

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

PROJECT TITLE: Blood Lead Levels in Iola, KS Exposure Investigation

SITE LOCATION: Iola, Kansas

REQUESTED BURDEN HOURS: 250

PROJECT SUMMARY

Principal Investigator(s):	<ul style="list-style-type: none"> • Lourdes Rosales-Guevara (ATSDR Headquarters) • Karen Scruton (ATSDR Headquarters) • Cory Kokko (ATSDR Region 7) • Spencer Williams (ASTDR Region 7)
Technical Assistance:	<ul style="list-style-type: none"> • Region 7 Environmental Protection Agency (EPA) • Kansas Department of Environment and Health (KDEH) • Southeast Kansas Multi-County Health Department (SEKMCHD) • DLS/NCEH/ATSDR laboratory
Source of Request (state, petition, etc.):	ATSDR EI will be conducted in coordination with EPA.
Project Goals:	<ol style="list-style-type: none"> 1. Evaluate Blood Lead Levels (BLLs) for susceptible populations who live in properties where EPA testing documents lead levels in soil of > 800 mg/kg. <ol style="list-style-type: none"> a. children younger than 6 years b. women who are pregnant or of childbearing age 2. Recommend case management for participants with BLL $\geq 5\mu\text{g/dL}$ <ol style="list-style-type: none"> a. Recommend follow-up with a Pediatrician/Obstetrician. 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 lead into the body. 3. Coordinate with EPA to use BLL results to prioritize site cleanup [i.e., participants with BLL $\geq 10\mu\text{g/dL}$ (from EI or any blood testing event) and yard soil levels $\geq 400\text{ mg/kg}$ (from EPA testing) will be given priority]
Project Objectives:	This exposure investigation will recruit community members living in the Iola, KS, who are at highest risk for exposure based on EPA soil testing. This will include children younger than 6 years and women who are pregnant or of childbearing age who live on those properties identified by EPA. 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. EPA is conducting soil testing in Iola, KS as part of the Remedial Investigation/Feasibility (RI/FS) process.
Biological Sampling to be Completed:	<p>Blood lead testing will occur in winter 2016/2017 and summer 2017. The following groups will be offered blood lead testing in Iola:</p> <p><u>Winter 2016/2017:</u></p> <ul style="list-style-type: none"> • 150 Children aged younger than 6 years old who live in properties where EPA testing documents lead levels in soil of > 800 mg/kg. • 50 women who are pregnant or of childbearing age, 15 to 44 years old who live in properties where EPA testing documents lead levels in soil of > 800 mg/kg. <p><u>Summer 2017 (200 participants from the winter testing will be invited to participate in the summer testing, in addition to 100 new participants):</u></p> <ul style="list-style-type: none"> • 225 Children aged younger than 6 years old • 75 women who are pregnant or of childbearing age, 15 to 44 years old <p>In addition, if the participant groups above do not fill all available appointments, the following groups will be offered testing for blood lead testing on a first come, first served basis:</p> <ul style="list-style-type: none"> • Siblings of participants that are older than 6 years • Any other child younger than 6 years old that was not recruited
Data Collection and Analysis Procedures:	<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"> ○ For the winter 2016/2017 sampling event, participants will be recruited from homes with lead in soil ≥ 800 mg/kg (identified from EPA soil testing) that has not been remediated by EPA. ○ For the summer 2017 sampling event, participants will be recruited from participants sampled during the winter event and any other child/woman that meets the age/condition criteria. • Collection: All participants will be provided a parental permission/child assent/adult consent form to sign. Child assent will be obtained for children 6 to 17 years of age and a consent form will be signed by women. Adult participants and

	<p>parental/guardian proxies for children will be asked questions to allow a better interpretation of blood results. The questionnaire to be used in the EI is attached (Attachment 4), and is estimated to take 20 minutes to complete.</p> <ul style="list-style-type: none"> • 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. • 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. <p><u>Analysis:</u></p> <ul style="list-style-type: none"> • The blood samples will be analyzed by the NCEH laboratory using state-of-art laboratory methods.
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 protections.
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:	<ul style="list-style-type: none"> • The EI will be conducted over a period of 5 days (Monday through Friday) for both winter 2016/2017 and summer 2017 sampling periods. Each sample collection will take approximately 30 minutes per participant, including questionnaire. • The participants will be provided results of the blood 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"> • Blood lead results will be provided to participants within 12 weeks of specimen collection. • If concentrations in blood are found at $\geq 5 \mu\text{g/dL}$, participants will be contacted sooner. • The EI report will be prepared, cleared and released as soon as possible.
Burden Hours Requested:	<p>250 hours</p> <ul style="list-style-type: none"> • 200 participants x 30 minutes per participant per testing event (winter and summer - 200 hours total) • 100 participants x 30 minutes per participant (summer only) - 50 hours

Attachments:

- 1. Supporting Statement A**
- 2. Supporting Statement B**
- 3. Iola, KS EI Parental Permission/Child Assent/Adult Consent Forms**
 - 3A. Parental Permission Form for Blood Lead Testing and Questionnaire: Children aged <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 old**
 - 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**