Drug Overdose Response Investigation (DORI) Data Collection

SUPPORTING STATEMENT
INFORMATION COLLECTION REQUEST

Part A

Supported by:

Department of Health and Human Services (DHHS)
Centers for Disease Control and Prevention (CDC)
National Center for Injury Prevention and Control (NCIPC)
Division of Unintentional Injury Prevention

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Drug Overdose Response Investigations (DORI) Data Collections

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC) is requesting approval for a 3-year period of a NEW Generic Information Collection Request (ICR) 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) and/or illicit drugs (e.g., heroin).

DORIs are data collections conducted in response to urgent requests from state and local health 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 health departments to NCIPC.

The goal of DORIs is to collect data to inform responses that can describe an apparent local drug overdose epidemic. When a DORI data collection is conducted in response to an urgent request from a state or local health authority, 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 what appears to be 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 potential 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.

Prior to this request, NCIPC has previously collected data on drug overdose incidents via the previously OMB-approved Emergency Epidemic Investigations ICR (OMB No. 0920-0008; expiration 7/31/2014). The Emergency Epidemic Investigations ICR was not reinstated following expiration, and depending on the nature of the drug overdose investigation and nature of the emergency, the ICR that replaced it (OMB No. 0920-1011) may not be appropriate to cover drug overdose investigations that involve data collection; therefore, we are requesting a generic ICR for DORIs conducted in response to urgent data collection requests from states. 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 health 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 need to be identified, drivers and risk factors are undetermined, 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 provide advice regarding appropriate action. CDC seeks approval for this Generic ICR to ensure that the Agency is poised to mobilize quickly and mitigate harm to the public when urgent epidemiologic data collection support is requested by our state and local health authority partners, and that data collection will be from ten or more respondents.

2. Purpose and Use of Information Collection

The purpose of this ICR is to allow for rapid data collection within Drug Overdose Response Investigations (DORIs) that are conducted in response to an urgent request for assistance from state or local health authorities. 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 have been rising steadily over the past two decades and have become the leading cause of injury death in the United States. Every day in the United States, 105 people die as a result of drug overdose, and another 6,748 are treated in emergency departments (ED) for the misuse or abuse of drugs. In 2010, of the 38,329 drug overdose deaths in the United States, 22,134 (60%) were related to pharmaceuticals. Of these prescription drug overdose deaths, 16,651 (75%) involved opioid analgesics (also called opioid pain relievers or prescription painkillers), and 6,497 (30%) involved benzodiazepines. In 2011, about 1.4 million ED visits involved the nonmedical use of pharmaceuticals. Among those ED visits, 501,207 visits were related to anti-anxiety and insomnia medications, and 420,040 visits were related to opioid analgesics. Benzodiazepines are frequently found among people treated in EDs for misusing or abusing drugs. People who died of drug overdoses often had a combination of benzodiazepines and opioid analgesics in their bodies.

State and local health authorities are responsible for tracking and controlling local epidemics. However, state and local health authorities often require epidemiologic assistance and support from CDC to assist in data collection so that complex and

immediate demands for information can be met. Authorities rely on CDC to respond quickly to their requests for short-term data collection support. NCIPC is uniquely qualified to assist in data collection 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 is being established to address drug overdose when there is a request from state or local health authorities 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 health authority, CDC makes every effort to respond by providing data collection support to inform public health action. Requests for DORIs will typically emerge through the Epi-Aid mechanism.

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)
- 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 and a data 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 support is to implement immediate prevention and control measures based on the findings from the investigation to minimize adverse health consequences.

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. On rare occasions, revisions are identified while investigators are in the field. 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 population; and resources available to local health 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 and in-person interviews.

Respondent type will vary by investigation. Likely respondents include:

- Public health authorities
- Law enforcement authorities
- Medical examiners
- Individuals who suffer from nonfatal overdose
- Families and friends of individuals who succumb to drug overdose
- Members of the general public, and individuals who are at higher risk for overdose (e.g., those suffering from addition)
- Health care providers/pharmacists; dispensers of prescription medication
- Emergency Medical Services personnel
- 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.

3. Use of Improved Information Technology and Burden Reduction

During DORIs, there often is not sufficient 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 health authorities responding to the public health problem.

4. Efforts to Identify Duplication and Use of Similar Information

Literature searches and discussions with local health 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 prescription drugs 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 health authorities related to drug overdose, NCIPC reaches out to other Centers conducting work on prescription drugs to ensure that similar information does not already exist to meet the state/local health authorities' 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.

The NCIPC OMB coordinator (Karen Angel) will 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 D**, the investigation protocol template). The protocol describes the circumstances, purpose, case definition, 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, if modifications to the protocol are required (which is anticipated to be a rare event), 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 the ICRL makes a determination that the modifications do not constitute a substantial change, CDC will use the revised instruments that incorporate the minor modifications (e.g., modifications to item wording). If a substantial change is needed (e.g., changes to burden, scope, respondent type), 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, along with an e-mail to the OMB Desk officer. The OMB desk officer will respond with approval or comments for revision within 3 business days. In this time frame, CDC will not use the revised GenIC until changes are approved by OMB. If no response is received within 3 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 E**).
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 14, 2014, Vol. 79, No. 157, page 47640 – 47641 (**Attachment B**). There were no comments to the 60-day Federal Register Notice.

B. Efforts to Consult Outside the Agency

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

Name: Rob Lyerla
Title: CAPT USPHS, Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration
Phone Number: 240.276.0548
Email: rob.lyerla@samhsa.gov
Consultation year: 2014

Name: Sharon Larson
Title: Director, Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration
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Consultation year: 2014

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the CIO 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 but de-linked from identifiers and subsequently retrieved by an assigned code rather than name or SSN. The lead epidemiologist of the 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. All personal identifiers are stripped from the data prior to establishing a final data analysis file. Results are published in aggregate form only.

