

Blood Lead and Urine Arsenic Levels in Anaconda, MT Exposure Investigation

ATSDR Exposure Investigations (EI) Generic Information Collection Request
OMB No. 0923-0048
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Supporting Statement Part A

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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

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Attachments:

1. Supporting Statement A
2. Supporting Statement B
3. Anaconda, MT EI Parental Permission/Assent/Consent Forms
 - 3A. Privacy Act Statement
 - 3B. Adult Consent Form for Blood and Urine Testing
 - 3C. Parental Permission Form for Blood and Urine Testing: Children younger than 18 years of age
 - 3D. Assent Form for Blood and Urine Testing: Children between 7 and 17 years of age
4. Anaconda, MT EI Questionnaire
5. Anaconda, MT EI Research Determination
6. Anaconda, MT EI Sample Results Letter
7. Example of Prior EI Final Report
8. Privacy Impact Assessment Form
9. Anaconda EI Protocol

Goal of the Study: This project has four primary objectives:

1. Evaluate Blood Lead Levels (BLLs) for Anaconda residents and recommend case management (follow-up with a primary care provider (PRP)) for participants with $BLL \geq 5 \mu\text{g/dL}$
2. Evaluate total and speciated urine arsenic levels for Anaconda residents and compare to appropriate National Health and Nutrition Examination Survey (NHANES) values to determine whether follow-up may be warranted.
3. To address both lead and arsenic exposure, the EI will
 - Recommend ways to lower exposure to contaminated soil
 - Recommend ways to lower exposure to dust, especially in attics
4. All participants will have the option of discussing their lead and/or arsenic findings with an ATSDR medical officer.

Intended Use of the Resulting Data: Data will determine whether participants have BLLs $\geq 5 \mu\text{g/dL}$, the CDC reference level, and will compare total and total inorganic urine arsenic values to those in the general population (NHANES). Soil in Anaconda was contaminated with heavy metals, especially lead and arsenic, from former smelter activities and the site has been designated a National Priority List (NPL) site (aka Superfund site). EPA is currently working in the community to address community concern and remediate residential properties. 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: A maximum of 200 blood lead and urine arsenic samples will be collected during the fall of 2018, which reflects the time where residents are likely to be outside and exposure is considered to be high. Recruitment will include sending postcards to residents in the Anaconda area inviting them to participate in the EI. Local partners, including the Montana Department of Public Health and Human Services (MDPHHS) and the Anaconda Deer Lodge County (ADLC) Health Department will assist ATSDR in recruitment efforts.

Subpopulation to be Studied: Given community concern regarding exposure to lead and arsenic, all community members are invited to participate in the EI as part of a convenience sample of 200 individuals (adults and children).

How Data will be Analyzed: The blood and urine samples will be analyzed by the CDC National Center for Environmental Health Division of Laboratory Science (NCEH/DLS) and the results 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 Medical Officer and follow-up will be conducted by Region 8 ATSDR and the ADLC health department. Participants with urine arsenic levels greater than appropriate NHANES levels will be contacted by the ATSDR Medical Officer to determine whether follow-up may be warranted. All participants will be provided information on how to reduce exposure to lead and arsenic.

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 Anaconda 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 Anaconda Company Smelter operated from 1884 through 1981. The Anaconda Copper Mining Company mined copper ore in nearby Butte, Montana and operated a smelter on the north side of Warm Springs Creek, adjacent to the town of Anaconda from 1884 to 1901. This area is now referred to as the “Old Works.” In 1902, ore processing commenced at the Washoe Reduction Works (the “New Works”) on Smelter Hill, east of town. Both smelters resulted in large volumes of waste that were disposed on the ground and in surface water, and used as fill. Airborne contaminants from stacks and waste (slag) piles resulted in widespread surface soil contamination with heavy metals (principally arsenic, cadmium, copper, lead and zinc). In 1983, the U.S. Environmental Protection Agency (EPA) placed the Anaconda Company Smelter site on the National Priorities List (NPL).

Atlantic Richfield Corporation (ARCO) purchased the ACM in 1977 and conducts the site clean-up as the potentially responsible party. Smelter operations ceased in 1980, and the 585-foot landmark brick stack is the only remaining structure from the Washoe operations. Various remedial activities have been conducted to address the environmental contamination including permanent relocation of people living in the Mill Creek neighborhood; remediation of residential yards; and removal, consolidation, and on-site containment of waste material and contaminated soil. While significant progress in site remediation and the concurrent reduction of potential exposures has been made to date, contamination, such as exposed slag and soils in residential areas, remains. Remediation of millions of cubic yards of mining wastes and roughly 20,000 acres of contaminated soil through the Superfund program continues. Additionally, interior dust clean up, required by a 2013 Amendment to the Community Soils Operable Unit Record of Decision to address arsenic and lead contamination, is not yet complete.

Arsenic is the primary contaminant of concern and potential exposures to inorganic arsenic are the fundamental health risk addressed in site remediation. Lead has been noted in soil and attic dust and lead is also considered a contaminant of concern at the site. The site includes the area

surrounding the former Anaconda smelter site and includes the communities of both Anaconda and Opportunity.

