

# **Blood Lead Levels in Iola, Kansas Exposure Investigation**

ATSDR Exposure Investigations (EI) Generic Information Collection Request  
OMB No. 0923-0048  
Expiration Date: 03/31/2019

## **Supporting Statement Part A**

**Submitted: November 14, 2016**

Science Support Branch (SSB)  
Division of Community and Health Investigations (DCHI)  
Agency for Toxic Substances and Disease Registry (ATSDR)

### **Program Official:**

Peter J. Kowalski, MPH, CIH  
Lead, Exposure Investigations and Data Analysis Team  
Science Support Branch  
Division of Community Health Investigations  
Agency for Toxic Substances and Disease Registry  
4770 Buford Hwy NE, MS F59  
Atlanta, GA 30341  
Phone: 770-488-0776  
Fax: 770-488-1542  
Email: [PKowalski@cdc.gov](mailto:PKowalski@cdc.gov)

## Table of Contents

A. Justification.....	6
A.1 Circumstances Making the Collection of Information Necessary.....	6
A.2. Purpose and Use of Information Collection.....	9
A.3. Use of Improved Information Technology and Burden Reduction.....	9
A.4. Efforts to Identify Duplication and Use of Similar Information.....	10
A.5. Impact on Small Businesses or Other Small Entities.....	10
A.6. Consequences of Collecting the Information Less Frequently.....	10
A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	10
A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	11
A.9. Explanation of Any Payment or Gift to Respondents.....	11
A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	11
A.10.1. Privacy Impact Assessment Information.....	11
A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	15
A.12. Estimates of Annualized Burden Hours and Costs.....	15
A.12.1. Estimates of Annualized Burden Hours.....	15
A.12.2. Annualized Cost to Respondents.....	16
A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	16
A.14. Annualized Cost to the Government.....	16
A.15. Explanation for Program Changes or Adjustments.....	17
A.16. Plans for Tabulation and Publication and Project Time Schedule.....	17
A.17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	18
A.18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	18

**Attachments:**

1. Supporting Statement A
2. Supporting Statement B
3. Iola, KS EI Parental Permission/Assent/Consent Forms
  - 3A. Parental Permission Form for Blood Lead Testing and Questionnaire: Children Younger than 18 years
  - 3B. Assent Form for Blood Lead Testing and Questionnaire: Children and Youth aged 6 to 17 Years
  - 3C. Consent Form for Blood Lead Testing and Questionnaire: Pregnant Women and Women of Childbearing Age aged 15 to <45 Years
4. Iola, KS EI Questionnaire
5. Iola, KS EI Research Determination
6. Iola, KS EI Sample Results Letters
  - 6A. Sample Results Letters to the Parent of a Participant aged Younger than 6 Years
  - 6B. Sample Results Letter to a Pregnant Woman or Woman of Child Bearing Age aged 15 to <45 Years
  - 6C. Inserts for Results Letters
  - 6D. Factsheets for Results Letters
7. Example of Prior EI Final Report
8. BLL Iola EI Protocol



**Goal of the Study:** This project has three primary objectives:

1. Evaluate Blood Lead Levels (BLLs) for susceptible populations
  - children younger than 6 years who live in properties where EPA testing documents lead levels in soil of > 800 mg/kg.
  - women who are pregnant or of childbearing age who live in properties where EPA testing documents lead levels in soil of > 800 mg/kg.
2. Recommend case management for participants with BLL  $\geq 5 \mu\text{g/dL}$ 
  - Recommend follow-up with a Pediatrician/Obstetrician
  - Recommend ways to lower exposure to contaminated soil
  - Recommend ways to lower exposure to dust in houses built before 1978.
  - Provide information on nutrition that will help to decrease the absorption of lead into the body.
3. Coordinate with EPA to use BLL results to prioritize site cleanup (i.e., participants with BLL  $\geq 10 \mu\text{g/dL}$  and yard soil levels  $\geq 400 \text{ mg/kg}$  will be given priority)

**Intended Use of the Resulting Data:** Data will be determine whether participants have BLLs  $\geq 5 \mu\text{g/dL}$ , the CDC reference level. Soil in Iola was contaminated with lead from former smelter activities and the site has been designated a National Priority List (NPL) site (aka Superfund site). EPA is currently remediating residential properties and the BLL results will be used to assist EPA in prioritizing locations for cleanup. The results of this EI are not intended to be generalized and are applicable only to the sampled participants.

