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

PROJECT TITLE: ASARCO Smelter Exposure Investigation

SITE LOCATION: Hayden/Winkelman, Arizona

REQUESTED BURDEN HOURS: 67

PROJECT SUMMARY

Principal Investigator(s):	• Bruce C. Tierney (ATSDR Headquarters) • Ben Gerhardstein (ATSDR Region 9)
Technical Assistance:	• Arizona Department of Health Services (ADHS) • Arizona Department of Environmental Quality (ADEQ) • DLS/NCEH/ATSDR laboratory
Source of Request (state, petition, etc.):	US Environmental Protection Agency (EPA)
Project Goals:	The goal of the EI is to determine whether soil and air contamination from historical and ongoing 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 in the communities of Hayden and Winkelman, AZ, which are in close proximity to the smelter site who are at highest risk for exposure. The smelter is a large complex of approximately 200 acres at the eastern end of the town. All of Hayden is located next to or within ½ mile of the smelter site. Winkelman is located between ¼ and 1 ½ miles from the smelter site. In addition, a mine tailings pile rises approximately 100 feet above the lowest area and extends for approximately ½ mile along the west side of Highway 177 which borders the western edge of Hayden. We will obtain parental permission/assent/consent for all participants. Up to 200 participants living in Hayden and Winkelman will be tested. This will include children ages 9 to <72 months of age (blood lead testing only) as well as children 6 to <12 years of age and pregnant women (blood lead testing and urine arsenic testing). In addition, if these three participant categories do not fill all 200 available appointments, adolescents 12 to <18 years of age and women of child bearing age from 15 to <45 years of age will be included on a first come, first served basis for blood lead and urine arsenic testing. We will 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:	Up to 200 participants living in Hayden and Winkelman will be offered testing between the following groups (recruitment of children 9 to <72 months of age and pregnant women will be emphasized before recruiting from the other groups): <u>Blood lead levels in:</u> • Children 9 to <72 months of age • Children 6 to <12 years of age • Pregnant women <u>Urine Arsenic in:</u> • Children 6 to <12 years of age • Pregnant Women In addition, if the participant groups above do not fill all 200 available appointments the following groups will be offered testing for blood lead and urine arsenic testing on a first come, first served basis: • Adolescents 12 to <18 years of age • Women of child bearing age from 15 to <45 years of age
Data Collection and Analysis Procedures:	<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. There are two communities located in close proximity to the current and historical smelter location. These communities will be canvased and participants will be identified from them. • Collection: All participants will be provided a parental permission/assent/consent form to sign (Attachment 3) and will be asked questions to allow a better interpretation of their 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. • 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. Collection of the blood sample is estimated to take 10 minutes to

	complete. • 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. <u>Analysis:</u> • 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 to differentiate between organic and inorganic arsenic if levels exceed 28.4 µg As/g creatinine.
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 (Saturday through Wednesday). Each sample collection will take approximately 30 minutes per participant. • The participants will be provided results of the blood and urine sampling within 12 weeks of 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.
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 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 (200 participants x 30 minutes per participant)

Attachments:

1. **Supporting Statement A**
2. **Supporting Statement B**
3. **ASARCO Smelter EI Parental Permission/Assent/Consent Forms**

a. **Parental Permission Form for Blood Lead Testing and Questionnaire: Children aged 9 to <72 Months**
b. **Parental Permission Form for Blood Lead and Urine Arsenic Sampling and Questionnaire: Children and Youth aged 6 to <18 Years**
c. **Assent Form for Blood Lead and Urine Arsenic Testing and Questionnaire: Children and Youth aged 7 to <18 Years**
d. **Consent Form for Blood Lead and Urine Arsenic Testing and Questionnaire: Pregnant Women and Women of Childbearing Age aged 15 to <45 Years**

4. **ASARCO Smelter EI Questionnaire**
5. **ASARCO Smelter EI NCEH/ATSDR Human Subjects Research Determination**
6. **ASARCO Smelter EI Sample Results Letters**
   - **6A. Sample Results Letters to the Parent of a Participant aged 9 to <72 Months**
   - **6B. Sample Results Letter to the Parent of a Participant aged 6 to <18 Years**
   - **6C. Sample Results Letter to a Pregnant Woman or Woman of Child Bearing Age aged 15 to <45 Years**
   - **6D. Inserts for Results Letters**
   - **6E. Factsheets for Results Letters**
7. **Example of Prior EI Final Report**