Poison Center Collaborations for Public Health Emergencies

OMB Control No. 0920-NEW
Generic Clearance

Supporting Statement Part A –
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Project Officer

Royal Law, PhD, MPH
National Center for Environmental Health
Centers for Disease Control and Prevention
4770 Buford Highway NE, MS F-60
Atlanta, Georgia 30341
Phone: (770) 488-3416
Fax: (770) 488-3450
Email: hua1@cdc.gov

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Part A. Justification

Goal of the study: The goal of this information collection is to create a timely mechanism which will allow a network of regional, state and local poison centers, supported by CDC, to obtain critical exposure and health information during a public health emergency. This additional information will improve public health response for the site-specific public health emergency or incident. As questions will be tailored to the nature of the public health emergency/incident—a generic mechanism is being employed for collections within this scope to permit rapid response to urgent public health problems. Data collection instruments and methods must be rapidly created and implemented to direct appropriate public health action. Data collection for investigations conducted under this generic will not exceed 60 days.

Intended use of the resulting data: To quickly characterize potential exposures, help identify potential risk factors, and identify illnesses related to the public health emergency and improve the public health response to the incident.

Methods to be used to collect: For selected events, poison center staff in collaboration with CDC, will re-contact callers, obtain verbal consent, and complete a call-back questionnaire over the phone about the public health emergency. The call-back questionnaire will include additional questions not asked during initial poison center calls but are important for public health response to reduce mortality and morbidity.

The subpopulation to be studied: Callers to a poison center regarding a public health emergency.

How data will be analyzed: Descriptive analyses and trend analysis using statistical software as appropriate.

A.1. Circumstances Making the Collection of Information Necessary

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), requests a three-year Paperwork Reduction Act (PRA) clearance for a new generic clearance information collection request (Generic ICR) titled the "Poison Center Collaborations for Public Health Emergencies."

NCEH is authorized to collect this information under the Public Health Service Act Section 301 [241] (**Attachment 1).** The 60-day Federal Register Notice (FRN) was published on 6/22/2016,

and is further discussed in Section A8 (**Attachment 2**)**.** The information will be collected in accordance with NCEH's mission to promote health and quality of life by preventing or controlling disease, injury, and disability related to the interactions between people and their environment outside the workplace.

Partnering with Poison Centers

CDC's key partner, the American Association of Poison Control Centers (AAPCC), is a national network of 55 poison centers working to prevent and treat poison exposures (**Attachment 3**). The poison centers service all states and US territories. Some states have a single poison center servicing the whole jurisdiction, some states have multiple poison centers servicing the state, and some states have poison centers outside the state servicing their jurisdiction. A free national hotline is available 24 hours a day, seven days a week to speak to poison center experts related to poison exposures. Callers using the national hotline are automatically routed to the poison center closest to the caller location.

Upon approval of this Generic ICR, CDC's collaboration with AAPCC will have two main components.

Surveillance - National Poison Data System (NPDS)

The National Poison Data System (NPDS) is not the subject of this Generic ICR. Already in existence and use, the AAPCC owns and operates the NPDS, a surveillance system compiling all calls to all poison centers in the US. On average, every 8 minutes, all poison centers upload data collected from calls made to their organizations to NPDS.[1] Data routinely uploaded into NPDS include basic demographic information of the exposed (age, gender), the substance of exposure, reported signs and symptoms following exposure, and medical outcome of the exposure.[2-3]AAPCC collects this data as part of its routine surveillance and CDC does not direct the NPDS data collection. Therefore, it has previously been determined that PRA clearance is not required for CDC's role in the NPDS. The regulatory definition of burden in *Controlling Paperwork Burdens on the Public* [1] provides the exception for why PRA clearance is not needed for NPDS.

Through an existing cooperative agreement with AAPCC (CDC-RFA-EH15-1506), however, CDC provides some funding to AAPCC for NPDS maintenance and data storage. A data sharing agreement between CDC and AAPCC is in place (**Attachment 4**) to facilitate CDC data access for secondary analysis. Since 2001, CDC and AAPCC have developed collaborative methods to use NPDS data for near real-time surveillance of exposures to hazardous substances.

Investigations - Select Public Health Emergencies

For this Generic ICR, CDC is requesting PRA clearance for follow-up investigations conducted by poison centers, on behalf of CDC, through call-back questionnaires about select public health emergencies. To support these investigations, CDC will work with AAPCC through its existing cooperative agreement, further described in Section A14.

