ATSDR Exposure Investigations (EIs)

OMB Control No. 0923-0048 (Expiration Date: 06/30/2025)

Extension

Supporting Statement Part A –

Justification

Program Official:

Karen Scruton, MS
Section Chief, Exposure Investigations Section
Office of Community Health Hazard Assessment
Agency for Toxic Substances and Disease Registry
4770 Buford Hwy NE, MS 106-5
Atlanta, GA 30341
Phone: 770-488-1325
Fax: 770-488-1542
Email: isg3@cdc.gov

Date: XX

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Part A. Justification

ATSDR Exposure Investigations (EI)

Goal of the study: Under this generic clearance, ATSDR conducts exposure investigations (EIs) to determine whether people are or have been exposed to unusual levels of pollutants at specific locations.

Intended use of the resulting data: Beginning in 1995, public health professionals, environmental risk managers, and other decision makers have used data from ATSDR's EI reports to determine if conditions warrant additional sampling and to decide if intervention is needed to minimize or eliminate exposure. ATSDR has completed over 250 EIs during the course of the EI program.

Using data collected under this generic clearance information collection request (ICR), decision makers can determine whether exposure resulting from environmental contamination has occurred in a community. The results of the EI are used to recommend methods for communities to reduce exposure, if needed.

Methods to be used to collect: The intent of using purposive, convenience sampling for participants is to identify and investigate the most highly exposed individuals in the community.

Subpopulation to be studied: An ATSDR team identifies a subpopulation for each EI based on the type of environmental contamination present at the site, for example, participants may be preschool children or pregnant women when testing blood for lead.

How data will be analyzed: Biological or environmental samples will be analyzed at an accredited laboratory and the data results will be evaluated using ATSDR Public Health Assessment (PHA) evaluation methods to determine whether participants have been exposed to environmental contaminants. ATSDR may also provide individual exposure information to participants, although this is not the primary purpose of the investigation.

A.1. Circumstances Making the Collection of Information Necessary

This is a request for a three-year extension of a generic clearance information collection request (ICR) titled the *ATSDR Exposure Investigations (EI)* (OMB 0923-0048, expiration date 06/30/2025) to continue to allow the Agency to carry out its public health activities in a timely and efficient manner. ATSDR is authorized to conduct EIs under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the "Superfund" Act, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986 (**Attachment 1**). Under CERCLA, ATSDR works closely with the U.S. Environmental Protection Agency (EPA) to evaluate the presence and nature of hazardous substances at specific sites and the levels at which these substances may pose a threat to human health. ATSDR works to prevent or reduce further exposure and the illnesses that result from such hazardous substances. The 60-day Federal Register Notice was published on November 4, 2024 (**Attachment 2**) and is further discussed in Section A.8.

The ATSDR Office of Community Health Hazard Assessment (OCHHA), formerly the Division of Community Health and Investigation (DCHI) conducts public health assessments (PHAs) at sites when requested by the U.S. EPA, states, organizations, or individual petitioners following the *Public Health Assessment Guidance Manual* (ATSDR, 2022).[1] The purpose of the agency's PHA process is to find out whether a community has experienced environmental exposures of concerns or is now being exposed to hazardous substances and, if so whether conditions warrant additional sampling and to decide if intervention is needed to minimize or eliminate exposure. The process also serves as a mechanism through which the agency responds to specific community health concerns related to hazardous waste sites.

In summary, the PHA process includes the following steps:

- Obtaining site information;
- Involving and communicating with the community;
- Exposure evaluation;
- Health outcome evaluation; and
- Determining conclusions and recommendations

Exposure assessment is the hallmark of the PHA process. ATSDR scientists review environmental data to see how much contamination is at a site, where it is, and how community residents might come into contact with it. Generally, ATSDR does not collect its own environmental sampling data but reviews information provided by federal and state government agencies and/or their contractors, potentially responsible parties, and the public.

