

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

PROJECT TITLE: Follow Up Biologic Testing for Exposure to Arsenic ASARCO Hayden Smelter Site, Hayden & Winkelman, Arizona Exposure Investigation

SITE LOCATION: Hayden, Arizona

REQUESTED BURDEN HOURS: 30

PROJECT SUMMARY

Principal Investigator(s):	<ul style="list-style-type: none"> • Bruce C. Tierney (ATSDR Headquarters) • Ben Gerhardstein (ATSDR Region 9) • Jamie Rayman (ATSDR Region 9) • Lourdes Rosales-Guevara (ATSDR Headquarters)
Technical Assistance:	<ul style="list-style-type: none"> • Region 9 Environmental Protection Agency (EPA) • Arizona Department of Health Services (ADHS) • Arizona Department of Environmental Quality (ADEQ) • DLS/NCEH/ATSDR laboratory
Source of Request (state, petition, etc.):	ATSDR exposure investigation (EI) will be conducted in coordination with EPA.
Project Goals:	<ol style="list-style-type: none"> 1. Repeat evaluation of Urinary Arsenic Levels for all participants in the initial ATSDR Hayden EI conducted in April 2015. <ol style="list-style-type: none"> a. Children and adolescents who were aged 6 years to 17 years at the time of the initial EI who participated in the initial EI. b. Women who were pregnant or of childbearing age at the time of the initial EI who participated in the initial EI. c. Additional full time residents of Hayden and Winkelman who request testing will be accommodated if space and testing equipment is available up to a maximum of 60 participants. 2. Recommend case management for participants with urinary arsenic levels above 28.4 grams per gram of creatinine <ol style="list-style-type: none"> a. Recommend follow-up with a Healthcare professional for evaluation and follow up as indicated. b. Recommend ways to lower exposure to contaminated soil. c. Recommend ways to lower exposure to dust in houses built before 1978. d. Provide information on nutrition that will help to decrease the absorption of arsenic into the body. 3. Coordinate with EPA and the Arizona Department of Environmental Quality (ADEQ) to provide Urinary Arsenic level

	<p>results for use in the Superfund Alternative Approach with the Asarco smelter site.</p>
<p>Project Objectives:</p>	<p>The primary objective of the information collected for the Hayden, AZ EI is to assess exposures to environmental arsenic. Because the ASARCO smelter site was shut down for maintenance during the time of the initial EI and arsenic levels in the air were not at a typical level for the site this follow up EI will provide a more accurate measure of the participants typical level of arsenic exposure at a time when the ASARCO smelter site is operating normally and arsenic levels in the air are at a typical level for the site. ATSDR will work with EPA to insure that the smelter site will be operational during the time period of testing. ATSDR will continue to evaluate air monitoring data provided by EPA before, during, and after the EI testing period to look for any evidence of a change in levels of arsenic in the air. Data obtained during this EI will include analytical measures of arsenic in urine. Information obtained from the participants assists the team in determining if exposure has occurred or is occurring. For this EI, a data collection system will include all of the measurements and procedures that are proposed to address data gaps in the urine sampling. We will compare the results with urinary arsenic levels from the previous ATDR Hayden EI and the levels of health concern. We will also provide participants with their individual results, interpretation and recommendations, and write a summary report (EI report, sample in Attachment 7).</p>
<p>Environmental Sampling to be Completed:</p>	<p>None. EPA has already conducted soil testing in Hayden and Winkelman, AZ as part of the Superfund Alternative Approach with the ASARCO smelter site.</p>
<p>Biological Sampling to be Completed:</p>	<p>Urine samples for urinary arsenic testing will occur in the fall of 2017. The following groups will be offered repeat urinary arsenic testing in the Hayden/Winkelman area:</p> <ul style="list-style-type: none"> • 58 participants in the initial EI that provided a urine specimen. This includes: <ul style="list-style-type: none"> • Children and adolescents who were aged 6 years to 18 years at the time of the initial EI who participated in the initial EI. • Women who were pregnant or of childbearing age at the time of the initial EI who participated in the initial EI. • In additional full time residents of Hayden and Winkelman who request testing will be accommodated if space and testing equipment is available up to a maximum of 60 participants. Although not required the focus for these additional tests will include: <ul style="list-style-type: none"> o Siblings of participants that are older than 6 years o Women who are pregnant