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[1] 5 CFR part 1320.3(b)(2): *The time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities (e.g., in compiling and maintaining business records) will be excluded from the "burden" if the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary.*

The national surveillance program through NPDS improves the ability of poison centers to respond to public health emergencies related to a wide variety of agents in the environment. CDC learns of potential public health emergencies through various means, including discussions among colleagues, media reports, and notifications from poison centers receiving an unusual number of calls about a particular exposure or calls about a novel exposure. Upon receiving this information, CDC and its AAPCC collaborators will hold a meeting to mutually decide whether the incident is a public health emergency that needs further investigation using the criteria discussed in Section A.2.

Table A1-1. Description of data currently collected by poison centers and the proposed data to be collected through this Generic ICR.

Description	**Data routinely collected by poison centers**	**Data uploaded to NPDS**	**Data collected in follow-up investigations through the Generic ICR**
Nature of the data	Data is collected by AAPCC as a part of the clinical triage function of poison centers and used for follow up	Select data fields from poison center data are uploaded to NPDS for national surveillance	Follow-up questionnaire administered by poison centers at CDC request
Is the activity sponsored by CDC?	No	No	Yes
Individually Identifiable Information?	Yes; name and contact information	No; age and sex only	No
CDC has access?	No	Yes	Yes
Data storage	Local poison centers servers	Password-protected web access	Microsoft Access database transmitted via secure FTP to CDC
Under this PRA clearance?	No	No	Yes

CDC uses the NPDS to improve public health surveillance for chemical and poison exposures and associated illnesses, to identify early markers of chemical events, and to enhance situational awareness during outbreaks.[4] Currently, the poison centers ask only those questions needed to diagnose and provide guidance for addressing the exposure. These items of information have proven useful for past surveillance efforts.[5-7] Table A1-2 includes examples of public health emergencies where NPDS contributed to effective emergency response.

Table A1-2. NPDS in Emergency Response

Event	Year	NPDS in emergency response [2,6,7]
Hurricane Sandy	2012	• Using NPDS data, identified over 250 potential carbon monoxide exposures related to Hurricane Sandy and notified the respective state health departments. • Rapidly published this data in an MMWR article to notify other public health officials of this public health threat.
Radiological	2011	• Used NPDS data to identify the ingestion of potassium iodide and

incident in Japan (Fukushima)		other iodine/iodide products as a potential public health concern within the US. Individuals were ingesting these products bought off internet sites to prevent radiation contamination even though no such recommendation was given in the US. • Findings were used to guide CDC and local health department's public health messaging and communication activities.
Deepwater Horizon Oil Spill	2010	• Used NPDS data to identify exposure trends and monitor severity of health effects due to exposure to the oil spill. • Findings aided CDC leadership in determining the public health impact of the oil spill on the general population and were an integral part of the Gulf Coast Oil Spill Response Surveillance Activities. • Information was also sent to each affected state to use in their surveillance activities and public health response efforts.
Salmonella outbreak in peanut butter	2009	• Through NPDS-based surveillance, five states captured probable cases that had not been previously identified by CDC. • Aggregate data from NPDS were reported daily to the Division of Foodborne and Mycotic Diseases at CDC to enhance their situational awareness.

These examples demonstrate that during a public health emergency, immediate action by CDC can minimize or prevent public harm. CDC seeks approval for this Generic ICR to ensure the agency is poised to mobilize quickly when urgent epidemiologic support is needed in an emergency situation. This Generic ICR will allow CDC and poison centers to collect and share critical data needed to allow public health officials to rapidly respond during emergencies.

A.2. Purpose and Use of Information Collection

The purpose of this Generic ICR is to create a timely mechanism to allow poison centers, supported by CDC, to follow-up with callers during select public health emergencies on exposure and health. For a public health emergency to be selected for call-back data collection, the event must meet the criteria below:

1. The event is an acute public health emergency that is believed to be causing adverse health effects.

2. Timely data are urgently needed to inform rapid public health action to prevent or reduce injury, disease, or death.

3. The event is characterized by (1) a natural or man-made disaster; (2) contaminated food/water; (3) a new or existing consumer product; or (4) an emerging public health threat.

4. The event has resulted in calls to a poison center, and the poison center agrees to conduct the call-back data collection.

