR. Based on previous experience, NCIPC anticipates that information will need to be collected to:

(a) understand sudden increases in drug use and misuse associated with fatal and nonfatal overdoses (e.g., collect data on type of drug, number of cases, time of increasing trend, morbidity and mortality;
(b) understand the drivers and risk factors associated with those trends (e.g., collect data on circumstances surrounding overdose); and,
(c) identify the groups most affected (e.g., collect data on emergency department admissions or decedents).

It is expected that investigations will often require collection of information from 10 or more respondents (or 10 or more organizations that serve as respondents), with the collection of information on the same topic and use of similarly structured questions.

In 2015, CDC received OMB approval (OMB control number 0920–1054) for a new OMB generic clearance for a 3-year period to collect information in response to urgent data collection requests from states. In 2018, OMB approval for this generic ICR was renewed for an additional 3 years. Although during the past approval the DORI generic mechanism was not used, the need to use this generic mechanism is expected to increase as the drug overdose epidemic continues to pose a serious threat. The DORI ICR was previously determined to assist CDC in responding to state requests given that the generic ICR that covers Emergency Epidemic Investigations (EEI) may not be an appropriate fit for data collections in response to drug overdose. The potential lack of fit is due to requirements of the EEI Generic ICR (that is, undetermined agent, source, mode of transition, or risk factors in urgent public health emergencies). The legal justification for conducting emergency requests from states about

drug overdose can be found in the Public Health Service Act (42 USC Sec. 301 [241] (a) (Authorizing Legislation, **Attachment A**).

Generic clearance is requested to ensure that timely information is collected during a DORI, which allows NCIPC to maintain critical mission function by working with state and local authorities to protect the public's health. During an unanticipated rise in a nonfatal or fatal drug overdose, where the substances responsible for the health event, drivers and risk factors, and/or subgroups at risk need to be identified, immediate action by CDC is necessary to minimize or prevent public harm. CDC must have the ability to rapidly deploy data collection tools to understand the scope of the problem and determine appropriate action. CDC seeks another extension for this GenIC to ensure that the Agency is poised to mobilize quickly and mitigate harm to the public when urgent data collection support is requested by state and local public agencies, and that data collection meets criteria for review under the Paperwork Reduction Act.

Over the last six years, this generic clearance was used to support one request from the Ohio Department of Health soliciting CDC's assistance with an investigation to identify risk factors for fentanyl-related overdose deaths in the state. Fentanyl, a synthetic, short-acting opioid analgesic, is 50–100 times more potent than morphine and is approved for the management of severe or chronic pain, typically among opioid-tolerant patients. In March 2015, the U.S. Drug Enforcement Administration (DEA) issued a nationwide alert on fentanyl as a threat to health and public safety. Identifying the circumstances and risk factors that contributed to this increase in deaths was critical to implementing prevention strategies to prevent additional deaths. Therefore, the Ohio Department of Health requested CDC assistance with an investigation to identify risk factors for fentanyl-related overdose deaths in the state. On 10/20/2015 CDC-NCIPC requested and received approval from OMB, through CDC-ICRO, for this DORI generic request titled "Undetermined risk factors for fentanyl-related overdose deaths- Ohio." During the previous ICR extension request, NCIPC reported to OMB the Ohio generic request along with the other DORI requests. A summary of previously approved DORI generic requests is provided in **Attachment E**.

Although CDC-NCIPC did not request OMB approval for a single GenIC during the most recent reporting period, we expect to receive more requests in upcoming years. As mentioned, in light of the deepening overdose crisis and NCIPC's enhanced overdose surveillance and prevention efforts, which have expanded staffing and fostered new connections with jurisdictions and public safety partners, we expect the number of states requesting assistance and our ability to respond to such requests to grow, particularly when we may be asked to participate in multistate investigations.

2. Purpose and Use of Information Collection

This revision of this generic clearance seeks the continuation of data collection for the "Drug Overdose Response Investigations (DORIs)." Renewal seeks the continued ability for data collection that meets requirements for review and approval under the Paperwork Reduction Act. There are no major changes requested for this data collection since the original request is still applicable. As stated, overdose deaths continue to rise and

information about the substances involved, associated drivers and risk factors, and groups most affected is still urgently needed to inform timely responses to control a local overdose epidemic. Further, as a result of its expanded overdose surveillance and prevention work, NCIPC anticipates many more state and local requests; it already counts on increased staff capacity to respond to such requests.