[1] Available at, https://www.atsdr.cdc.gov/pha-guidance/index.html.

When adequate environmental or exposure information to assess human exposures and possible related health effects do not exist, however, ATSDR will perform an EI. The EI team conducts point of human-contact sampling focused on geographic areas where exposures are expected to be high. EIs may include environmental (e.g., soil, drinking water, sediment, food sources) or biological sampling (e.g., blood or urine), or both (ATSDR, 2022).

Within ATSDR, the OCHHA Exposure Investigations (EI) Team is a multidisciplinary group of 6-8 scientists with expertise in environmental health science and engineering, industrial hygiene, data analysis, epidemiology, toxicology, and medicine. To conduct an EI, requesters must receive approval from the EI team based on the answers to the following questions:

1. Can an exposed subpopulation be identified?
2. Does a data gap exist that affects the ability to determine if a health hazard exists?
3. Can an EI be designed that will address this data gap?
4. How will the EI results impact the public health decision-making for the site?

If the answers to these questions indicate that an EI would allow ATSDR to make a better-informed public health call, the OCHHA EI Team may conduct agency-led EIs. An EI, using purposive convenience sampling, aims to identify the most highly exposed individuals and measure their exposure. The results of the investigation are site-specific and apply only to the participants from the site. An EI is not considered a health study or research, and any data gathered will thus not be disseminated as such. Furthermore, the EI is not designed to provide individual diagnoses, nor are participants' results intended to be generalized to other populations and other communities. No participants from external comparison groups are included in the data collection. As a public service and incentive to participate, EIs provide individual exposure information back to the participants.

The EI team also coordinates and lends technical assistance to states, tribal, and territorial health departments that conduct their own EIs. Currently, ATSDR is administering a multi-year cooperative agreement program called the "ATSDR's Partnership to Promote Localized Efforts to Reduce Environmental Exposure (APPLETREE) Program" Award No. CDC-RFA-TS-23-0001) [2] which sponsors state-led non-research EIs. ATSDR anticipates that future OCHHA cooperative agreement programs will also include this long-established PHA process and underlying EI activity under the scope of this generic clearance. If future revisions to the scope of the generic clearance are necessary, ATSDR will request OMB review and approval for changes via a formal ICR revision request.

During the past three years, one generic EI information collection request was submitted. The EI conducted under this clearance period was an EI in Jasper and Newton Counties, Missouri to evaluate exposure to lead in a former mining community. ATSDR collected blood samples from

[2] The APPLETREE cooperative agreement program specifies that funded state, tribal, and territorial partners are limited to conducting nonresearch EIs. For these, ATSDR may provide technical assistance.

community members most vulnerable to the impacts of lead exposure: children 5 years old and younger along with pregnant women and women of childbearing age. ATSDR partnered with the U.S. Environmental Protection Agency (EPA) and the Missouri Department of Health and Senior Services (MDHSS) who collected environmental samples, including soil, dust wipes, drinking water and paint, to evaluate along with the results of the blood sampling. Appropriate EI procedures, including use of appropriate consent forms and questionnaires were used in the EI. The environmental sampling was submitted under this OMB control number with a burden of 426 hours.

In order to continue this necessary public health function, ATSDR is requesting approval of this extension of the existing generic ICR. Public health concerns leading to requests for an EI can be time-critical to document that an exposure exists and to address a number of public health hazard categories, such as urgent public health hazards.[3] The EI team will ensure that OMB can perform a timely and expedited review for individual EIs under this generic clearance by submitting a standardized review packet that will provide all necessary information.