5. The event is domestic.

6. Data collection will be completed in 60 days or less.

Additional criteria for the investigations, also called generic information collections (GenICs) under the Generic ICR, include:

1. No request for technical assistance by state, local, or regional public health is required to initiate a GenIC.

2. The investigations will be non-research GenICs designed to identify, characterize, and to assist with an immediate public health emergency and the knowledge gained will directly benefit the affected community.

3. Investigations conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research (e.g., to contribute to generalizable knowledge) are excluded from this generic pathway.

4. Investigations related to non-urgent outbreaks or events are excluded from this pathway.

Respondents selected for poison center investigations will comprise those who initially call a poison center about triage and treatment of potential poison exposures related to the select public health emergency. CDC will identify and recruit the respondents based on information already collected in NPDS. In their daily operations, poison centers track a caller's contact information for the purposes of medical follow-up; this information will be used to contact the caller for the call-back data collection. These respondents to the poison center investigations include:

- Adults (18 years and older)
- Adolescents (15 up to 18 years)
- Parents or guardians of children (less than 15 years)

Table A2-1 describes the role of the CDC and the poison center staff during the data collection.

Table A2-1. Delineation of roles

Organization	Role in the data collection
CDC	• Determines whether an event is a public health emergency that meets the scope of the ICR • Obtains a signed Research Determination • Obtains PRA Clearance • Modifies questions as appropriate • Selects respondents based on incident-specific exposure data collected in NPDS. If NPDS ID No. (unique identifier generated by NPDS when data are uploaded) is available, then CDC uses this as a linking variable for

	poison center follow-up. • Communicates with poison centers during the data collection process • Analyzes de-identified data
Poison Center	• Obtains consent or assent from participants over the phone • Administers questionnaire over the phone • Enters data into secure database • Provides de-identified data to CDC

These data collections will obtain information on sources of exposure, scenario of exposure, health seeking behaviors following exposure, and awareness of health communication messaging. These additional data can help CDC identify interventions to improve health messaging meant to reduce exposure; improve disaster and emergency response and preventing future events. CDC will use this information to improve the public health response, including public health messaging for the specific area or incident of interest.

The negative consequences of not having the information is CDC would not have access to valuable information critical for response and public health messaging. Without this data there would be:

- Barriers to collecting information on sources of exposure, scenario of exposure, health seeking behaviors following exposure, and awareness of health communication messaging
- Less effective interventions to improve health messaging meant to reduce exposure
- Limitations to effective and timely assessment of public health needs during public health emergencies
- Limitations to linking potentially related exposures
- Limitations on improving disaster and emergency response
- Limitations on preventing future events

The information collected will enable CDC to quickly provide information to regional, state and local health departments responding to the emergency and to later disseminate information to the larger public health community through Morbidity and Mortality Weekly Report (MMWR) publications, Center reports, CDC web pages, and posters/presentations. As respondents participating in a collection for a given public health emergency will be limited to those individuals who call a participating poison control center, any publication of outcomes, presentations, or dissemination of findings gathered from this generic will clearly describe the non-generalizability of outcomes to broader populations.

Only events that meet the criteria as outlined in A.2 will be eligible for information collection. Because of the need to rapidly obtain information to appropriately respond to the urgent public health emergency, data collection must be completed within 60 days.

A.3. Use of Improved Information Technology and Burden Reduction

No improved technology in the form of computer aided telephone interviews (CATI) will be employed. Data collection via telephone is the preferred method because it utilizes the same mode of contact that the exposed persons utilized when they first contacted the poison center. A poison center staff member will administer the questionnaire over the phone and enter the data into a password-protected Microsoft Access database created by CDC. The data collection instrument will be designed to collect the minimum information necessary for the purposes of this project.

A.4. Efforts to Identify Duplication and Use of Similar Information

If existing information already exists, a poison center follow–up investigation will be deemed unnecessary. Redundant data collection is avoided and the utility of the data collected are maximized. The poison centers will ask exposure-specific questions not initially collected and which are specifically tailored to minimize duplication of information already collected through normal poison center operations. Ensuring no duplication of information collection will reduce undue burden on the poison center callers who subsequently agree to follow-up.

Literature searches and discussions with other health authorities will be conducted to determine the extent of existing information. If found, previous information is used whenever appropriate to contribute to an investigation. However, a public health emergency generally requires the collection of data specific to the event because each situation is unique in many aspects (e.g., exposure, location, affected populations, sources of exposure, and modes of transmission, risk factors, and environmental factors). Each investigation will contribute to better understanding a particular type of outbreak or incident for the requesting agency, and data collections are designed to incorporate knowledge gained from similar situations in the past.