There are two minor changes, however, in anticipation of receiving more requests:

a. The types of authorities that can request data collection were expanded to include any public agency, which would include health authorities, law enforcement agencies, and other public safety partners. NCIPC increasingly works with public safety as one of its main pillars of overdose prevention and through that work has learned that public safety authorities are increasingly tracking overdoses, and in the event of an overdose spike, in need of assistance to understand the associated drivers, risk factors, and affected populations, so they can tailor response efforts accordingly.

b. The anticipated annual number of DORIs was increased to 53 to accommodate the new requests NCIPC expects to receive from not only public safety agencies but also the other authorities funded through its other enhanced surveillance and prevention activities. However, there is no change in the total annualized burden hours.

This data collection will allow for the gathering of information about drug use and misuse and associated fatal and nonfatal overdoses to identify actions that can be taken to control a local drug overdose epidemic. To accomplish this objective, data on the conditions surrounding and preceding the onset of the drug overdose events of interest must be collected rapidly. The negative consequence of not performing this data collection is the inability to respond to state technical assistance requests and resulting increase or sustained morbidity and mortality associated with the local drug overdose epidemic.

Need. Deaths from drug overdose continue to be a national crisis in the United States. Drug overdoses resulted in more than 67,000 deaths in 2018 alone and 69.5% involved an opioid. The age-adjusted opioid-involved death rate increased from 9.0 per 100,000 in 2014 to 14.6 in 2018. This increase was driven largely by increases in deaths involving heroin and synthetic opioids other than methadone. The proportion of overdose deaths involving cocaine and psychostimulants increased from 2016 to 2017 by 34 and 33 percent, respectively. Additionally, benzodiazepines, cocaine, or methamphetamines were present in 63% of opioid-involved deaths in 2018. Further, the Drug Enforcement Administration (DEA) found that the number of drug products obtained by law enforcement that tested positive for fentanyl nationally increased more than 10-fold from 2014 to 2019. In addition, 967,615 nonfatal drug overdoses were treated in U.S. emergency departments in 2017. From 2018 to 2019, rates of suspected nonfatal overdoses treated in emergency departments increased for overdoses involving opioids (9.7%), cocaine (11%), and amphetamines (18.3%).

State and local agencies are responsible for tracking and controlling local epidemics. However, state and local agencies often require assistance and support from CDC to assist in data collection and analysis so that complex and immediate demands for information can be met. These agencies rely on CDC to respond quickly to their requests for short-term data collection and analysis support. NCIPC is uniquely qualified to assist in data collection and analysis on drug overdose using DORIs given its expertise in investigating emerging trends in drug overdose, the drivers and risk factors associated with trends, and the groups most affected.

Circumstances. This generic clearance was established to address drug overdose when there is a request from state or local agency to investigate alarming and emerging trends in drug overdose that require immediate response, the drivers and risk factors associated with such trends, and the groups most affected. When assistance is requested by a state or local agency, CDC makes every effort to respond by providing data collection support to inform public health action. Requests for DORIs may emerge through the Epi-Aid mechanism or through direct requests from state or local agencies to NCIPC.

When the need to collect data from 10 or more entities is indicated, the circumstances that justify an urgent DORI data collection include:

- Increased overdoses (e.g., increase in number of nonfatal or fatal overdoses or accelerating trends);
- Occurrence of a rare or unknown cause of morbidity or mortality related to drug overdose (e.g., inclusion of rare substances, such as in the case of fentanyl-laced heroin, fentanyl analogues, or other new synthetics);
- Opportunity to identify new information, such as risk factors previously unassociated with drug overdose or a change in indicators of death (e.g., reports of changes in breathing function prior to death that could signal the need for intervention);
- Occurrence among a particular population (e.g., children)
- Public or political concern (e.g., state governor declaration of a public health emergency in a given state).

The circumstances that would not justify a DORI include:

- Investigations for the purposes of program evaluation, surveillance, needs assessment, or research conducted primarily to contribute to generalizable knowledge.

