

ASARCO Smelter Exposure Investigation

ATSDR Exposure Investigations (EI) Generic Information Collection Request

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Supporting Statement Part B

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Attachments:

1. Supporting Statement A
2. Supporting Statement B
3. ASARCO Smelter EI Parental Permission/Assent/Consent Forms
 - 3A. Parental Permission Form for Blood Lead Testing and Questionnaire: Children aged 9 to <72 Months
 - 3B. Parental Permission Form for Blood Lead and Urine Arsenic Sampling and Questionnaire: Children and Youth aged 6 to <18 Years
 - 3C. Assent Form for Blood Lead and Urine Arsenic Testing and Questionnaire: Children and Youth aged 7 to <18 Years
 - 3D. 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

B. Collections of Information Employing Statistical Methods

Although no statistical methodology is used for the investigations, we will use this section of the submission to describe how the data are collected.

B.1. Respondent Universe and Sampling Methods

Since the Agency for Toxic Substances and Disease Registry (ATSDR) does not use the exposure investigation (EI) results to generalize or estimate the total exposed population, the respondent universe and statistical methods for determining sample size are not a factor. The purpose of this EI is to determine if community exposures of health concern to lead and arsenic are occurring by collecting blood serum and urine samples from people with a high potential for exposure to lead and/or arsenic from historic and ongoing smelting operations in Hayden, AZ. An EI is not a research study. Participant selection is specifically biased to participants with the greatest potential for exposure rather than statistical random selection methods used in research to generate or contribute to generalizable knowledge. In this EI, the population thought to be at greatest risk of exposure are residents located closest to the historic and ongoing smelting operation site. This includes the communities of Hayden and Winkelman, AZ. The ASARCO Smelter is a large complex of approximately 200 acres at the eastern end of the town of Hayden. Two large emission stacks dominate the horizon. One is about 1,000 feet tall and the other is 250 feet tall. All of Hayden is located next to or within $\frac{1}{2}$ mile of the smelter site. Winkelman is located between $\frac{1}{4}$ and $1\frac{1}{2}$ miles from the smelter site. Ideally EIs attempt to recruit every person thought to be at high risk for exposure. In very small at-risk populations this may be possible. But in a larger population, which is the case in this EI, the number of participants who can be tested may be limited by available resources such as staffing and budgetary constraints. Most EIs, including this one, are location-based. We estimate the potential respondent universe based on street maps and census information.

B.2. Procedures for the Collection of Information

A list of questions, provided in Attachment 4, will be administered in person at the site of blood collection. Participants will be recruited by teams made up of ATSDR EI team members, ATSDR Region 9 staff and Arizona state and local public health officials. Teams will canvas the neighborhoods closest to the smelter location. Emphasis will be placed on the most vulnerable populations to these chemicals. 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 will be included on a first come, first served basis for blood lead and urine arsenic testing. The blood testing will be performed at a central location in the community. Urine collection will be performed in the participants' homes or at the blood collection facility. The team will also participate in one or more community open houses (dependent on what can be arranged in the

community) to recruit as many volunteers as possible who meet the defined EI eligibility criteria as most likely to be exposed to the smelter site up to the limit that allocated resources for this EI will permit (up to 200 participants). The EI team will be identified by name to potential participants along with their qualifications or experience in conducting similar EIs.

Quality Control Procedures

Prior to the interviews, the EI team is trained on the site-specific questions to be asked (e.g., the purpose of each question, how to capture answers, place for comments, etc.). The list of questions and individual's answers are stored in a secure database or locked filing cabinet.

Each participant is given information regarding the name of the EI, a telephone number to answer questions, and the address of the ATSDR website where they can find more information about the EI (Attachment 3). Each participant receives a copy of their personal results (Samples provided in Attachment 6). Individual results will be protected to the full extent provided by law and will not be shared publically in any published reports.

B.3. Methods to Maximize Response Rates and Deal with Non-response

The ASARCO Smelter EI was requested by the US Environmental Protection Agency (EPA) to evaluate potential exposure. ATSDR is generally looking for participants that are the most highly exposed. We identify them through a location or an activity that they engage in. If activity-based (e.g., recreating on the slag pile at the location of the smelter) we may need to contact people to encourage their participation.

We invite people to participate based on who would likely be most exposed. For the ASARCO Smelter EI, we will be recruiting up to 200 participants: including 1) children aged 9 to <72 months of age (blood lead only), 2) children aged 6 to <12 years of age, 3) pregnant women; and if space for testing remains available 4) adolescents from 12 to <18 years of age and women of child-bearing age from 15 to <45 years of age. In ATSDR's experience, getting sufficient numbers of participants has not been a problem since EI communities often request the testing before we arrive. We often achieve close to a 100% response rate. However, because we are interpreting each individual's response to his or her specific exposure and not attempting to determine population level exposures, we can interpret results without 100% participation.

In addition the EI Team will provide a service to those residents who live in Hayden and Winkelman, AZ, near the smelter site and who chose to participate in the EI. Residents will be advised that testing is being offered at no charge to them. Participants will receive their individual test results for blood lead and urine arsenic.

B.4. Test of Procedures or Methods to be Undertaken

The EI team will use the questions provided in Attachment 4.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Statistical sampling methods are not used to determine participation in EIs. Rather, all the community residents with the greatest likelihood of exposure are asked to participate. Among all participants, the presence of a single blood lead level or urine arsenic level above the reference values as defined in the EI protocol indicates that exposure is occurring in the community and that further investigation is warranted.