This new information collection will fill a gap in current surveillance efforts by enabling CDC and poison centers to collect in-depth exposure information for public health emergencies to improve public health for specific incidents.

A.5. Impact on Small Business or Other Small Entities

This data collection will not involve small businesses

A.6. Consequences of Collecting the Information Less Frequently

Each poison center investigation will be a one-time information collection undertaken during or immediately after a public health emergency.

There are no legal obstacles to reduce the burden.

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

Often, data need to be collected within hours or days of the request. Therefore, NCEH requests 5-day approval, or within 72 or 24 hours, if urgently needed. Because of the need to rapidly obtain information to appropriately respond to the urgent public health emergency, data collection must be completed within 60 days.

To comply with the regulation 5 CFR 1320.5 and at the same time ensure that public health data are collected in a timely manner as necessary to protect the health of the public, public health emergencies that fit the criteria for data collection will adhere to the following timeline and processes:

1. After an emergency incident is identified, the NCEH project officer reviews the "Step-by-Step How to use the Generic Clearance" guide (**Attachment 5**) and notifies the NCEH/ATSDR ICR Liaison (ICRL) of a potential poison center GenIC.
2. NCEH engages AAPCC to determine if the incident is an eligible public health emergency and ensures all data collection criteria are met (refer to Section A2).
3. Following concurrence from AAPCC, NCEH requests poison center(s) to collect follow-up information.
4. If a 72 or 24-hour approval will be requested, the NCEH project officer prepares and routes the Advance Notification Email with justification (**Attachment 6**) to the ICRL to provide as much advance warning as possible that the request is being prepared. This step is not needed for a 5-day approval.
5. The ICRL routes the 72 or 24-hour advance notification to the CDC Information Collection Request Office (ICRO), which in turn alerts the United States (US) Department of Health and Human Services (HHS) and the OMB desk officers to expect a new urgent poison center GenIC. Again, a 5-day approval will not require advance notification.
6. The NCEH project officer prepares and submits the GenIC package to the ICRL, which includes:
    a. GenIC Request for Approval (**Attachment 7**)
    b. Supporting Statement B
    c. Consent Form (**Attachment 8** - sample consent forms)
    d. Questionnaires for adults, adolescents, and parent or guardian of child (**Attachment 9-11** – sample questions that can be quickly modified)
    e. Worksheet 2
    f. GenIC NCEH Research Determination

g. Any other supporting documents

7. The ICRL reviews and submits the GenIC package to ICRO for processing with HHS and OMB.
8. The OMB desk officer responds with approval or comments on the proposed investigation within the time frame is requested (default is 5 days unless otherwise requested).
9. The OMB desk officer may provide approval and comments orally (followed by e-mail for written documentation) or e-mail directly. This may occur before the GenIC request is submitted and received by OMB through the official ICR tracking system.
10. Data collection proceeds upon approval and may not exceed 60 days.
11. Within 5 days of the completion of the data collection, the investigators submit the final data collection instrument(s), consent forms, and associated burden using the "Burden Memo" form (**Attachment 12**) to the ICRL.
12. On a quarterly basis, the ICRL will submit a non-substantive change request for all GenICs conducted in the prior quarter. The following documents will be submitted to support the request: burden memos, final questionnaires, and final consent forms.

The NCEH/ATSDR PRA contact serves in the role of the ICRL. The ICRL oversees the clearance process for individual GenICs.

The NCEH program will maintain a library of data collection instruments that includes all final data collection instruments conducted under this Generic ICR.

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

A 60-day Federal Register Notice was published on June 22, 2016, Vol. 81, No. 120, pp. 40698 (**Attachment 2**)**.** No public comments were received in reference to this Generic ICR.

The following agencies and organizations outside of CDC have been consulted on the need for data collection with the audiences, and for the purposes, described in this package:

Table A8-1. 2015 CDC External Consultations

Name	Title	Affiliation	Email
Jay Schauben, PharmD	President	American Association of Poison Control Centers	schauben@poison.ufl.edu
Stephen Kaminski, JD	Executive Director	American Association of Poison Control Centers	kaminski@aapcc.org
Michael Fraser, MPH	Acting Director	American Association of Poison Control	fraser@aapcc.org

	Data Services	Centers

A.9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

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

The NCEH/ATSDR Information Systems Security Officer (ISSO) reviewed this submission and determined that the Privacy Act does not apply and that no Privacy Impact Assessment is needed. A System of Record Notices (SORNs) will not be created.