Scope of data collection. The jurisdiction requesting assistance determines the specific data collection needs that CDC can fulfill. CDC staff may provide technical assistance with developing questionnaires, interview guides, and a data collection and analysis plan. CDC staff may be deployed to the field to assist in some or all of the operations of the investigation. This can include conducting training, determining sampling frames, and collecting data. CDC staff may analyze the data (either locally or from Atlanta) and assist in report writing and presenting the final report to the local jurisdiction. The overarching goal when providing data collection and analysis support is to implement immediate

prevention and control measures based on the findings from the investigation to minimize adverse health consequences.

The information collected varies by DORI depending on the nature of the event. Based on previous experience, NCIPC anticipates that state requests will result in the need to collect data to (a) understand sudden increases in drug use and misuse associated with fatal and nonfatal overdoses (e.g., collect data on type of drug, number of cases, place and time of increasing trend, morbidity and mortality, medical conditions or symptomology information), (b) understand the drivers and risk factors associated with those trends (e.g., collect data on circumstances surrounding overdose, environmental factors, potential exposures, risk behaviors), and (c) identify the groups most affected (e.g., collect data on emergency department admissions or decedents to determine differences by demographics or location).

In DORIs, draft data collection instruments are developed prior to investigation initiation in the field. However, sufficient information is most often not available to allow for complete development of data collection instruments far in advance. Data collection instruments and methods must be rapidly created and implemented to meet the unique needs of the situation and the agency requesting assistance, often immediately before deployment, with needed revisions identified while investigators are in the field. Specific questions might change or new questions could evolve during the course of the investigation as new information is revealed. The choice of data collection mode may be influenced by what is already known about the problem; the location, size, and characteristics of the affected or target population; and resources available to local authorities and the team in the field.

Examples of data collection modes that could be employed during DORIs include:

- archival record abstraction and review
- face-to-face interview
- telephone interview
- web-based questionnaire
- self-administered questionnaire

Multiple data collection modes can be employed in a single investigation. It is anticipated that the most common data collection modes will include record abstraction, web-based questionnaires, and interviews.

Respondent type will vary by investigation. Likely respondents include:

- Public health authorities
- Law enforcement authorities (i.e. police officers, correctional staff)
- Other public safety authorities (i.e. emergency medical personnel, fire and rescue)
- Medical examiners
- Participants of overdose prevention and response services
- Individuals who have experienced nonfatal overdose
- Families and friends of individuals who have experienced drug overdose
- Members of the general public and individuals who are at higher risk for overdose

- Health care providers/pharmacists; dispensers of prescription medication
- Representatives of community organizations (e.g., substance use service providers)

Data could be collected in multiple cities, counties, or even states depending on the size and scope of the epidemic. For example, out of state residents can access health providers and dispensers in another state to inappropriately access prescription drugs; contaminated or high potency drugs could be distributed over a large geographic area causing spikes in overdoses. It is anticipated that there will be no more than 53 DORIs per year.

3. Use of Improved Information Technology and Burden Reduction

During DORIs, there often is not enough time to develop, test, and launch electronic systems for collection of data. However, DORIs will employ online or electronic submission of responses when feasible. If this mode is utilized, it will be password-protected. To minimize burden, existing data from medical records, for instance, could potentially be used to pre-populate data collection tools.

Data collection protocols are designed to be as unobtrusive as possible, and only the minimal information necessary is collected to reduce burden to the respondent. The specific data collection protocol is tailored to meet the immediate needs of the local authorities responding to the public health problem.

4. Efforts to Identify Duplication and Use of Similar Information

Literature searches and discussions with local authorities are initially conducted to determine the extent of existing information. If found, previous information is used, whenever appropriate, to contribute to an investigation. However, an emergency situation generally requires the collection of data specific to the particular event as each situation is unique in many aspects (e.g. class of drug, method of drug administration, location, affected populations, risk factors, and environmental factors).

