

Blood Lead Levels in Iola, KS Exposure Investigation

ATSDR Exposure Investigations (EI) Generic Information Collection Request

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Supporting Statement Part B

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ATTACHMENTS

Attachments:

1. Supporting Statement A
2. Supporting Statement B
3. Iola, KS EI Parental Permission/Assent/Consent Forms
 - 3A. Parental Permission Form for Blood Lead Testing and Questionnaire: Children Younger than 18 Years
 - 3B. Assent Form for Blood Lead Testing and Questionnaire: Children and Youth aged 6 to 17 Years
 - 3C. Consent Form for Blood Lead Testing and Questionnaire: Pregnant Women and Women of Childbearing Age aged 15 to <45 Years
4. Iola, KS EI Questionnaire
5. Iola, KS EI NCEH/ATSDR Human Subjects Research Determination
6. Iola, KS EI Sample Results Letters
 - 6A. Sample Results Letters to the Parent of a Participant aged Younger than 6 Years
 - 6B. Sample Results Letter to a Pregnant Woman or Woman of Child Bearing Age aged 15 to <45 Years
 - 6C. Inserts for Results Letters
 - 6D. Factsheets for Results Letters
7. Example of Prior EI Final Report
8. BLL Iola EI Protocol

B. Collections of Information Employing Statistical Methods

This is no statistical methodology used for this investigation. Section B.1 of the submission (below) describes how the data will be 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.

Past zinc smelting activity in the city of Iola resulted in lead contamination in the soil throughout the city. EPA listed the site on the National Priority List (NPL) in 2013 and is in the process of remediating soil within the city of Iola. The purpose of the Iola, KS EI is to sample children (≤ 6 years old) and women (pregnant and of childbearing age) for blood lead during the winter and summer seasons.

For the winter 2016/2017 sampling round, participants will be recruited from homes with soil lead ≥ 800 mg/kg that have not yet been remediated by EPA. For the summer 2017 sampling, the participants from the winter sampling will be recruited along with additional participants from the community that meet the criteria (e.g., younger than 6 years old and women that are pregnant or a childbearing age). The results of the BLL sampling will be used to identify participants that may be impacted by the health effects of lead. The results will also be used by EPA to prioritize cleanup at the site (i.e., BLL greater than 10 $\mu\text{g/dL}$ and lead in soil greater than 400 mg/kg will be prioritized for cleanup).

B.2. Procedures for the Collection of Information

Recruitment for both the winter 2016/2017 and summer 2017 sampling events will include:

- Sending a letter of invitation and fact sheet one to two weeks prior to the sampling event. The letter and fact sheet will be sent to :
 - Winter 2016/2017: homes with lead in soil ≥ 800 mg/kg that have not been remediated
 - Summer 2017: participants in the winter sampling event and all other homes within the Iola community
- Door to door recruitment will take place one week prior to each sampling event. Participants will be invited to participate and will be signed up for a specific time for the sampling at a central location within Iola.

Recruitment will focus on:

- Children younger than 6 years old

- Women who are pregnant or of childbearing age
- Siblings of participants older than 6 years old, at the parent's request
- Any other person that meets the above criteria but was not included in the recruitment effort.

Participants in the investigation will be instructed to make an appointment at a blood collection center to have a blood sample drawn. A list of questions, provided in Attachment 4, will be administered in person at the central collection site. Blood samples will be obtained using certified phlebotomists at the blood collection center. ATSDR personnel will pack and ship all samples overnight to the NCEH or a contract laboratory from the sample collection site.

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 4). Each participant receives a copy of their personal results (sample results letters 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

ATSDR has a list of all addresses of homes located in the small community of Iola, KS. A letter of invitation and a fact sheet will be provided to all the homes in an attempt to notify all eligible participants in Iola. In addition, a letter and fact sheet will be provided to facilities including daycares/preschools/elementary schools to focus recruitment on young children.

EPA is currently remediating residential soil in Iola so it is anticipated that residents will be aware of the cleanup effort and be willing to be included in the EI. Even without 100% participation, we can interpret results because we are providing participants an individual result and are not attempting to determine population level exposures.

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 calculations are not used to determine participation in EIs.