**Generic Information Collection (GenIC) Submittal Form for**

**OMB Review of ATSDR Exposure Investigations (EIs) (0923-0048)**

**PROJECT TITLE:** Jasper and Newton Counties (JNC) Missouri Lead Exposure Investigation

**SITE LOCATION: Jasper and Newton County, Missouri**

**REQUESTED BURDEN HOURS: 426**

**PROJECT SUMMARY**

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| **Principal Investigator(s):** | * Aaron Young (ATSDR Headquarters)
* Erin Evans (ATSDR Region 7)
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| **Technical Assistance:** | * U.S. Environmental Protection Agency (EPA) Region 7
* Missouri Department of Health and Senior Services (MDHSS)
* Jasper County Health Department
* Newton County Health Department
* Joplin City Health Department
* Mid-America Pediatric Environmental Health Specialty Unit (PEHSU).
* DLS/NCEH/ATSDR laboratory
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| **Source of Request (state, petition, etc.):** | EPA request for assistance from ATSDR in blood lead sampling. |
| **Project Goals:** | The EI will measure blood lead levels (BLLs) in children (<72 months) and pregnant women or women of childbearing age (15-44 years) near the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings Superfund sites. EPA and MDHSS will sample lead contamination in and around households to allow a better evaluation of BLLs. ATSDR will compare the results with levels of health concern (BLLs ≥ 3.5 µg/dL for children and BLLs ≥ 5 µg/dL for adults), provide participants with their individual results and interpretation/ recommendations, and write a summary report (EI report).This EI will result in an increased education about preventing lead exposure, improved access to recommendations for remedial or removal actions, and to the knowledge needed to guide future remediation of lead in the area.  |
| **Project Objectives:** | The EI has the following objectives:1. Evaluate BLLs in Jasper and Newton County residents, who are children (<72 months) and women who are pregnant or of childbearing age (15-44 years) that participate in the investigation.
2. Review environmental sampling data collected by state and federal partners. Samples will be taken from participating residents’ indoor and outdoor environments including soil, drinking water from private wells at the tap, public water collected at the tap, household dust, and interior and exterior painted surfaces.
3. Administer a survey questionnaire to document demographic, behavioral, occupational, and educational information of participants. Parents/guardians will complete the survey for the child participants.
4. Evaluate lead levels in environmental samples and the association between environmental lead levels with BLLs.
5. Recommend ways to lower environmental exposures to lead.
6. Provide an opportunity for all participants and parents/guardians of child participants to discuss their blood lead findings with an ATSDR medical officer.
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| **Environmental Sampling to be Completed:** | The EI will include environmental sampling, conducted by the EPA and MDHSS, to determine lead levels in the environment. Samples will be taken from participating residents’ indoor and outdoor environments including soil, drinking water from private wells at the tap, public water collected at the tap, household dust, and interior and exterior painted surfaces.EPA is responsible for collecting, processing, and analyzing residential soils and drinking water from private residential wells. Samples will only be collected from participating households. The laboratory analysis will be performed by EPA Region 7’s Science and Technology Center or contracted laboratories.MDHSS is responsible for collecting and analyzing household dust, measuring lead in interior and exterior painted surfaces, and analyzing drinking water from public water supplies. Laboratory analysis for dust wipe and public water samples will be performed by the Missouri State Public Health Laboratory (SPHL). |
| **Biological Sampling to be Completed:** | This EI will measure participants exposure to lead via venous blood draw. The maximum number of EI participants is 300 (225 children [≤ 72 months] and 75 pregnant women or women of childbearing age [15-44 years] to determine blood lead levels (BLLs) in the community. If the goal of 300 is not met, ATSDR will fill the remaining number with minor siblings of participants ≥ 72 months, if requested by a parent or guardian, as a public health service to the community. However, their results will not be included as part of the EI report, and they will not be compensated.ATSDR is responsible for designing the study protocol, recruiting participants, collecting blood, and reporting the study results. |
| **Data Collection and Analysis Procedures:** | Recruitment of Participants:Participants for the EI will be recruited from the areas within the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings Superfund sites’ boundaries. The EI will seek participants who reside in areas where soil lead contamination is highest or suspected to be present. ATSDR will use site investigations and historic site sampling data provided by EPA Region 7 to identify these areas. ATSDR will perform the following recruitment activities:1. ATSDR will create a mailing list for the residents in Jasper and Newton Counties where lead contamination is known to be present or where environmental investigations are pending. Contact information will be provided for participants to make appointments for testing.
2. Fact sheets, fliers, and postcards providing information on testing will be prepared by ATSDR and provided to LPHAs, distributed to eligible participants, and printed in local news publications and online outlets.
3. Digital recruitment material will be developed, and targeted social media advertising will be purchased. Click and impression advertisements will be purchased through Facebook and Instagram. Advertisements will target women with children, women who are pregnant, women of childbearing age, men with children, and grandparents.
4. ATSDR will develop a webpage to display information about the EI, eligibility criteria, and enrollment information.
5. ATSDR will focus on daycares, preschools, and elementary schools in the area to request partnership to recruit from client families.
6. ATSDR will recruit through established or newly created in-person connections with the community. Recruitment will occur through local events or public information sessions aimed at community groups, religious organizations, or other influential community members including elected officials.
7. ATSDR will work with LPHAs and local media outlets to broadcast recruitment information via radio or local news channels.
8. ATSDR will work with MDHSS, LPHAs, and the PEHSU to provide recruitment information and material to area PCPs, pediatricians, clinicians, and other area healthcare providers.
9. A $20 token of appreciation in the form of a cash gift card will be provided to each eligible participant. The gift card will be given to adult participants, or the parent or guardian (for child participants) at the time of blood draw.
10. Recruitment efforts will stop once the participation goal of 225 children <72 months and 75 pregnant women or women of childbearing age (15-44 years) has been met.