NCIPC has reached out to other Centers within CDC (the National Center for Environmental Health, Division of Environmental Hazards and Health Effects) to determine the type of information collected by those Centers (within Epi-Aids and otherwise) related to and overdose prevention and response to ensure that the collection of information is not duplicative and that other Centers are not collecting similar information. When Epi-Aid or other urgent data collection requests are received from state and local public agencies related to drug overdose, NCIPC reaches out to other Centers conducting work on to ensure that similar information does not already exist to meet the state/local agencies' needs. NCIPC has also reached out to the Substance Abuse and Mental Health Services Administration to ensure the proposed data collection is not duplicative of any of their efforts in working with states.

A CDC staff person will continue to serve in the role of DORI Information Collection Request Liaison (ICRL). The ICRL will be responsible for maintaining a data collection instrument library which will include the final data collection instruments administered in

DORIs under this ICR. In the event a collection is requested from a CDC program, the ICRL will require the program to determine whether or not the information already exists, and to use data collection instruments (or components of such instruments) that have already been approved in previous DORIs.

5. Impact on Small Businesses or Other Small Entities

Every effort is made to minimize the burden on all respondents during the collection of information during drug overdose investigations. Information collected is held to the absolute minimum required to inform immediate effective prevention and control measures to ease impact on small businesses or entities. No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

DORIs involve one-time, rapid data collection efforts related to a specific event. Not collecting this information impedes CDC from responding to state technical assistance requests and identifying effective prevention and control measures that could lead to reduced morbidity and mortality associated with the local drug overdose epidemic.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Often, data need to be collected within days or weeks of the request made by the state or local agency. Given the need for rapid data collection to minimize threats to public health, respondents are asked to respond to requests for data in fewer than 30 days.

To ensure that data on drug overdoses are collected in a timely manner to identify immediate prevention and control measures that can protect the health of the public, DORIs will adhere to the following timeline and processes:

1. At the request of the state or local health authority and after consultation with our external partners, CDC decides to organize and deploy a team to provide epidemiological assistance to our partners;
2. Through CDC/ICRO, the OMB Desk officer is notified of the DORI immediately via e-mail from CDC, followed by receipt of the GenIC "Request for Drug Overdose Response Investigation." This GenIC will include the protocol for the investigation (see **Attachment C**, the investigation protocol template). The protocol describes the circumstances, purpose, case definition (if applicable), study population, variables of interest, respondents, anticipated burden hours, data analysis plan, synthesis of results, and draft data collection instruments.
3. The OMB desk officer responds with comments on the proposed GenIC DORI within 5 business days. If no response is received within 5 business days, the team assumes that the information collection is cleared.
4. While in the field, minor modifications may be needed to data collection instruments or number of respondents based on new information about the drug overdose events or available data sources. If modifications to the protocol are required, the team will provide a copy of revised data collection instruments and

protocol to the ICRL. The ICRL will make a determination as to whether the modifications entail a substantial change in scope or burden hours. If a substantial change is needed, the ICRL will work with the investigators to submit a GenIC with the revised data collection instruments to ICRO. ICRO will send the GenIC with the revised data collection instruments to the OMB desk officer for review. The OMB desk officer will respond with approval or comments for revision within 2 business days. If no response is received within 2 business days, the team assumes that the revisions have been accepted.

5. At the completion of the DORI, the investigators submit the final data collection instrument(s) and associated burden to the ICRL using the "burden memo" (see **Attachment D**).
6. CDC maintains a library of data collection instruments that includes all final data collection instruments conducted under this Generic ICR.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on August 13, 2020, Vol. 85, No. 157, page 49375 (**Attachment B**). CDC received no public comments.

B. Efforts to Consult Outside the Agency

The following are the individuals we consulted with to inform the development of this package. There were no major problems that could not be resolved during the consultation.

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9. Explanation of Any Payment or Gift to Respondents

Respondents receive no gift or payment for their participation in any information collections.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission was reviewed by the NCIPC's Information Systems Security Officer, on November 1, 2020, who determined that the Privacy Act does not apply. Data are treated in a secure manner, unless otherwise compelled by law. CDC maintains respondent information by using unique, study identification numbers on all data collection forms. Data may be collected in identifiable form by state partners but de-linked from identifiers and subsequently retrieved by an assigned code rather than name or SSN for CDC use. The lead epidemiologist of the local state investigation will assign and maintain the code and linking information. Personal identifiers and the linkage to the study identification number are maintained separately in locked file cabinets or in encrypted computer files by the state/locality. All personal identifiers are stripped from the data prior to establishing a final data analysis file. Results are published in aggregate form only.