A.2. Purpose and Use of the Information Collection

The primary objectives of the information collected for EIs under this generic information request are to assess exposures to environmental contaminants using purposive, convenience sampling. Data obtained during EIs include biological (blood, urine and other biological samples) and environmental (water, air, soil and other environmental media) sampling. Information obtained from the participants assists the team in determining if exposure has occurred or is occurring; exposure findings will be compared to scientific literature regarding potential harm at those exposure levels. Data collected from the participants will not be utilized to assess for health outcomes in respondents. For each EI, a data collection system will include

[3] ***Public health hazard categories*** **-** Public health hazard categories are statements used in PHAs about whether environmental conditions in a community are such that people could be harmed by conditions present at the site in the past, present, or future. One or more hazard categories might be appropriate for each site. There are five public health hazard categories (ATSDR, 2005). 1) ***No public health hazard*** - A category used in ATSDR's public health assessment documents for sites where people have never and will never come into contact with harmful amounts of site-related substances. **2) *No apparent public health hazard* -** A category used in ATSDR's public health assessments for sites where human exposure to contaminated media might be occurring, might have occurred in the past, or might occur in the future, but where the exposure is not expected to cause any harmful health effects. **3) *Indeterminate public health hazard* -** The category used in ATSDR's public health assessment documents when a professional judgment about the level of health hazard cannot be made because information critical to such a decision is lacking. 4) ***Public health hazard* -** A category used in ATSDR's public health assessments for sites that pose a public health hazard because of long-term exposures (greater than 1 year) to sufficiently high levels of hazardous substances or radionuclides that could result in harmful health effects. 5) ***Urgent public health hazard* -** A category used in ATSDR's public health assessments for sites where short-term exposures (less than 1 year) to hazardous substances or conditions could result in harmful health effects that require rapid intervention.

all of the measurements and procedures that are proposed to address data gaps in biological and environmental sampling.

The data collection system for EIs will be characterized by the following:

A. Who can use the EI Generic Clearance?

The OCHHA EI team and the ATSDR staff and partners in the OCHHA cooperative agreement program will use the EI Generic Clearance for OMB submittals for each EI.

The OCHHA cooperative agreement operates across ten ATSDR regions across the nation. In 2012, the site work in the ten regions were functionally reorganized (Federal Register, Volume 77 No. 221, 15 Nov 2012, Pages 68125-7; seehttps://www.atsdr.cdc.gov/states/index.html. ATSDR OCHHA was divided into three functional units that administer its ten regions and its cooperative agreement program: Eastern Branch, Central Branch and Western Branch. The EI Team supports all three OCHHA branches. It is uncertain at this time how many EIs across the states, regions, and branches will require an expedited approval at the same time. **Attachment 3** provides a map of the EPA regions and ATSDR branches. The National Center for Environmental Health (NCEH) may also use this generic clearance mechanism to perform some of their important work.

B. Who can be included as part of the EI Generic Clearance?

EI participants will vary based on the nature of the EI but will likely include community members that ATSDR has identified as being at high risk of exposure to a contaminant and those who are concerned that they have been exposed to environmental contamination. As previously described, the EI will be conducted if the potentially exposed sub-population can be identified at a particular site. Investigations tend to focus on the most highly exposed at the site, such as those living in proximity to the site. On occasion, small businesses may be included as EI participants. Based on past experience, we estimate that 2 percent of the EI participants per year may involve small businesses.

C. What types of questions may be asked as part of the EI Generic Clearance?

Attachment 4 provides a bank of questions that may be used to evaluate chemical exposure of individuals and communities for EIs. It is not required that the questions in **Attachment 4** be used in the EI, but these questions will be considered. Further details regarding the types of questions that may be included as part of the EI are discussed in the following sections.

D. What are the benefits to using the EI Generic Clearance?

The benefits to using the EI Generic Clearance include providing a standardized review package for each EI. The template will provide all needed information in a clear, concise document to expedite PRA clearance.