In May 2018 ATSDR, in coordination with the Montana Department of Public Health and Human Services (MDPHHS), which is funded, in part, by the ATSDR state cooperative agreement program, and the Anaconda Deer Lodge County (ADLC) Health Department, conducted a public listening session to assess community health concerns. The community identified exposure to arsenic and lead as the primary public health issues associated with environmental contamination.

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 Anaconda MT 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 8 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 and Urine Arsenic Levels in Anaconda, MT Exposure Investigation

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

1. Can an exposed population be identified?

Yes. Soil sampling data and biological testing data (blood lead and urine arsenic) indicate that sensitive populations could be at risk for exposure to harmful levels of lead and arsenic in this community.

2. Does a data gap exist that affects our ability to decide that a public health hazard exists?
Additional blood lead and urine arsenic data will better identify whether residents may have been exposed to the lead and arsenic contamination in the community.

3. Can an Exposure Investigation address the data gap?

Yes. Completing blood lead and urine arsenic testing will provide additional information on the impact of environmental contamination on the community.

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

The results of the blood lead and urine arsenic testing will assist the ADLC health department and the MCPHHS to evaluate and prioritize available resources from ARCO (e.g., funds for case management, lead paint screening in homes, dust sampling in attics in the community).

Certain traits put people at higher risk for lead and arsenic exposure. Some characteristics contribute to susceptibilities (e.g., age, race, sex) and others to vulnerability (e.g., socioeconomic status) [Binder et al 1978]. In addition to the risks posed by living in the city of Anaconda with lead and arsenic 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 the 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.

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.

A.2. Purpose and Use of Information Collection

The objectives of the EI in Anaconda include:

1. Evaluate blood lead levels (BLLs) for Anaconda residents that participate in the investigation.
 - Recommend case management for participants with BLL \geq 5 micrograms per deciliter ($\mu\text{g}/\text{dL}$) (CDC reference level)
 - Recommend follow-up evaluation with a Primary Care Physician (PCP) for retesting and developmental and behavioral screening, as needed
 - Recommend an early intervention program for children with developmental and behavioral issues, as needed
 - Provide information on nutrition that may help to decrease the absorption of lead into the body
2. Evaluate total and inorganic urine arsenic levels for Anaconda residents that participate in the investigation.

- Each participant's creatinine-corrected, total urinary arsenic level will be compared to the most up-to-date 95th percentile value reported in the National Health and Nutrition Examination Survey (NHANES). Currently, a value of 29.9 micrograms per gram of creatinine ($\mu\text{g/g Cr}$) is reported for children aged 6-11 years; 30.5 $\mu\text{g/g Cr}$ for children aged 12-19 years and 54.0 $\mu\text{g/g Cr}$ for adults aged 20 years and older (2013-2014 data).
 - For participants whose creatinine-corrected, total urinary arsenic level is above the appropriate 95th percentile NHANES value, total inorganic urinary arsenic results will be compared to the most up-to-date 95th percentile values specific to age group that are reported in NHANES.
3. Recommend ways to lower exposure to lead and arsenic in the home.
 - Recommend ways to lower exposure to lead- and arsenic-containing dust in homes (e.g., attics)
 - Assist the community with the identification of available resources for home assessments
 4. All participants will have the option of discussing their lead and/or arsenic findings with an ATSDR medical officer.

Data from ATSDR's Anaconda MT 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) at the sample collection location and may also complete a hard-copy questionnaire with the participants. The information will be recorded electronically on a laptop computer.

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

In the past, several biomonitoring investigations have been conducted evaluating potential exposure to residents exposed to environmental contaminants from smelting activities. The ATSDR Health Consultation [ATSDR 2007] provides information on the past biomonitoring events in the Anaconda area. The results of biomonitoring events from 1977-1997 indicated that arsenic levels are elevated above background levels (arsenic in hair, blood and urine were higher in Anaconda than in non-smelter-related towns). A correlation between soil arsenic and speciated urine arsenic has also been found in Anaconda.

The 2007 ATSDR Health Consultation concluded that “biomonitoring of children in the Anaconda area has been useful to indicate elevated past exposures while the smelter operated and, later, in the Mill Creek area of the site. More recent measurements showed average urine arsenic levels to be similar to control towns; however, some children still had elevated arsenic levels, indicating the need to continue to address arsenic exposures at the site” [ATSDR 2007].

In 2013, ARCO contracted with ENVIRON International Corporation in consultation with ADLC to conduct a baseline blood lead and urinary arsenic biomonitoring study to evaluate potential exposure of residents in the Anaconda area. Blood lead and urine arsenic sampling was offered to community members. Results indicated that blood lead (maximum of 5.4 µg/dL in a participant 7 years or older) and urine arsenic were found in Anaconda residents.

The results of past biomonitoring events indicate that residents are likely to still be exposed to lead and arsenic in the environment as a result of past smelting activities in Anaconda.