Information collected through DORIs will be shared in aggregate, summary format with state and local public agencies and other partners engaged in controlling the local epidemic (e.g., health care providers, law enforcement medical examiners, and community organizations). Findings from data analysis will be used by state and local professionals to implement immediate prevention and intervention measures (e.g., task

force convening, provision of guidance to Boards of Pharmacy on how to track prescribing and provide feedback to practitioners and implement controls, development of reporting regulations, media outreach efforts).

Information in identifiable form (IIF) may be collected from or about members of the public by states and localities. Examples of IIF categories for which data may be collected include: name, mailing address, e-mail address, phone numbers, and medical information and notes. IIF is only collected when essential to the objective of the investigation. Personal identifiers are not transmitted to CDC; thus, CDC is not collecting IIF. IIF data will not be disclosed unless compelled by law. In no case are IIF included in any report from the investigation.

Individuals are informed that providing information is voluntary. If the respondent participates, consent for participation and sharing of data in aggregate form is assumed.

Official, written consent is only obtained when it is determined that the data collection involves human subjects research. If research is proposed to accompany the response efforts, all efforts will be taken to ensure that the proposed research complies with all human subjects requirements, including consent requirements. All personal identifiers are stripped from the data prior to delivery of data to CDC or establishing a final data analysis file. Results are only published in aggregate form. A system of records is not being created under the Privacy Act.

Local public agency policies and procedures for data storage and security are followed during each field investigation. Though the type of access control(s) implemented vary according to local policies and procedures, examples include technical controls (e.g., password protection, storage on Virtual Private Network), physical controls (e.g., storage in locked cabinets or rooms), and administrative controls (e.g., daily offsite file back-ups, signed confidentiality agreements by staff who have access to files). Information collection is conducted according to a security plan developed in consultation with the relevant local health authorities. Only staff with approval from the study lead has access to the data. Approvals are granted based on roles or a “need to know basis.”

Personal identifiers are not transmitted to CDC. CDC maintains the integrity of respondent information by using unique, study identification numbers on all data collection forms.

Data are permanent federal records and are maintained in accordance with CDC’s records control schedule (https://www.archives.gov/records-mgmt/grs.html). The process for handling security incidents is defined in the system’s Security Plan. Event monitoring and incident response is a shared responsibility between the system’s team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events are directed to the component’s Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

Research is not a primary focus of DORIs, and CDC will not have access to identifiable information; however, if research is proposed to accompany the response efforts, the proposed research will comply with all human subjects' requirements. All data sent to CDC will be stripped of identifiers and transmitted in aggregate format. A Determination of human subjects' review applicability will be included with each submitted generic request.

Justification for Sensitive Questions

Questions that might be considered sensitive (e.g., regarding risk behaviors, attitudes, or medical condition diagnoses) are included only when necessary for the public health response. Before administering data collections, investigators inform respondents (either verbally or in writing) that participation is voluntary, respondents can refuse to answer any questions, and that respondents are not personally identified in any published reports of the study. Participants are also informed the data are being collected in response to drug overdose events, and that the information they provide may help to identify effective prevention and control strategies. Social security numbers are not collected.

12. Estimates of Annualized Burden Hours and Costs

There are no major changes requested for this data collection since the original request. The projected average number of respondents is expected to be the same and is determined by the state or local authority requesting organization. CDC estimates that approximately 6000 respondents will participate in DORIs each year and the average burden per response is 0.5 hours and each respondent is asked to respond once. Therefore, the total estimated annual burden in hours is same 3000 previously requested. While this number may seem high in light of the past infrequent use of DORI, the fact the opioid crisis is still declared a national emergency combined with NCIPC's enhanced opioid surveillance and prevention efforts, the projection is reasonable. The actual number of respondents in each information collection and the number of responses per respondent varies depending on the purpose of each individual generic request.