Where needed, additional questions will be developed for the EI to assess environmental exposures (Tables A.2-1 and A.2-2). In deciding where and from whom to gather information, ATSDR considers the following:

- Can we identify and test the highly exposed sub-population?
- Can we identify vulnerable sub-populations, including children or those more susceptible to specific contaminants?
- How should we test children and other sensitive populations? For example, it may not be appropriate to collect the required sample (70-ml blood) for dioxins from a small child, pregnant woman, or an anemic or underweight person.
- If we do pre- and post-testing to check intervention or environmental remediation effectiveness, how will participants be selected if the original participants are not available? If pre- and post-testing will be performed, separate ICRs will be prepared for each time frame.

ATSDR asks approximately 12-20 questions per investigation that are pertinent to environmental exposure. This number can vary depending on the number of chemicals being investigated, the route of exposure (breathing, eating, touching), and number of other sources of the chemical(s) (e.g., products used, jobs done).

Although some of the information is entered on paper, where practical, we load the information collection form onto a laptop and record the answers electronically. ATSDR computers comply with the HHS Standard 2008-0007.001S for encryption. We generally interview people in their homes or at a central testing location.

All environmental and biological sampling will be overseen by the federal or state EI lead. Environmental samples will be collected by appropriate EI personnel (assistance from state and local partners and contractors may be obtained) and shipped directly to the appropriate laboratories for analysis. Biological samples and documentation will be obtained by trained personnel, such as registered nurses (RNs), and shipped directly to qualified laboratories for analysis. Appropriate Quality Assurance Plans will be prepared and implemented by ATSDR, states, and contractors, as appropriate.

Examples of the information that may be collected during environmental and biological sampling events are provided in Tables A-2.1 and A-2.2.

Table A-2.1

EI Activities Requiring Information from Property Owner or Resident for Environmental Sampling

Information Collection Methods	Examples of Needed Information
Demographic questionnaire (see Question Bank provided in Attachment 4 for suggested questions)	- Demographic data and residential history - Daily activities - Occupational history
Household questionnaire (see Question Bank provided in Attachment 4 for suggested questions)	- Indoor home heating fuel - Water source, and household filtration system - Volatile organic compound (VOC) storage
Visual inventory of home by Field Interviewer	- Layout of home in relation to environmental surroundings (e.g., proximity to a water sources, location of private well or septic systems)

Table A-2.2

EI Activities Requiring Information from Property Owner or Resident for Biological Sampling

Information Collection Methods	Examples of Needed Information
Demographic questionnaire (see Question Bank provided in Attachment 4 for suggested questions)	- Demographic data and residential history - Daily activities - Occupational history
Household questionnaire (see Question Bank provided in Attachment 4 for suggested questions)	- Indoor home heating fuel - Water source, and household filtration system - VOC storage
Visual inventory of home by Field Interviewer	- Layout of home in relation to environmental surroundings (e.g., proximity to a water sources, location of private well or septic systems)

Biological sampling of participant by appropriate health professional	- Height and weight - Urine sample collected for biological indicators or specific environmental contaminants - Blood specimen collected for biological indicators or specific environmental contaminants

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

Generally, ATSDR interviews people in their homes either in-person or over the phone. Where practical, we will record the results of the interview electronically as we are interviewing the participants. The use of electronic data collection as compared to paper collection has steadily increased with time. Any data on laptops will be encrypted in accordance with information systems security requirements for safeguarding personally identifiable information. That information is stored in a secure database along with the laboratory and/or modeling results.

Several procedures may be used to sign up participants for the EI, such as newsletters or recruitment posters. Usually, the participants are targeted for inclusion in the EI and initial contact is made with potential participants through mail or phone.

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

ATSDR determined through literature and internet searches, discussions with other public health and environmental professionals, and attendance at meetings that other agencies are asking or have asked similar questions. *However, their questions and resulting data are being used for population-based research and modeling, policy setting, or behavioral change through education.* Since our information collection is *inherently person- or location-specific*, we cannot use the results of national probability surveys to inform our site-specific work. Again, the intent of the EI is <u>not</u> to generalize information to represent population-based data or to draw conclusions about the health or medical effects of the exposures documents, but to match the unique answers given by participants with their laboratory results or environmental samples to determine whether community intervention is needed to reduce exposures. We have, however, found some of the questions from other federal agencies' surveys useful to identify appropriate

chemical exposure questions. We have also used reference values from the *Fourth National Report on Human Exposure to Environmental Chemicals* as national comparison values for EI participant results (see http://www.cdc.gov/exposurereport/).