**Methods to be Used to Collect:** BLL sampling will be done during two seasons: winter 2016/2017 and summer 2017. For the winter sampling event, participants will be recruited from homes that have  $\geq 800 \text{ mg/kg}$  lead in soil that has not yet been remediated by EPA. The summer sampling event will attempt to retest the participants from the winter event as well as additional community members.

**Subpopulation to be Studied:** The EI will recruit children younger than 6 years old and women that are pregnant or of childbearing age. For the summer sampling event, the participants in the winter sampling event will be invited to participate in the second round of sampling. Additional participants may include siblings of participants that are older than 6 years of age, at the parent's request or any other child in Iola that was not recruited.

**How Data will be Analyzed:** The blood samples will be analyzed by the CDC National Center for Environmental Health Division of Laboratory Science (CDC/NCEH/DLS). The results will be provided to the EI team. The participants will be provided the results via a letter sent via US mail. Participants with BLL  $\geq 5 \mu\text{g/dL}$  will be personally contacted by the ATSDR Principal Investigator and follow-up will be conducted by Region 7 ATSDR and Pediatric Environmental Health Specialty Unit (PEHSU).

## A. Justification

### A.1 Circumstances Making the Collection of Information Necessary

This data collection is being conducted using the Generic Information Collection mechanism of the Agency for Toxic Substances and Disease Registry (ATSDR) Exposure Investigations (EIs) – OMB Control No.0923-0048, expiration date 3/31/2019. The data collection for the Former United Zinc and Associated Smelters site EI aligns with the agency’s mission.

The data collection is authorized by 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.

### ATSDR Public Health Assessment Process and the Role of the Exposure Investigation

The Former United Zinc and Associated Smelters site operated from 1902 to 1925. Smelting operations resulted in soils in the city of Iola, Kansas being heavily contaminated with lead. EPA began a removal investigation in 2005 and performed a Time-Critical Removal Action in 2005-2006. The site was placed on the NPL in 2013. A Remedial Investigation/Feasibility (RI/FS) study was finalized in July, 2016 and a proposed plan for cleanup of the site is available for comment through September, 2017.

In December 2003, the Kansas Department of Health and Environment (KDHE) began testing soil at the site. Lead was detected at levels as high as 49,000 mg/kg. EPA began testing soil in Iola in 2005 at residential homes, daycare facilities, schools and commercial area. Maximum concentrations of lead in soil were 2,290 mg/kg in residential yards and 6,433 mg/kg at commercial properties. EPA has sampled a total of 2800 locations: 1,700 in 2005-2006 and 1,100 in 2013.

EPA has divided the site into three categories called operable units (OUs). EPA often portions a site into smaller units, or OUs, to assist in site management and ultimate cleanup at a site. The criteria for the categorization into OUs are described below:

OU	Criteria	Remedial Action
<b>OU-00</b>	<ol style="list-style-type: none"> <li>1. Residential properties with soil lead greater than 800 mg/kg,</li> <li>2. Commercial areas such as schools and daycares where composite sample results exceed 400 mg/kg,</li> <li>3. Residential properties with soil lead between 400 and 800 mg/kg where a</li> </ol>	479 properties identified to date <ul style="list-style-type: none"> <li>• 129 residential properties remediated in 2005-2006</li> <li>• Two emergency removal actions were completed at Iola schools in 2005 (maximum soil level of</li> </ul>

	child with a BLL greater than 10 µg/dL resides. BLL from the EI may be used by EPA to identify these residential locations.	5,500 mg/kg) <ul style="list-style-type: none"> <li>• 350 residential properties currently being remediated</li> </ul>
<b>OU-01</b>	Residential properties with soil lead between 400 and 800 mg/kg where the blood level values are not known.	763 properties identified to date <ul style="list-style-type: none"> <li>• To be remediated after EPA chooses a remedy (in progress as part of the RI/FS process)</li> </ul>
<b>OU-02</b>	Commercial properties	Elevated lead soil levels will be remediated in the future

ATSDR Region 7 submitted a Health Consultation to the site partners that identified lead in soil at the site as a potential health risk to the Iola community. Partners include KDHE, EPA, the Southeast Kansas Multi-County Health Department (SEKMCHD) and the Pediatric Environmental Health Specialty Unit (PEHSU).

### The Exposure Investigation Criteria and Recommendation Process

Four criteria must be met for the EI to be approved and conducted. The criteria are:

1. Can an exposed population 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. Will the EI results impact the public health decision 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 DCHI EI Team may conduct agency-led EIs. For the Iola, KS site, the responses to the four questions (provided below) indicated that an EI is warranted at the site.

The EI Team from the DCHI Science Support Branch (SSB) and the ATSDR Region 7 Office will lead the investigation, evaluate the results, and communicate their public health findings and recommendations to the community (further discussed in Section A.2)

### Blood Lead Levels in Iola, KS Exposure Investigation

The four questions used to establish whether it was appropriate to conduct an EI for the Iola, KS site were as follows: Responses to ATSDR’s EI criteria are provided below:

1. *Can an exposed population be identified?*

Yes. EPA records indicate that there are 215 residential properties where testing documents lead levels in soil of > 800 mg/kg that have not been remediated. Both EPA and ATSDR consider these soil levels to pose a significant present threat to children's health requiring immediate intervention. While EPA has mobilized to perform time-critical removal of lead contaminated soils, an immediate response on the part of ATSDR is required to identify children and pregnant women who need clinical follow-up. .

2. *Does a data gap exists that affects our ability to decide that a public health hazard exists?*

Yes. Blood lead surveillance from 2007 to 2012 indicates that children in Allen County and Iola had a high prevalence (~15%) of blood levels above the CDC reference level. A CDC-funded blood lead surveillance program has not been in place since 2012. ATSDR has no information on the blood levels of children and pregnant women living in homes with lead-contaminated soils. This is the primary data gap that this exposure investigation will address.

3. *Can an Exposure Investigation address the data gap?*

Yes. The EI will provide venous BLL's results for the young children and pregnant women who live in properties where EPA testing documents lead levels in soil of > 800 mg/kg . To ensure the data gap is addressed, the EI team has develop a robust community outreach plan to motivate broad participation in the community and will evaluate exposure during two seasons of the year (winter and summer).

4. *How will the Exposure Investigation results impact public health decision making?*

Impacts to public health decision making include:

- Case management for participants (children and pregnant women) with BLL  $\geq 5$   $\mu\text{g}/\text{dL}$  will be provided by Region 7 ATSDR and PEHSU.
- Prioritization of residential yard cleanup by EPA based on the results of the BLL (i.e., remedial prioritization will be given to homes with  $\geq 400$  mg/kg lead in soil and a BLL of  $\geq 10$   $\mu\text{g}/\text{dL}$  in a child at the residence).

Certain traits put people at higher risk for lead exposure (Brink et al. 2013). Some characteristics contribute to susceptibilities (e.g., age, race, sex) and others to vulnerability (e.g., socioeconomic status). In addition to the risks posed by living in the city of Iola with lead contaminated soil other major risks factors for higher lead levels are, living in older housing, and poverty.

