

**Generic Information Collection (GenIC) Submittal Form for  
OMB Review of ATSDR Exposure Investigations (EIs) (0923-0048)**

**PROJECT TITLE:** Blood Lead and Urine Arsenic Levels in Anaconda, MT Exposure Investigation:  
Anaconda II EI

**SITE LOCATION:** Anaconda, MT

**REQUESTED BURDEN HOURS:** 150

**PROJECT SUMMARY**

<b>Principal Investigator(s):</b>	<ul style="list-style-type: none"> <li>• Karen Scruton (ATSDR Headquarters)</li> <li>• Arthur Wendel (ATSDR Region 10 – Medical Officer)</li> <li>• Mateusz Karwowski (ATSDR Headquarters)</li> <li>• David Dorian (ATSDR Region 8)</li> </ul>
<b>Technical Assistance:</b>	<ul style="list-style-type: none"> <li>• Region 8 Environmental Protection Agency (EPA)</li> <li>• Montana Department of Public Health and Human Services (MDPHHS)</li> <li>• Anaconda Deer Lodge County (ADLC) health department</li> <li>• NCEH/DLS laboratory</li> </ul>
<b>Source of Request (state, petition, etc.):</b>	<p>ATSDR EI will be conducted in coordination with EPA. This is follow-up testing to the EI previously conducted in September 2018. EPA is funding the laboratory costs associated with the additional testing.</p>
<b>Project Goals:</b>	<p>An EI was conducted at the Anaconda National Priority List (NPL) site in Anaconda, Montana in September, 2018. The Anaconda area was contaminated with heavy metals from past smelting activities in the area. The EI included the testing of 191 residents to determine the levels of lead in blood and arsenic in urine in residents in the Anaconda community. Community interest in the testing event was considerable and ATSDR was not able to test all interested participants. Therefore, EPA committed to fund additional laboratory testing in the community; ATSDR, ADLC and MDPHHS will conduct the additional testing in the community.</p> <p>The Anaconda II EI is a follow-up to the EI conducted in September 2018 and has the same basic objectives and follow-up activities as the first EI:</p> <ol style="list-style-type: none"> <li>1. Evaluate blood lead levels (BLLs) and recommend case management for participants with BLL <math>\geq</math>5 micrograms per deciliter (<math>\mu\text{g}/\text{dL}</math>) (CDC reference level) <ul style="list-style-type: none"> <li>▪ Recommend follow-up evaluation with a Primary Care Physician (PCP) for retesting and developmental and behavioral screening, as needed</li> <li>▪ Recommend an early intervention program for</li> </ul> </li> </ol>

	<p>children with developmental and behavioral issues, as needed</p> <ul style="list-style-type: none"> <li>▪ Provide information on nutrition that may help to decrease the absorption of lead into the body</li> </ul> <p>2. Evaluate total and inorganic urine arsenic levels. Compare the creatinine-corrected total urinary arsenic level to the most up-to-date 95<sup>th</sup> percentile value reported in NHANES. Currently, a value of 29.9 µg As/g Cr is reported for children aged 6-11 years; 30.5 µg As/g Cr for children aged 12-19 years and 54.0 µg As/g Cr for adults aged 20 years and older (2013-2014 data) [CDC 2018].</p> <ul style="list-style-type: none"> <li>▪ For participants whose creatinine-corrected total urinary arsenic levels are above the appropriate 95<sup>th</sup> percentile NHANES value, total inorganic urinary arsenic results will be compared to the most up-to-date 95<sup>th</sup> percentile values specific to age group that are reported in NHANES [CDC 2018].</li> </ul> <p>3. Recommend ways to lower exposure to lead and arsenic in the home.</p> <ul style="list-style-type: none"> <li>• 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, including testing and remediation of yard soil and attics</li> </ul> <p>4. All participants will have the option of discussing their lead and/or arsenic findings with an ATSDR medical officer.</p>
<p><b>Project Objectives:</b></p>	<p>This exposure investigation will recruit a maximum of 300 community members living in the Anaconda, MT area to be tested for blood lead and urine arsenic. As a follow-up to the testing conducted in September 2018, approximately 250 adults and 50 young children will be included in the testing. Given the lack of representation of young children in the testing completed in September 2018, young children will be recruited by contacting Head Start, the preschools and elementary schools in Anaconda. We will compare the results with levels of health concern (blood lead levels <math>\geq 5</math> µg/dL) or levels in the U.S. population [arsenic levels compared to appropriate National Health and Nutrition Examination Survey (NHANES) levels], provide participants with their individual results and interpretation/recommendations, and write a summary report (EI report).</p>
<p><b>Environmental Sampling to be Completed:</b></p>	<p>None. EPA is conducting remedial action at the site as part the Remedial Investigation/Feasibility (RI/FS) process.</p>
<p><b>Biological Sampling to be Completed:</b></p>	<p>Follow-up blood lead and urine arsenic testing will occur in fall 2018. Young children and pregnant women are more susceptible to the</p>