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

Every effort is made to minimize the burden on all participants in EIs. Very few of our EIs (approximately 2 percent) have involved small businesses. On occasion, ATSDR has asked for participation from employees and attendees of daycare facilities and schools. When such an entity will be involved in an EI, ATSDR will identify these in each request for approval under this generic clearance.

A.6. Consequences of Collecting the Information Less Frequently

The vast majority of EIs are a one-time sampling or modeling event related to a specific exposure situation. At times, the results of the first sampling event require that we collect additional samples (either environmental or biological). Participants in EIs are generally asked one set of questions per sampling event. If we need to conduct additional sampling (e.g., to assess the effectiveness of an intervention), we would request that the participants answer another set of appropriate questions.

If ATSDR determines that additional follow-up investigation is needed, ATSDR would obtain a separate PRA clearance under this generic mechanism to conduct that investigation.

There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* Vol 89, No. 213, pg. 87579, November 4, 2024 (**Attachment 2**). CDC/ATSDR did not receive public comments related to this notice.

B. Below is a list of individuals and groups outside of the agency who were consulted in 2006, to obtain their views on the availability of data, the clarity of instructions and information, and the completeness of the material.

- *Sharon Lee*, Division of Environmental & Occupational Disease Control,
  CA Dept of Health Services
  & Facilitator of the Interstate Chemical Terrorism Workgroup

  ATSDR solicited comments through Ms. Lee from the Interstate Chemical Terrorism Workgroup and requested information on other surveys. More than 30 state representatives reviewed the chemical exposure questions. ATSDR received oral and written comments from 10 representatives and added questions from other surveys.

- *Laura Fenster*, PhD., Epidemiologist
  Occupational Health Branch
  CA Dept of Health Services

  Dr. Fenster reviewed the chemical exposure questions and provided comments. She also provided information on other surveys and ATSDR incorporated some of the questions into the chemical exposure questions.

- *Bruce Bernard, M.D., M.P.H.*
  Medical Section Chief
  Hazard Evaluations and Technical Assistance Branch
  Div of Surveillance, Hazard Evaluations & Field Studies
  National Institute for Occupational Safety and Health (NIOSH)
  Centers for Disease Control and Prevention (CDC)

  Dr. Bernard provided review of portions of the package pertaining to occupational exposure.

Subsequent to 2006, ATSDR has not sought additional consultations because EI methods have been long established and have been successful for the stated goals of the EI program. ATSDR has completed over 250 EIs over the time that the EI program has been in place. After 2005, ATSDR discovered that PRA clearance was required; therefore, 31 of those EIs were completed under *NCEH/ATSDR Exposure Investigations (EI)* (OMB Control No. 0923-0040, expiration date 12/31/2012). From 2012 to 2025, ATSDR completed 8 EIs under the current generic clearance (OMB Control No. 0923-0048; expiration date 06/30/2025).

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

Although EIs usually do not involve any payments, occasionally ATSDR may request approval for monetary tokens of appreciation. For all instances in which incentives are provided for participation, a comprehensive justification will be provided for the amount requested describing why a token of appreciation is necessary and evidence supporting the dollar amount. If respondents participate in these kinds of studies remotely, via phone, or Internet, any proposed incentive must be justified to OMB and must be considerably less than that provided to respondents in in-person studies, who have to travel to the agency or other facility to participate. If such information collections include hard-to-reach groups and the agency plans to offer non-standard payments, the Agency will provide OMB with additional justifications in the request for clearance of these specific activities.