CDC will not have access to individually identifiable information (IIF) for this data collection. IIF (e.g., name, phone number) is collected and maintained by the poison center as part of its routine collection for its own follow-up when an individual first contacts the poison center (refer to Table A1-1). The poison center will use this identifying information to reach back to ask more questions via this Generic ICR. Data collected by poison centers as described in this package will not have IIF and will be stored in a password-protected Microsoft Access database (**Attachment 14**). CDC will only receive de-identified information once data collection is complete. If an NPDS ID No. is available, then CDC will use this as a linking variable between NPDS records and poison center follow-up.

IIF owned by and stored on local poison center servers for the purposes of follow up is not uploaded to NPDS nor ever shared with CDC. Each individual poison center system is encrypted and password protected. The systems have very strict access rights that follow HIPAA guidelines. Each individual poison center owns their data.

Verbal consent will be obtained from respondents over 18 years of age. For respondents between 15 and up to 18 years old, assent and parental permission will be obtained. For children less than 15 years of age, the parent or legal guardian will consent to respond on behalf of the child. Sample consents are provided in **Attachment 8.**

For each investigation, we expect a questionnaire will be tailored for adults (**Attachment 9**) or adolescent (**Attachment 10**) to respond for themselves or for parents or guardians who are proxies for their children (**Attachment 11**). They will have approximately 25-31 questions that fall under various categories**.** Table A10-1 below summarizes the typical breakdown of questions in the example questionnaire.

Table A10-1. Overview of questions types used for data collection

Question Type	# of Questions Used
Exposure information	16
Health effects and medical treatment	8
Health messaging	3

Data is collected and sent to CDC in an encrypted Microsoft Access database, sample template is provided in **Attachment 14**. If needed at CDC, data will be exported from Access and analyzed in SAS. Because Access database encryption is not Federal Information Processing Standards (FIPS) 140-2 compliant, the data will be transmitted through CDC's secure and FIPS-compliant file transfer protocol (FTP) site.

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

The NCEH Human Subjects Contact has reviewed and classified the overall scope of these investigations to be non-research (**Attachment 13**). Investigations will be undertaken to identify, characterize, and assist with an immediate public health emergency. The knowledge gained will directly benefit the affected community. Although the investigations will use systematic methods, they will not be designed to develop or contribute to generalizable knowledge to other populations or other public health emergencies. As such, information collection and information dissemination activities are not intended to guide significant policy or rulemaking.

Each GenIC submitted under this Generic ICR will be reviewed to assure human subjects protections. A separate research determination will be completed and submitted to OMB.

The majority of questions asked will not be of a sensitive nature. However, some respondents may find thinking about and discussing symptoms of an exposure unpleasant, or a portion of respondents could consider questions about race, ethnicity, demographic characteristics, or behaviors to be sensitive. Where relevant to the information collection, race and ethnicity data will be collected consistent with HHS policy and standard OMB classifications.

Additionally, some respondents may feel uncomfortable answering particular questions about their course of treatment as a result of the exposure. Such questions, if asked, would be necessary for the purposes of a targeted CDC activity and thus to the information collection. To minimize psychological distress, the poison center interviewer will inform participants that they do not have to respond to any questions they do not want to answer and they may stop participating at any time.

Social security numbers will not be needed and will not be collected.

A.12. Estimates of Annualized Burden Hours and Costs

Table A12-1 presents the estimated annual time burden to respondents for this data collection. The respondents for the information collection include adults, adolescents, and parents or guardians of children with an exposure during an emergency. The time burden for each respondent will average 40 minutes as the upper limit for the telephone questionnaire. The estimated total number of respondents for all information collections has been calculated based on the following assumption: two incidents per year with a sample size of approximately 150 respondents (total = 150*2 = 300). These estimates were derived from information gathered during previous data collections that had utilized NPDS. The number of participants can vary due to poison center capacity, the number of poison centers participating, the number of individuals affected, and funding constraints. The respondent populations for a single incident have been an average of 150 respondents or less, which we believe is a conservative estimate for each incident that is submitted under this data collection request. Using these calculations, we anticipate a total annualized burden of 200 hours (300*40/60).