Table A-12.1 Estimated Annualized Burden Hours

Type of	Form Name	No. of	No. of	Avg.	Total Burden

Respondents		Respondents	Responses per Respondent	Burden per Response (in hrs.)	(in hrs.)
Drug Overdose Response Investigation Participants	DORI Data Collection Instruments	6000	1	30/60	3000
				Total	3000

There are no anticipated costs to respondents other than time. The U.S. median national hourly wage for all occupations in 2020 based on data from the Bureau of Labor Statistics (available at http://www.bls.gov/oes/current/oes_nat.htm#00-0000) is $19.14. This wage is assumed for all DORI participants because of the variety of types of participants expected.

Table A-12.2 Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden (in hrs.)	Hourly Wage	Total Respondent Cost
Drug Overdose Response Investigation Participants	DORI Data Collection Instruments	3000	$19.14	$57,420

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

Respondents will incur no capital or maintenance costs.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The cost factors considered are related to routine procedures of the investigators in planning investigations; design, preparation, printing, and distribution of questionnaires; and editing, coding, tabulation, analysis, and presentation of the information. The annual cost is estimated based on the U.S. national average hourly wage for epidemiologists in 2019 ($37.64) based on data from the Bureau of Labor Statistics (available at https://www.bls.gov/oes/current/oes_nat.htm#00-0000). On average, CDC staff and contractors contribute 200 hours per DORI, and CDC is anticipated an increase in the annual number of DORIs to 53 for a total annualized cost to the Government of $398,984 (see Table A-14.1).

Table A-14.1 Estimated Annualized Cost to the Government

Staff or Contractor	Average Hours per DORI	Average Annual DORI requests	Average Hourly Rate	Total Annualized Cost
Epidemiologist	200	53	$37.64	$398,984

15. Explanation for Program Changes or Adjustments

There are no major changes requested for this data collection since the original request is still applicable. As stated, overdose deaths continue to rise and information about the substances involved, associated drivers and risk factors, and groups most affected is still urgently needed to inform timely responses to control a local overdose epidemic. Further, as a result of its expanded overdose surveillance and prevention work, NCIPC anticipates many more state and local requests; it already counts on increased staff capacity to respond to such requests.

There are two minor changes, however, in anticipation of receiving more requests:

c. The types of authorities that can request data collection were expanded to include any public agency, which would include health authorities, law enforcement agencies, and other public safety partners. NCIPC increasingly works with public safety as one of its main pillars of overdose prevention and through that work has learned that public safety authorities are increasingly tracking overdoses, and in the event of an overdose spike, in need of assistance to understand the associated drivers, risk factors, and affected populations, so they can tailor response efforts accordingly.

d. The anticipated annual number of DORIs was increased to 53 to accommodate the new requests NCIPC expects to receive from not only public safety agencies but also the other authorities funded through its other enhanced surveillance and prevention activities. However, there is no change in the burden hours.

16. Plans for Tabulation and Publication and Project Time Schedule

The epidemiologic data collected in each DORI provides information necessary for an effective public health response to drug use and misuse and associated fatal and nonfatal overdose. Therefore, collecting data as soon as possible after the onset of the overdose events is critical to the analysis. The duration of the data collection varies by DORI.

Project Time Schedule	
Activity	Time Schedule
Letter received from public agency requesting assistance	Investigation initiation

Convening of health scientists, epidemiologists, etc.	Within 1 week after investigation initiation
Development of data collection instrument or selection from instrument library	Weeks 1 to 3 after investigation initiation
GenIC submission and approval	Week 3 after investigation initiation
Deployment into the field	Weeks 4 to 6 after project initiation
Data collection in the field	Weeks 4 to 10 after project initiation (staff may be in the field for up to 3 weeks)
Data collection from CDC	Weeks 6 to 12 after investigation initiation (all data collected within 3 months)

For each DORI, the lead investigator is responsible for developing an analysis plan and conducting the data analysis. A preliminary report summarizing the early findings of the investigation is written by the lead investigator within 14 days of the completion of the investigation. Any publication of data derived from a DORI is subject to review by relevant local public agencies, CDC, or collaborating federal agencies.

CDC may receive requests to release the information (e.g., congressional inquiry, Freedom of Information Act requests). The Agency disseminates the findings when appropriate, strictly following the Agency's "Guidelines for Ensuring the Quality of Information Disseminated to the Public."

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.