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

For the initial 2013 PRA clearance, it was determined that the Privacy Act does apply. There are no proposed changes to the system. The applicable Privacy Act System of Records Notice (SORN) is No. 09-19-0001, "Records of Persons Exposed or Potentially Exposed to Hazardous or Toxic Substances (retrievable by name or SSN).

The following IIF Categories apply to this information collection (**Attachment 4**):

❑ Name	❑ Phone Numbers
❑ Date of Birth	❑ Biological Specimens
❑ Mailing Address	❑ Email Address

A Privacy Impact Assessment (PIA) form provides information that will be collected from respondents and how it will be secured (**Attachment 6**). A Privacy Act Statement is included in the consent package (**Attachment 5**).

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. Once we conduct a convenience sampling EI, we match the unique answers given by participants with their laboratory results or environmental samples to determine whether intervention is needed on an individual level. The information collection is therefore *inherently person- or location-specific.* Participation is completely voluntary; participants can stop participating in the EI at any time.

ATSDR uses the IIF only to contact respondents. IIF is necessary to facilitate the personal contact with respondents to conduct the survey, to obtain consent to participate, and to provide them their results. All IIF maintained by the agency will be managed by ATSDR and is

subject to the ATSDR Comprehensive Record Control Schedule (CRCS), B-371, which contains authorized disposition instructions for ATSDR's administrative and program records.

For EIs completed by states, Sunshine Laws may apply. Sunshine Laws require openness in government, which may result in personal identification being accessible by the general public. For those states with Sunshine Laws, the consent form will include a statement indicating that these laws may apply.

Data are treated in a private manner, unless otherwise compelled by law. The paper document containing IIF are kept in locked file cabinets at ATSDR. Access to computer files is password-protected and access is limited to authorized EI personnel. All staff working on the project agree to safeguard the data and not to make unauthorized disclosures. Any data on laptops will be encrypted in accordance with information systems security requirements for safeguarding personally identifiable information. Data are safeguarded in accordance with applicable statutes. Responses in published reports are presented in aggregate form and no individuals are identified by name.

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

Federal Regulations for Protection of Human Subjects (45 CFR 46) state that "*research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." In contrast, EIs are generally intended to be systematic investigations but are not designed to develop or contribute to generalizable knowledge. An EI is considered a service, and not a health study. Comparison populations are not used and the results of the investigation are site-specific and applicable only to the participants of the investigation.

However, ATSDR does require that participants in EIs be fully informed of the potential risks and benefits of their participation and that the privacy of the participants' information be protected. All consent forms will be EI-specific and will include all appropriate information from the Privacy Act including authority and purpose for collecting the data, with whom identifiable information will be shared, the voluntary nature of the information collection and the effect upon the respondent for not participating. Examples of assent/consent/parental permission forms that may be used to conduct an EI and included in an OMB package are provided in **Attachment 5**. All consent forms accompanying a particular EI will be submitted as supplementary documentation in the generic submission.

Through convenience sampling, EIs are generally a non-research activity and human subjects review by an Institutional Review Board (IRB) will not be required. A program research determination is provided in **Attachment 7**. On occasion as indicated in the *Public Health*

Assessment Guidance Manual (ATSDR, 2005),[4] state or CDC IRB review will be obtained if the purpose or methods of the EI is expanded to provide more than basic service (e.g., secondary use of identifiable EI data to answer a research question, if vulnerable populations will be involved, or if circumstances would be considered greater than minimal risk in a research setting).

All ATSDR EIs are reviewed by the NCEH/ATSDR Human Subjects Coordinator who is designated to make human subjects research-or-non-research determinations on an EI-by-EI basis.

ATSDR sometimes gathers information that may be considered sensitive about individual characteristics (e.g., sex, age, weight, ethnicity, and race) to assist with interpretation for biological samples. For example, if ethnicity and race information is collected, the individual's laboratory results are compared to similar ethnicity and race results in the *National Report on Human Exposure to Environmental Chemicals* (see citation above). Beyond that, generally, questions of a sensitive nature are not asked.