Table A12-1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Adult Poison Center Callers	Sample Questionnaire - Adults	210	1	40/60	140
Adolescent Poison Center Callers	Sample Questionnaire – Adolescent	30	1	40/60	20
Parent or Guardian Poison Center Callers	Sample Questionnaire – Parent or Guardian	60	1	40/60	40
Total					**200**

Table A12-2 presents the estimated annual burden costs to respondents for this data collection. Hourly mean wage information is from the U.S. Department of Labor's Bureau of Labor Statistics website, specifically originating from the 2014 National Occupational Employment and Wage Estimates for the United States (http://www.bls.gov/oes/current/oes_nat.htm#00-0000). Since this data collection would include collecting data from members of the general public, an average rate for all occupations, or $22.71 per hour, is used. For adolescents, the federal minimum wage rate of $ 7.25, is used (https://www.dol.gov/whd/minwage/q-a.htm). Using the burden hours

calculated in Table A12-1 and our wage estimates, the total estimated annualized respondent cost is $4,232. (180*$22.71 plus 20*7.25).

Table A12-2: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adult Poison Center Callers	Sample Questionnaire - Adults	140	$22.71	$3,179
Adolescent Poison Center Callers	Sample Questionnaire - Adolescents	20	$7.25	$145
Parent or Guardian Poison Center Callers	Sample Questionnaire – Parent or Guardian	40	$ 22.71	$908
Total				**$4,232**

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

No capital, start-up, or maintenance costs are involved.

A.14. Annualized Cost to the Federal Government

There are no equipment or overhead costs. The only direct cost to the federal government would be the salary of CDC staff supporting the data collection activities preparation and data analysis. The estimated annualized direct cost to the federal government is $6960. Table A14-1 describes how this cost estimate was calculated.

These data collections will be conducted by poison center staff. Since the data collection effort will go beyond the regular business operations of poison centers, participating poison centers will be paid for the tasks by CDC through the existing cooperative agreement (CDC-RFA-EH15-1506) in place with AAPCC. Participating poison centers will be identified using a vetting process through AAPCC where payment will be on a per-incident basis. The estimated cost to the federal government for these other expenses is $120,000. Estimates of the costs of reimbursing the poison centers for their data collection efforts are included in Table A14-1.

The total annualized cost to the federal government, including direct costs and contractual costs is $122,784.

Table A14-1: Estimated Annualized Cost to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Cost to the Federal Government		
Associate Service Fellow (GS-12) – Develops and changes the instrument, prepares OMB package, analyzes data	$34.80 hourly salary, 40 hours staff time per data collection; 2 data collections per year $34.80*40*2	$2,784
Subtotal, Direct Costs to the Government per year		**$2,784**
Cooperative Agreement Cost and Other Expenses		
Funding for poison center data collection costs	Estimates derived from a previous study with costs of approximately $400 per response ($400*300)	$120,000
Subtotal, Contract and Other Expenses per year		*$120,000*
Total of all annualized expenses		***$122,784***

A.15. Explanation for Program Changes or Adjustments

This is a new information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The epidemiologic data collected in each investigation provides information necessary for an effective public health response to an incident with adverse health consequences. Therefore, it is critical to collect data as soon as possible after the incident is identified. The duration of each investigation varies; however, data collection must be completed within 60 days of the incident.

For each investigation, the CDC staff is responsible for developing an analysis plan and conducting the data analysis of the de-identified data (**Attachment 14 – Example dataset**). Data analysis could include data cleaning, descriptive analyses, and trend analysis. Appropriate statistical software (e.g., SAS, etc.) will be utilized, as necessary.

Findings are generally provided to emergency responders and epidemiologists at the federal, state, and local level for situational awareness. Findings are shared with the CDC Emergency Operations

Center (EOC), if activated, state emergency responders, and state epidemiologists. Any publication of data derived from an investigation is subject to review by CDC, AAPCC, poison centers and state health departments where the incident occurred, and other collaborating federal agencies.

Final findings will be disseminated to the larger public health community through presentations and/or posters at meetings and publications in peer-reviewed journals. Abstracts, poster presentations, and manuscripts will undergo an internal scientific review prior to submission to conferences or journals. CDC may also disseminate the findings, as appropriate, through Morbidity and Mortality Weekly Report (MMWR) publications, Center reports, or CDC web pages. Information that is disseminated will remain de-identified.

In some cases, the results of information collection will not be published; instead, the information will be used to inform activities across CDC or the community impacted by the public health incident.

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

The display of the OMB expiration date is not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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