Once the EI data collection and analysis from both the winter and summer sampling rounds are complete, the ATSDR Team will conduct a public availability session for participants in the EI and for the community as a whole to discuss recommendations to reduce exposure and potential health concerns related to lead. ATSDR will also make recommendations to the EPA for prioritization of remediation: homes with children with BLL  $\geq 10$   $\mu\text{g}/\text{dL}$  and soil lead levels  $\geq 400$  mg/kg may be prioritized for cleanup by EPA.

A full EI Final Report is also completed and made available to the public and to all partners once all samples and data have been collected and analyzed. An example of a past EI Final Report is included as Attachment 7. The cleared Iola EI protocol is included as Attachment 8.

## **A.2. Purpose and Use of Information Collection**

The goal of the EI is to determine whether area contamination from historical smelting operations is resulting in community members being exposed to lead in soil at levels of health concern. If this is the case, ATSDR will make recommendations people can take to reduce their exposures and will recommend prioritization of remediation to EPA. If exposures are found at levels that might cause health concerns ( $\geq 5 \mu\text{g/dL}$ ), ATSDR may recommend the following:

- a. Recommend case management for participants with BLL  $\geq 5 \mu\text{g/dL}$ 
  - i. Recommend follow-up with a Pediatrician/Obstetrician
  - ii. Recommend ways to lower exposure to contaminated soil
  - iii. Recommend ways to lower exposure to dust in houses built before 1978.
  - iv. Provide information on nutrition that will help to decrease the absorption of lead into the body.
- b. Coordinate with EPA to use BLL results to prioritize site cleanup (i.e., participants with BLL  $\geq 10 \mu\text{g/dL}$  and yard soil levels  $\geq 400 \text{ mg/kg}$  will be given priority)

Data from ATSDR's Iola, KS EI report may also be used by public health professionals, environmental risk managers, and other decision makers in determining the source and extent of the exposures.

ATSDR will produce this needed information to support public health action. Further, the results of this EI are not intended to be generalized and are applicable only to the participants.

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. Once we conduct an 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*.

Data are treated to protect privacy; access to computer files is password-protected and access is limited to authorized EI personnel, including contractors. All staff working on the project agrees to safeguard the data and not to make unauthorized disclosures. Published reports may present responses in aggregate form and no individuals are identified by name.

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

ATSDR will conduct computer-assisted personal interviews (CAPIs) as well complete a hard-copy questionnaire with the participants at the blood collection location. The information will be recorded electronically on a laptop computer.

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

The state of Kansas has not had a formal CDC-funded child blood lead surveillance system in place since 2012. Blood testing efforts in Iola from 2006 to date are as follows:

Year	Location	Total number sampled (<6 yrs old)	BLL results in children (number of children)		% $\geq 5$ $\mu\text{g/dL}$
			$\geq 5$ $\mu\text{g/dL}$	$\geq 10$ $\mu\text{g/dL}$	% $\geq 5$ $\mu\text{g/dL}$
2007-2010 <sup>1</sup>	Allen County	625	28	28	15.3%
2007-2010 <sup>1</sup>	Iola	390	63	17	16.2%
<b>2012</b> <sup>1</sup>	Iola	117	17	4	15.0%
<b>2015-2016</b> <sup>2</sup>	Iola (WIC)	160	9	0	5.6%
NHANES (2007-2010) <sup>3</sup>					$\approx 2.5\%$

Data sources:

- (1) <http://www.cdc.gov/nceh/lead/data/state/ksdata.htm>
- (2) Personal communication with Chardel Hastings, Southeast Kansas Multi County Health Department to William Edwards (ATSDR), October 17, 2016
- (3) CDC, 2012a

The blood testing in Iola and Allen County from 2007 to date indicate the BLLs for children are above the current CDC reference level for children’s blood lead ( $\geq 5$   $\mu\text{g/dL}$ ).

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

The only small businesses that may be included in the Iola, KS EI include daycare centers and preschool/elementary schools. These facilities will be approached for recruitment of children that attend the facility.