1. Privacy Impact Assessment

1.1 Overview of the Data Collection System.

In response to urgent technical assistance requests from state and local health authorities where data collection is required to inform intervention measures, data will be collected within 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) and/or illicit drugs (e.g., heroin). It is anticipated that there will be no more than 10 DORIs per year. The data collection protocol and measures will vary across DORIs, depending on the nature of the request for CDC assistance. Broadly, data will be collected to (a) understand sudden increases in drug use and misuse associated with fatal and nonfatal overdose (e.g., 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., data on circumstances surrounding overdose), and (c) identify the groups most affected (e.g., data on emergency department admissions or decedents). Data will be collected through a variety of mechanisms, depending on the needs of the specific DORI, and may include archival record abstraction and review, face-to-face interview, telephone interview, web-based questionnaire, or self-administered questionnaire. Respondent type will vary by investigation. Likely respondents include: Public health authorities, law enforcement authorities, medical examiners, individuals who suffer from nonfatal overdose, families and friends of individuals who succumb to drug overdose, members of the general public, and individuals who are at higher risk for overdose (e.g., those suffering from addition), clinicians, Emergency Medical Services personnel, and representatives of community organizations (e.g., substance use service providers). Data are permanent federal records and are maintained in accordance with CDC's records control schedule (http://isp-v-maso-apps/RecSched/ViewSchedule.aspx?RID=29).

1.2 Items of Information to Be Collected.

<u>Example of data collection methods and instruments</u>

To assist in the review of this ICR, below you will find descriptions of the types of data collection activities that are anticipated for DORIs that would be subject to Paperwork Reduction Act review and approval and would be included within a GenIC. We have also provided examples of past Epi-Aids that presented circumstances that would be similar to justify a DORI covered under the proposed generic package. See **Attachment C1** for a description of these Epi-Aids, in addition to example data collection instruments used in previous Epi-Aid investigations that illustrate sample questions that are consistent with the information collection activities below (**Attachments C2-C5**).

1.3 How the Information will be Shared.

Information collected through DORIs will be shared in aggregate, summary format with state and local health authorities and partners engaged in controlling the local epidemic (e.g., 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).

1.4 Impact of Proposed Collection on Respondent's Privacy

Information in identifiable form (IIF) may be collected from or about members of the public. 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 to be transmitted to CDC unless this is necessary for public health purposes. IIF data will not be disclosed unless compelled by law. In no case are IIF included in any report from the investigation.

1.5 Whether individuals are informed that providing the information is voluntary or mandatory.

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

1.6 Opportunities to consent, if any, to sharing and submission of information.

Potential respondents are informed. 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. Personal identifiers and the linkage to the study identification number are maintained separately in locked file cabinets or in encrypted computer files. All personal identifiers are stripped from the data prior to 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.

1.7 How the information will be secured.

Local health authority 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 to be transmitted to CDC unless this is necessary for public health purposes, which is a rare occurrence. IIF that is transmitted to CDC is treated in a secure manner. 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 (http://isp-v-maso-apps/RecSched/ViewSchedule.aspx?RID=29). 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.

1.8 Whether a system of records is being created under the Privacy Act.

This submission has been reviewed by the CIO who determined that the Privacy Act does not apply. Data are treated in a secure manner, unless otherwise compelled by law.

IRB Approval

Research is not a primary focus of DORIs, and CDC does not usually have access to identifiable information; however, 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. All data sent to CDC will be stripped of identifiers and transmitted in aggregate format. A NCIPC Determination of human subjects review applicability will be included with each submitted GenIC (Attachment F).

11. 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

CDC projects multiple DORIs annually in response to urgent drug overdose events. The projected average number of respondents is determined upon initial contact by the state

or local health authority or requesting organization. CDC estimates 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 1000. The actual number of respondents in each information collection and the number of responses per respondent varies depending on the purpose of each individual GenIC.

Table A-12.1 Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Drug Overdose Response Investigation Participants	DORI Data Collection Instruments	2000	1	0.5	1000
				Total	1000

There are no anticipated costs to respondents other than time. The U.S. median national hourly wage for all occupations in 2013 based on data from the Bureau of Labor Statistics (available at http://www.bls.gov/oes/current/oes_nat.htm#00-0000) is $16.87. This wage is assumed for all DORI participants because of the variety of types of participants expected. With a maximum annual respondent burden of 1000 hours, the overall annual cost of respondents' time for the proposed collection is estimated to be a maximum of $16,870 (1000 burden hours x $16.87).

Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)	Hourly Wage	Total Respondent Cost
Drug Overdose Response Investigation Participants	DORI Data Collection Instruments	2000	1	0.5	1000	$16.87	$16,870
				Total	1350		

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 2013 ($35.11) based on data from the Bureau of Labor Statistics (available at http://www.bls.gov/oes/current/oes_nat.htm#00-0000). On average, CDC staff and contractors contribute 200 hours per DORI, for a total annualized cost to the Government of $70,220 (see Table A-14.1).

Table A-14.1 Estimated Annualized Cost to the Government

Staff or Contractor	Average Hours per DORI	Average Hourly Rate	Number of DORIs Annually	Total Annualized Cost
Epidemiologist	200	$35.11	10	$70,220

15. Explanation for Program Changes or Adjustments

This is a new data collection

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 epidemiologic analysis. The duration of the data collection varies by DORI.

Project Time Schedule	
Activity	Time Schedule
Letter received from health 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 and provided to CDC within 14 days of the completion of the investigation. Any publication of data derived from a DORI is subject to review by relevant local health authorities, 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.