	<p>effects of heavy metals, especially lead, and, given their underrepresentation in the testing conducted in September 2018, they will be specifically recruited and a minimum of 50 testing appointments will be reserved for young children.</p>
<p><b>Data Collection and Analysis Procedures:</b></p>	<p><u>Recruitment of Participants:</u> Supporting Statements A and B are provided in Attachments 1 and 2. The Supporting Statements outline the EI data collection and analysis procedures.</p> <ul style="list-style-type: none"> <li>• Recruitment: <ul style="list-style-type: none"> <li>a) Testing a maximum of 300 participants for blood lead and urine arsenic levels, with a minimum of 50 appointments reserved for the testing of young children.</li> <li>b) Contacting people on the waiting list from the first testing event and offering them testing.</li> <li>c) Recruiting young children and women of childbearing age by: <ul style="list-style-type: none"> <li>• Having the ADLC health department reach out to the local Head Start program and offer testing to young children and their families at the Head Start facility. The testing will be conducted at the Head Start facility on one of the testing days. Young children from the area daycares will be provided with the Anaconda EI fact sheet and will be offered testing at the Head Start facility.</li> <li>• Providing the Lincoln Primary School with the Anaconda EI fact sheet to disseminate information on the testing event.</li> </ul> </li> </ul> </li> <li>• Collection: <ul style="list-style-type: none"> <li>a) Participants will bring the first-morning urine they collected and will give it to ATSDR personnel at the blood collection location.</li> <li>b) The total time in the investigation is 30 minutes per participant. <ul style="list-style-type: none"> <li>• Adult participants and parental/guardian proxies for children will be asked questions to allow a better interpretation of blood and urine results. The questionnaire to be used in the EI is attached (Attachment 4), and is estimated to take 20 minutes to complete.</li> <li>• The blood samples will be obtained using certified phlebotomists at a designated location within the community. ATSDR personnel will pack and ship the blood and urine samples overnight to the NCEH/DLS</li> </ul> </li> </ul> </li> </ul>

	<p>laboratory from the blood collection site. Collection of the blood and urine samples is estimated to take 10 minutes to complete.</p> <ul style="list-style-type: none"> <li>The human subjects determination is provided in Attachment 5. The EI is not considered a research study; its primary intent is to provide a public health service for the community.</li> </ul> <p><u>Analysis:</u></p> <ul style="list-style-type: none"> <li>The blood and urine samples will be analyzed by the NCEH/DLS laboratory using state-of-art laboratory methods.</li> </ul>
<b>Information Collection Mode (in-person or remote):</b>	In-person
<b>Plans for Payment to Participant (if applicable):</b>	Not Applicable
<b>Privacy Protections:</b>	Privacy will be protected to the fullest extent allowable by law. The consent forms contain information about privacy protections.
<b>Other Ethical Concerns/Issues:</b>	Blood will be drawn from children and adults, which may cause some fear and discomfort for the participants.
<b>Projected Time Frame:</b>	<ul style="list-style-type: none"> <li>The EI will be conducted over a period of 4 days (Saturday through Tuesday) in the fall of 2018. Data and sample collection will take approximately 30 minutes per participant, including the questionnaire, blood draw, and urine collection.</li> <li>The participants will be provided results of the blood and urine testing within 12 weeks of collection.</li> <li>The EI report will be prepared, cleared, and released as soon as possible.</li> </ul>
<b>Plans for Publication and Dissemination of Results:</b>	<ul style="list-style-type: none"> <li>Blood lead and urine arsenic results will be provided to participants within 12 weeks of specimen collection.</li> <li>If concentrations of lead in blood are found at <math>\geq 5 \mu\text{g/dL}</math> or if total arsenic or total inorganic arsenic levels are above concentrations in the U.S. population (NHANES data), participants will be contacted sooner.</li> <li>The EI report will be prepared, cleared and released as soon as possible.</li> </ul>
<b>Burden Hours Requested:</b>	<p>150 hours</p> <ul style="list-style-type: none"> <li>300 participants x 30 minutes per participant</li> </ul>

**Attachments:**

1. Supporting Statement A
2. Supporting Statement B
3. Anaconda, MT II EI Parental Permission/Assent/Consent Forms
  - a. Privacy Act Statement
  - b. Adult Consent Form for Blood and Urine Testing
  - c. Parental Permission Form for Blood and Urine Testing: Children younger than 18 years of age

- d. Assent Form for Blood and Urine Testing: Children between 7 and 17 years of age
- 4. Anaconda, MT II EI Questionnaire
- 5. Anaconda, MT II EI Research Determination
- 6. Anaconda, MT II EI Sample Results Letter
- 7. Example of Prior EI Final Report
- 8. Privacy Impact Assessment Form
- 9. Anaconda II EI Protocol