#### A.6. Consequences of Collecting the Information Less Frequently

This request is for a two-time data collection: one collection in winter 2016/2017 and one in summer 2017. There are no legal obstacles to reduce the burden.

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

There are no special circumstances associated with this data collection. The data collection will fully comply with the guidelines of 5 CFR 1320.5 and will be voluntary.

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

This data collection is being conducted using the generic clearance for Exposure Investigations – OMB Control No. 0923-0048 (expiration date: 03/31/2019). A 60-day Federal Register Notice was published in the *Federal Register*, Vol. 80, No. 189 on Wednesday, September 30, 2015. No comments were received.

ATSDR is conducting this EI in collaboration with KDHE, EPA, SEKMCHD, and the Region 7 PEHSU.

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

ATSDR will not provide payments or gifts to participants.

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

This submission has been reviewed by the NCEH Information Systems Security officer (ISSO) who determined that the Privacy Act does apply. The relevant Privacy Act System of Records Notice (SORN) for this EI is Privacy Act System Notice 09-19-0001, Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances (HHS/ATSDR). This SORN is intended to allow for the implementation of the legislated mandate of ATSDR to identify the public health threat caused by exposure to toxic and hazardous substances using exposure investigations.

Data obtained during the EI will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Kansas Open Record Laws require openness in government, which may result in personal identification being accessible by the general public. The EI will comply with all appropriate requirements.

### **A.10.1. Privacy Impact Assessment Information**

The Iola, KS EI will involve up to 300 participants, including children, pregnant women, and women of child-bearing age. ATSDR provides participants with information on the EI process and what it can and cannot determine. After providing the participants this information, ATSDR

will ask for parental permission and minor assent, or adult consent to participate in the EI. Participation is completely voluntary; participants can stop participating in the EI at any time.

## Overview of the Data Collection System

The primary objective of the information collected for the Iola, KS EI is to assess exposures to environmental lead. Data obtained during this EI will include analytical measures of lead in blood. Information obtained from the participants assists the team in determining if exposure has occurred or is occurring. For this EI, a data collection system will include all of the measurements and procedures that are proposed to address data gaps in the blood and urine sampling.

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

1. Who will use the EI Data Collection System?

The DCHI SSB EI Team and the ATSDR Region 7 staff will use the Data Collection System to perform the blood collection and laboratory analysis during the Iola, KS EI.

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

EI participants for the Iola, KS EI are identified as the most highly exposed and/or susceptible populations and will be offered testing. The participants will be targeted for inclusion by canvassing the Iola community:

- Children younger than 6 years old,
- Women who are pregnant or of childbearing age
- Siblings of participants that are older than 6 years old, at parent's request.
- Any other person that meets the above criteria but was not included in the recruitment effort.

ATSDR will recruit up to 300 people (225 children and 75 adults) living in Iola. The participants will be tested in winter 2016/2017 and in summer 2017 to assess potential exposure during two seasons.

For the winter sampling round, participants will be recruited from homes with  $\geq 800$  mg/kg lead in soil that has not been remediated by EPA. For the summer sampling, the participants sampled in the winter round will be invited to participate along with children and adults in the Iola community that meet the criteria provided above. The participants will be tested in both winter and summer to evaluate difference in exposure between the seasons.

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

For the Iola, KS EI, the medium of concern is soil contaminated with lead. Attachment 4 provides the information collection form that will be used to evaluate lead exposure of EI participants.

### **Items of Information to be Collected**

Collecting identifying information is necessary to facilitate personal contact with participants, to obtain their parental permission/assent/consent to participate and to provide them with results. The information is also used by ATSDR to better interpret the results of the sampling. ATSDR uses the information only to contact respondents. Data is treated in a private manner, unless otherwise compelled by law.