In May 2018, ATSDR, in partnership with the MDPHHS and the ADLC Health Department, hosted a listening sessions in Anaconda to address community concerns. Fifty-four people provided detailed accounts of their health concerns as they relate to contamination at the site.

Many concerns related to potential exposure to arsenic from soil, household dust, and particulate matter blowing off the slag piles on windy days. Community members also worried about children’s health and expressed concern that autoimmune and neurodegenerative diseases were elevated in Anaconda.

An Exposure Investigation will address community concerns associated with continued exposure to lead and arsenic in site media.

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

The only small businesses that may be included in the Anaconda MT 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 one-time data collection in the fall of 2018. 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 Information Collection mechanism 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 Region 8 EPA, the Montana Department of Public Health and Human Services (MDPHHS), and the Anaconda Deer Lodge County (ADLC) health department.

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

ATSDR/NCEH Information Systems Security officer (ISSO) has determined that the Privacy Act does apply for the Anaconda EI. 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).

A Privacy Impact Assessment (PIA) form provides information on information that will be collected from respondents and how it will be secured (Attachment 8). A Privacy Act Statement is included in the consent package (Attachment 3).

Data obtained during the EI will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Montana 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 Anaconda, MT EI will involve up to 200 participants, including children and adults. 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 (Attachment 3). 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 Anaconda, MT EI is to assess exposures to environmental lead. Data obtained during this EI will include analytical measures of lead in blood and arsenic in urine. 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 8 staff will use the Data Collection System to perform the blood and urine collection and laboratory analysis during the Anaconda, MT EI.
2. Who can be included as part of the EI Generic Clearance?
EI participants for the Anaconda, MT EI are identified any resident of Anaconda and the rural surrounding area. For lead, young children and pregnant women are most susceptible to the effects of lead exposure, but given community concern, all residents are welcome to participate in the EI.
3. What types of questions may be asked as part of the EI Generic Clearance?

For the Anaconda, MT EI, the media of concern are soil and attic dust contaminated with lead and arsenic. Attachment 4 provides the information collection form that will be used to evaluate lead and arsenic 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 and arsenic in environmental media. 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 and arsenic 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.

An example of a completed Exposure Investigation is provided as Attachment 7 and the final Anaconda, MT Protocol is provided as Attachment 9.

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 and arsenic 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 Anaconda, MT 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). Montana 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 Anaconda, MT 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 Anaconda, MT 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 Anaconda, MT 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 60 questions, taking approximately 20 minutes to complete.

Blood draw and urine collection are estimated to take 10 minutes for a total of 30 minutes per respondent. The total estimated burden hours are 100.

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	Participant Questionnaire and Sample Collection	200	1	30/60	100
Total					100

A.12.2. Annualized Cost to Respondents

Using a mean hourly rate of \$24.34/hr., the annualized cost to respondents for the hour burdens for the collection of information is \$2,434.00. The hourly wage rate is based on the U.S. Department of Labor, Bureau of Labor Statistics’ most current statistics [May 2017 National Occupational Employment and Wage Estimates United States, 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	100	1	\$24.34	\$2,434.00

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)	500	\$54.24	\$27,120.00
Headquarters Health Scientist (GS-13)	750	\$45.90	\$34,425.00
Regional Representative (Health Scientist – GS-13)	400	\$45.90	\$18,360.00
Estimated Total Personnel Cost of Exposure Investigation			\$79,905.00

Non-Personnel		Cost
Travel costs		
Atlanta Personnel		\$7,400.00
Regional Personnel		\$3,200.00
Laboratory costs		
Includes phlebotomist, shipping and sample analysis		\$72,000.00
Estimated Total Non-personnel Cost of Exposure Investigation		\$82,600.00
Total EI Cost (Personnel + Non-personnel costs)		\$162,505.00

The travel costs include the following:

- Travel to the site from Atlanta (2 people) for two weeks
- Travel to the site from Denver (1 person) for two weeks
- Travel to the site from Atlanta (2 person) and Denver (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 Anaconda, MT EI is as follows:

Activity	Time Schedule
Start of data collection and field work2 weeks after OMB approval
Data and laboratory analysis.....	2-3 months after OMB approval
Respond to participants4 months after OMB approval
Written report released.....	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.

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.

References:

[ATSDR 2007] Agency for Toxic Substances and Disease Registry. 2007. Health Consultation: Evaluation of Residential Soil Arsenic Action Level. Anaconda Co. Smelter Site, Anaconda, Deer Lodge County, MT. EPA Facility ID: MTD093291656

Brink LL, Talbot EO, Sharma RK, March GM, Wu WC, Rager JR, Strosnider HM (2013). Do U.S. Ambient Air Lead Levels Have a Significant Impact on Childhood Blood Lead Levels: Result of a National Study. J. Environ and Public Health. Available at: <http://www.hindawi.com/journals/jeph/2013/278042/>.

[CDC 2018] Centers for Disease Control and Prevention. Fourth Report on Human Exposure to Environmental Chemicals, Updated Tables, (March 2018). Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. <https://www.cdc.gov/exposurereport/>