<p>Data Collection and Analysis Procedures:</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"> • Recruitment: <ul style="list-style-type: none"> ○ Participants (or their parent/guardian) will be contacted via mail (Attachment 8) to inform them of the opportunity for retesting and offered an opportunity to schedule an appointment. ○ Participants who do not respond to the mail contact will be contacted by ATSDR or partner staff during a door to door canvas of the community. • Collection: All participants will be provided a parental permission/child assent/adult consent form to sign for children being tested. Child assent will be obtained for children 7 years to less than 18 years of age and a consent form will be signed by women. Adult participants and parental/guardian proxies for children will be asked questions to allow a better interpretation of urinary arsenic 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 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. • Participants will be provided an appropriate urine specimen sample cup provided by the CDC Division of laboratory Sciences. Where possible these specimen cups will be provided to participants in advance along with instructions for collection of the specimens as a first morning void. Specimen cups will also be available to collect a spot sample as necessary at the collection site. ATSDR personnel will pack and ship the samples overnight to the NCEH laboratory from the collection site. Collection of the urine sample is estimated to take 10 minutes to complete. <p><u>Analysis:</u></p> <ul style="list-style-type: none"> • The urine samples will be analyzed by the NCEH laboratory using state-of-art laboratory methods.
<p>Information Collection Mode (in-person or remote):</p>	<p>In-person</p>
<p>Plans for Payment to Participant (if applicable):</p>	<p>Not Applicable</p>
<p>Privacy Protections:</p>	<p>Privacy will be protected to the fullest extent of the law. The consent forms contain information about privacy protections.</p>
<p>Other Ethical Concerns/Issues:</p>	<p>Urine samples will be obtained from children and adults. There are no expected complications from urine sample collection.</p>
<p>Projected Time Frame:</p>	<ul style="list-style-type: none"> • The EI will be conducted over a period of 3 days (Friday

	<p>through Sunday). Each sample collection will take approximately 30 minutes per participant, including questionnaire.</p> <ul style="list-style-type: none"> • The participants will be provided results of the 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:	<ul style="list-style-type: none"> • Urinary arsenic results will be provided to participants within 12 weeks of specimen collection. • If concentrations or arsenic in urine are found at ≥ 28.4 grams per gram of creatinine participants will be contacted sooner. • The EI report will be prepared, cleared and released as soon as possible.
Burden Hours Requested:	<p>30 hours</p> <ul style="list-style-type: none"> • 60 participants x 30 minutes per participant

Attachments:

1. Supporting Statement A
2. Supporting Statement B
3. Hayden, AZ EI Parental Permission/Assent/Consent Forms
 - a. Parental Permission Form for Urine Arsenic Testing and Questionnaire: Children 6 to less than 18 years of age
 - b. Assent Form for Urine Arsenic Testing and Questionnaire: Children and Youth aged 7 to less than 18 Years of age
 - c. Consent Form for Urine Arsenic Testing and Questionnaire: Adults aged 18 years and over
4. Hayden, AZ EI Questionnaire
5. Hayden, AZ EI Research Determination
6. Hayden, AZ EI Table of Sample Results Letters Templates
 - 6A. Sample Results letter to the Parent of a Participant 6 to less than 18 - Total Arsenic below follow up level
 - 6B. Sample Results Letter for Participant 6 to less than 18 Years of Age - Total As Above, Organic As Not Elevated, Inorganic As Elevated
 - 6C. Sample Results Letter for Participant 6 to less than 18 Years of Age - Total As Above, Organic As Elevated, Inorganic As Not Elevated
 - 6D. Sample Results Letter for Participant 6 to less than 18 Years of Age - Total As Above, Organic As Elevated, Inorganic As Elevated
 - 6E. Sample Results Letter to a Pregnant Woman or Woman of Child Bearing Age 15 to less than 45 years - Total Arsenic Below Follow-up Level
 - 6F. Sample Results Letter to a Pregnant Woman or Woman of Child Bearing Age 15 to less than 45 years) - Total As Above, Organic As Not Elevated, Inorganic As Elevated
 - 6G. Sample Results Letter to a Pregnant Woman or Woman of Child Bearing Age 15 to less than 45 years - Total As Above, Organic As Elevated, Inorganic As Not Elevated

6H. Sample Results Letter to a Pregnant Woman or Woman of Child Bearing Age 15 to less than 45 years) - Total As Above, Organic As Elevated, Inorganic As Elevated

6I. Factsheet with Tips for Reducing Exposure to Arsenic to Include with Result Letters to Participants with High Arsenic Levels

- 7. Example of Prior EI Final Report**
- 8. Arsenic Retest Recruitment Letter**
- 9. Urine Collection Instructions**
- 10. Hayden & Winkelman Site Map and Demographics**
- 11. Tips for Reducing Exposure to Arsenic**