ATSDR collects contact information (e.g., name, address, phone number, email address) to provide the participant with their individual results. General information, which includes age/date of birth, race, gender, etc., will be collected since we are recruiting specific age groups in the EI.

ATSDR will ask participants questions about their recreational activities that could increase their potential exposure to lead in the soil. Only questions needed to determine the extent of exposure in a particular situation will be asked. The questions are intended to estimate how long and how frequently participants may have contact with soil in the neighborhoods surrounding the site.

In addition, ATSDR will also collect information on other possible sources of lead exposure such as age and construction characteristics of the home, foods eaten, hobbies, time spent outdoors, etc. That information represents their individual exposure history.

The blood collection will be overseen by ATSDR personnel, obtained by trained phlebotomists, and shipped directly to the CDC National Center for Environmental Health (NCEH) laboratory in Atlanta for analysis. Appropriate Quality Assurance Plans will be prepared and implemented by ATSDR. Blood lead samples will be collected at a central location within the community.

### **Sharing and Purpose of Collected Information**

The information collected for the EI will be used to evaluate whether participants may have been exposed to lead in the soil in the area near the former smelter site. Participants will be notified of their individual results and an EI report will be prepared that will present the results of the investigation.

### **Securing of Collected Information**

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. Once we conduct an 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*.

Data are treated to protect privacy; access to computer files is password-protected and access is limited to authorized EI personnel, including contractors. All staff working on the project agree to safeguard the data and not to make unauthorized disclosures. Published reports may present responses in aggregate form and no individuals are identified by name.

Data are treated in a private manner, unless otherwise compelled by law. Paper documents containing personal identifiers are kept in locked file cabinets at ATSDR. ATSDR computers comply with the HHS Standard 2008-0007.001S for encryption in accordance with information systems security requirements for safeguarding personally identifiable information. Access to computer files is password-protected and access is limited to authorized EI personnel. That information is stored in a secure database along with the laboratory results.

### **Applicability of the Privacy Act**

A. The Privacy Act is applicable. The applicable System of Records Notice (SORN) is No. 09-19-0001, “Records of Persons Exposed or Potentially Exposed to Hazardous or Toxic Substances.”

B. Identifying information such as name, address, phone number and email are collected. ATSDR uses the information only to contact respondents. Identifying information is necessary to facilitate the personal contact with respondents to conduct the questionnaire, to obtain consent to participate, and to provide them their results.

All identifying information 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.

C. Respondent Consent –ATSDR will require that EI participants be fully informed of the potential risks and benefits of their participation and that the privacy of the participants’ information will be protected. The parental permission, minor assent, and adult consent forms for the Iola, KS EI 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

(Attachment 3). Kansas Sunshine Laws require openness in government and will be followed. The EI will comply with all appropriate requirements.

D. Voluntary Nature - Respondents are told that their participation in the EI is voluntary and they may refuse to answer any of the questions.

### **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, this EI is intended to be a systematic investigation but is not designed to develop or contribute to generalizable knowledge. The Iola, KS EI is a nonresearch activity and human subjects review by an Institutional Review Board (IRB) is not required. The EI was reviewed by the NCEH/ATSDR Human Subjects Coordinator (Attachment 5).

ATSDR will gather information about individual characteristics (e.g., gender, age, ethnicity, and race) to assist with interpretation for biological samples. For example, the individual’s laboratory results are compared to similar ethnicity and race results in the *National Report on Human Exposure to Environmental Chemicals* (<http://www.cdc.gov/exposurereport/>). Beyond that, questions of a sensitive nature will not be not asked.

We will not ask questions on symptoms, medical outcomes, or drug and medication use. For the Iola, KS EI, ATSDR will ask questions pertaining to recent or current pregnancy status because pregnancy makes a woman and her unborn child more vulnerable to the effects of lead.

Social security numbers are not needed nor will they be requested.

