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

PROJECT TITLE: Colorado Smelter Exposure Investigation

SITE LOCATION: Pueblo, Colorado

REQUESTED BURDEN HOURS: 100

PROJECT SUMMARY

Principal Investigator(s):	• Lourdes Rosales-Guevara (ATSDR Headquarters) • David Dorian (ATSDR Region 8)
Technical Assistance:	• Pueblo City County Health Department (PCCHD) • DLS/NCEH/ATSDR laboratory
Source of Request (state, petition, etc.):	Pueblo City County Health Department (PCCHD)
Project Goals:	The goal of the EI is to determine whether soil contamination from historical smelting operations is resulting in community members being exposed to lead and arsenic at levels of health concern. If this is the case, ATSDR will make recommendations for people to reduce their exposures and will recommend contaminant mitigation to the appropriate government agencies (e.g., the U.S. Environmental Protection Agency (EPA) and their state equivalent).
Project Objectives:	This exposure investigation will recruit community members living within a ½ mile of the former smelter, who are at highest risk for exposure. We will obtain their assent/consent/parental permission, test blood for lead in children (aged 9 months to 72 months and aged 6 to 17 years) and women of childbearing age/pregnant women, and urine for arsenic in children (aged 6 to 17 years) and women of childbearing age/pregnant women; compare the results with levels of health concern; provide participants with their individual results and interpretation/recommendations; and write a summary report (EI report).
Environmental Sampling to be Completed:	None
Biological Sampling to be Completed:	<u>Blood lead levels in:</u> • Children aged 9 to 72 months (up to 6 years of age) – 200 participants • Children aged 6 to 17 years of age and women of childbearing age/pregnant women (15 to 44 years) – total of 100 participants between these two groups <u>Arsenic in urine in:</u> • Children aged 6 to 17 years old and women of childbearing age/pregnant women (15 to 44 years) – total of 100 participants between these two groups

Data Collection and Analysis Procedures:	Recruitment of Participants: There are two neighborhoods located within one-half mile of the former smelter location. These neighborhoods will be canvased and participants will be identified from these neighborhoods. As discussed above, the EI will target identification of 200 children aged 9 to 72 months for testing of lead in blood. In addition, blood lead and urine arsenic will be tested in children between age 6 and 17 years and women of child-bearing age/pregnant women. We will be targeting a total of 100 people between these two groups. Collection: • Children aged 9 to 72 months will only be tested for blood lead. • Children aged 6 to 17 years and women of childbearing age/pregnant women (15 to 44 years) will be tested for both blood lead and urine arsenic. • Supporting Statements A and B for the OMB EI are provided in Attachments 1 and 2. The Supporting Statements outline the EI data collection and analysis procedures. • All participants will be provided an assent/consent/parental permission form to sign (Attachment 3) and will be asked questions to allow a better interpretation of the results. The questionnaire to be used in the EI is attached (Attachment 4). • The human subjects documentation is provided in Attachment 5. The EI is not considered a research study; its primary intent is public health practice. • The blood samples will be obtained using certified phlebotomists at a designated location within the community. ATSDR personnel will pack and ship the samples overnight to the NCEH laboratory from the blood collection site. • Participants will be given a specimen cup for urine void collection when they are recruited. They will be asked to collect a spot sample of urine the morning of the appointment date to collect blood. EI personnel will pack and ship the samples overnight to the NCEH laboratory from the blood collection site. Analysis: • The blood and urine samples will be analyzed by the NCEH laboratory using state-of-art laboratory methods • The arsenic in urine will be speciated if arsenic levels exceed 50 ug/L.
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 of the law. The consent

	forms contain information about privacy expectations.
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 5 days (Sunday through Thursday). Each sample collection will take approximately 20 minutes per participant. • The participants will be provided results of the blood and urine sampling within 16 weeks of collection. • If concentrations in blood and/or urine are found at levels of health concern, participants will be contacted sooner. • The EI 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 14-18 weeks of specimen collection. • If concentrations in blood and/or urine are found at levels of health concern, participants will be contacted sooner. • The EI report will be prepared, cleared and released as soon as possible.
Burden Hours Requested:	100 hours (300 participants x 20 minutes per participant)

ATTACHMENTS

1. **Supporting Statement A**
2. **Supporting Statement B**
3. **Assent/Consent/Parental Permission Forms**
4. **Pueblo, Colorado Smelter Exposure Investigation Questionnaire**
5. **Human Subjects Documentation**