Occasionally, we may need to ask sensitive questions on symptoms, medical outcomes, or drug and medication use to assist us in interpreting an individual's laboratory results. ATSDR may also ask questions pertaining to recent or current pregnancy status for one of two reasons: 1) pregnancy makes a woman and her unborn child more vulnerable to the effects of some chemicals (e.g., lead) or 2) some blood tests require a large quantity of blood. For example, it is generally difficult to collect a 70-ml blood sample for dioxins from a small child, pregnant woman, or an anemic or underweight person.

Social security numbers are not needed nor will be requested.

A.12. Estimates of Annualized Burden Hours and Costs

A. Estimates of Annualized Burden Hours

Generally, the number of participants per investigation ranges from 10 to 100. Therefore, we estimate that the maximum total number of respondents annually is 1,200 (12x100). Generally, we ask the questions once.

The time burden per respondent is estimated at 30 minutes. A typical survey may include up to 20 general questions taking less than 30 seconds each to respond and 20 more in-depth exposure specific questions requiring less than one minute each. This estimate is consistent with our results from EIs conducted in the past few years. The total estimated annual time burden remains unchanged at 600 hours.

Estimated Annualized Burden Hours

Type of	Form	No. of	No. of	Average Burden	Total Burden

[4] http://www.atsdr.cdc.gov/hac/PHAManual/PDFs/PHAGM_final1-27-05.pdf. See Page 6-31.

Respondents	Name	Respondents	Responses per Respondent	per Response (in hours)	(In Hours)
EI participants	Chemical Exposure Questions	1,200	1	30/60	600

B. Annualized Cost to Respondents

Using a rate of $31.48/hr, the annualized cost to respondents for the hour burdens for the collection of information is $18,888. The hourly wage rate is based on the U.S. Department of Labor, Bureau of Labor Statistics' most current statistics [May 2023 National Occupational Employment and Wage Estimates United States, Online February 2025, https://www.bls.gov/oes/current/oes_nat.htm].

Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per Response (In hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
EI participants	Chemical Exposure Questions	1,200	1	30/60	600	$31.48	$18,888

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

There is no other total annual cost burden to respondents or record keepers.

A.14. Annualized Cost to the Federal Government

Costs for ATSDR personnel and cooperative agreement state personnel were estimated based on experience with previous EI activities.

For the past 3 years, the annual budget for EIs has been $960,000. This includes: FTEs (including benefits), contractors, travel, per diem, and laboratory, supply, and equipment costs. We expect the budget to remain unchanged for the next three years.

A.15. Explanation for Program Changes or Adjustments

The burden has not changed from the burden shown in the current inventory.

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

A project Time Schedule will be provided for each EI submitted under the generic clearance. The Time Schedule for the EI will be variable, based on site-specific conditions. The time frame for collecting the environmental and/or biological data for an EI can range from one day to several months, depending on the sampled medium and complexity of the EI. The following is a general schedule that is anticipated for most EIs.

Table A.16.1

Project Time Schedule	
Activity	Time Schedule
Start of Data Collection	1—2 months after OMB approval
Field Work	1—8 months after OMB approval
Analysis	8—12 months after OMB approval
Respond to Participants	12—18 months after OMB approval
Written Report	18—36 months after OMB approval

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

The display of the OMB expiration date is appropriate.

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

There are no exceptions to the certification.

List of Attachments

Attachment 1. Authorizing Legislation -CERCLA

Attachment 2. 60-day Federal Register Notice

Attachment 3: Map of EPA and ATSDR Regions

Attachment 4: Chemical Exposure Question Bank

Attachment 5: Example Consent Form

Attachment 6: Privacy Impact Assessment (PIA)

Attachment 7. Program Research Determination