### **A.12. Estimates of Annualized Burden Hours and Costs**

#### **A.12.1. Estimates of Annualized Burden Hours**

The estimate for burden hours for the Iola, KS EI is based on similar EIs that the EI team has conducted in the past. The time burden per respondent is estimated at 30 minutes. A typical questionnaire may include up to 20 general questions taking less than 30 seconds each to respond and 10 more in-depth exposure specific questions requiring less than one minute each. Blood draw is estimated to take 10 minutes for a total of 30 minutes per respondent. The total estimated burden hours are 250.

Estimated Annualized Burden Hours

Type of Respondents	Name of Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (In Hours)
EI Participants who are recruited in winter 2016/2017 and in summer 2017	Participant Questionnaire (winter 2016/2017)	200	2	30/60	200
EI Participants who are recruited in summer 2017 only	Participant Questionnaire (summer 2017)	100	1	30/60	50
Total					250

**A.12.2. Annualized Cost to Respondents**

Using a rate of \$23.23/hr., the annualized cost to respondents for the hour burdens for the collection of information is \$5,807.50. The hourly wage rate is based on the U.S. Department of Labor, Bureau of Labor Statistics’ most current statistics [May 2015 National Occupational Employment and Wage Estimates United States, [http://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](http://www.bls.gov/oes/current/oes_nat.htm#00-0000)].

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	No. Responses per Respondent	Hourly Wage Rate	Total Respondent Costs
EI Participants who are recruited in winter 2016/2017 and in summer 2017	200	2	\$23.23	\$4646.00
EI Participants who are recruited in summer 2017 only	50	1	\$23.23	\$1161.50

Total				\$5807.50
-------	--	--	--	-----------

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

There will be no direct costs to the participants other than their time to participate in the EI.

### A.14. Annualized Cost to the Government

Costs for ATSDR personnel are estimated based on experience with previous EI activities.

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Medical Officer (Lead Investigator – GS-14)	750	\$50	\$37,500
Headquarters Health Scientist (GS-13)	750	\$43.70	\$32,750
Regional Representative (Health Scientist – GS-13)	400	\$43.70	\$17,480
Regional Representative (Health Scientist – GS-13)	400	\$43.70	\$17,480
Estimated Total Personnel Cost of Exposure Investigation			\$105,210

Non-Personnel		Cost
Travel costs		
Atlanta Personnel		\$13,634.00
Regional Personnel		\$8,102.00
Laboratory costs		
Includes phlebotomist, shipping and sample analysis		\$49,624.00
Estimated Total Non-personnel Cost of Exposure Investigation		\$71,360.00
Total EI Cost (Personnel + Non-personnel costs)		\$176,570.00

The travel costs include the following:

- Travel to the site from Atlanta (2 people) for four weeks (two sampling events of two weeks each: one week for recruiting and one week for blood sampling)
- Travel to the site from Kansas City (2 people) for four weeks (two sampling events of two weeks each: one week for recruiting and one week for blood testing)
- Travel to the site from Atlanta (2 person ) and Kansas City (1 person ) to provide the results to the community

### A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

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

### **A.16.1 Project Time Schedule**

The project Time Schedule for the Iola, KS EI is as follows:

<b>Activity</b>	<b>Time Schedule</b>
<u>Winter Sampling</u>	
Start of data collection and field work .....	1 week after OMB approval
Data and laboratory analysis.....	1-2 months after OMB approval
Respond to participants .....	3 months after OMB approval
<u>Summer Sampling</u>	
Start of data collection and field work.....	5 months after OMB approval
Data and laboratory analysis.....	6-7 months after OMB approval
Respond to participants.....	8 months after OMB approval
Written report.....	TBD - based on clearance process

Response letters to the participants will be sent for those with elevated and normal results (Samples are provided in Attachment 6). An example of a prior Exposure Investigation report is provided as Attachment 7. Attachment 8 provides the cleared protocol for the site.

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

We are not requesting an exemption.

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

There are no exceptions to certification for Paperwork Reduction Act.