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

SITE LOCATION: Anaconda, MT

REQUESTED BURDEN HOURS: 100

PROJECT SUMMARY

Principal Investigator(s):	• Karen Scruton (ATSDR Headquarters) • Lourdes Rosales-Guevara (ATSDR Headquarters) • Mateusz Karwowski (ATSDR Headquarters) • David Dorian (ATSDR Region 8)
Technical Assistance:	• Region 8 Environmental Protection Agency (EPA) • Montana Department of Public Health and Human Services (MDPHHS) • Anaconda Deer Lodge County (ADLC) health department • NCEH/DLS laboratory
Source of Request (state, petition, etc.):	ATSDR EI will be conducted in coordination with EPA.
Project Goals:	1. Evaluate blood lead levels (BLLs) for Anaconda residents that participate in the investigation. • Recommend case management for participants with BLL ≥5 micrograms per deciliter (µg/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 (µg/g Cr) is reported for children aged 6-11 years; 30.5 µg/g Cr for children aged 12-19 years and 54.0 µg/g Cr for adults aged 20 years and older (2013-2014 data) [CDC 2018]. • 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 [CDC 2018]. 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.
Project Objectives:	This exposure investigation will recruit a maximum of 200 community members living in the Anaconda, MT area to be tested for blood lead and urine arsenic. Given community concerns, all community members will be invited to participate. We will compare the results with levels of health concern (blood lead levels ≥5 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).
Environmental Sampling to be Completed:	None. EPA is conducting remedial action at the site as part the Remedial Investigation/Feasibility (RI/FS) process.
Biological Sampling to be Completed:	Blood lead and urine arsenic testing will occur in fall 2018. Young children and pregnant women are more susceptible to the effects of heavy metals, especially lead, but given community concerns, all residents of the Anaconda area are invited to participate in the EI.
Data Collection and Analysis Procedures:	Recruitment of Participants: Supporting Statements A and B are provided in Attachments 1 and 2. The Supporting Statements outline the EI data collection and analysis procedures. • Recruitment: o A recruitment postcard providing information on the EI and inviting residents to participate will be sent to participants in the Anaconda area approximately 2 weeks prior to the testing. o Local partners, ADLC and MDPHHS, will assist ATSDR in sharing information on the EI effort by distributing fact sheets and posters in the Anaconda area and promoting the EI effort via social media. o Participants will contact ATSDR via a toll free number to make an appointment of the testing. o Participants will be provided a urine collection kit which will include instructions on how to collect, freeze and bring the same to the blood collection site. o Participants will be provided a consent/parental permission/assent form, as appropriate, when the urine collection kit is provided to participants. Parental permission forms will be completed for all children

	younger than 18 years old and a child assent form will be completed for all children aged 7 to 17 years. • Collection: o Participants will bring the first-morning urine they collected and will give it to ATSDR personnel. o The total time in the investigation is 30 minutes per paticipant. o 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. o 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 laboratory from the blood collection site. Collection of the blood and urine samples is estimated to take 10 minutes to complete. • 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. <u>Analysis:</u> • The blood and urine samples will be analyzed by the NCEH/DLS laboratory using state-of-art laboratory methods.
Information Collection Mode (in-person or remote):	In-person
Plans for Payment to Participant (if applicable):	Not Applicable
Privacy Protections:	Privacy will be protected to the fullest extent allowable by law. The consent forms contain information about privacy protections.
Other Ethical Concerns/Issues:	Blood will be drawn from children and adults, which may cause some fear and discomfort for the participants.
Projected Time Frame:	• 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. • The participants will be provided results of the blood and urine testing within 12 weeks of collection. • The EI report will be prepared, cleared, and released as soon as possible.
Plans for Publication and Dissemination of Results:	• Blood lead and urine arsenic results will be provided to participants within 12 weeks of specimen collection. • If concentrations of lead in blood are found at ≥5 µg/dL or if total arsenic or total inorganic arsenic levels are above concentrations in the U.S. population (NHANES data),

	participants will be contacted sooner. • The EI report will be prepared, cleared and released as soon as possible.
Burden Hours Requested:	100 hours • 200 participants x 30 minutes per participant

Attachments:

1. Supporting Statement A
2. Supporting Statement B
3. Anaconda, MT 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 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