Collection: 1. There will be two blood collection events. There will be one event at a central location for each county, to reduce travel burden on participants (ATSDR).
2. Administer a questionnaire to document demographic, behavioral, occupational, and educational information of participants (ATSDR). Parent/guardians will complete the survey for child participants.
3. Environmental samples will be collected from participants’ households within 90 days of blood collection (EPA and MDHHS).

Analysis:1. Review environmental sampling data collected by state and federal partners from participating residents’ indoor and outdoor environments.
2. Evaluate lead levels in environmental samples and the association between environmental lead levels and BLLs.
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| **Information Collection Mode (in-person or remote):** | In-person |
| **Plans for Payment to Participant (if applicable):** | A $20 token of appreciation in the form of a gift card will be provided to each eligible participant. Eligible participants will receive the gift card at the time of blood draw.  |
| **Privacy Protections:** | Privacy will be protected to the fullest extent allowable by 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:** | * The blood collection of the EI will be conducted over a period of 2 weeks in the summer of 2022. The environmental sampling will occur within 90 days of blood collection. At minimum, three sampling events will occur on different days: 30 minutes for the questionnaire and blood draw by ATSDR; 35 minutes for indoor paint, dust, and public water sampling by MDHHS; and 25 min for outdoor dust and private water sampling by EPA.
* There is a maximum of 426 total estimated burden hours assuming that all 300 participants will have a separate sampling event for indoor dust with public water and outdoor soil with private water. The total burden will likely be less than 426 due to some homes containing multiple participants that will not each require separate environmental samples.
* Blood samples will be collected and shipped by ATSDR to DLS for analysis after the conclusion of the 2-week EI. Analysis of samples will take approximately 6 weeks.
* Indoor and outdoor lead paint, dust, and public water samples will be collected and analyzed in batches by MDHHS. All samples will be analyzed within 4-6 weeks after collection.
* Exterior soil, and private water samples will be collected and analyzed by EPA. All samples will be analyzed within 4-6 weeks after collection.
* The participants will be provided results of the blood testing and environmental testing within 12 weeks of receipt of the environmental results from EPA and MDHSS.
* The EI report will be prepared, cleared, and released as soon as possible.
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| **Plans for Publication and Dissemination of Results:** | * Blood lead results will be provided to participants within 12 weeks of ATSDR’s receipt of environmental results from EPA and MDHSS.
* If concentrations of lead in blood are found at ≥3.5 µg/dL in children or ≥5 µg/dL in adult participants, participants will be contacted sooner.
* The EI report will be prepared, cleared, and released as soon as possible.
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| **Burden Hours Requested:** | 426 hours  |

**ATTACHMENTS**

1. Supporting Statement A
2. Supporting Statement B
3. JNC EI List of Attachments
4. Example of Prior EI Final Report
5. ATSDR Cleared Factsheets for Reducing Exposure to Lead

5A. Keep Lead Out of the Body by Eating Healthy Food

5B. Protect Your Family from Lead in Your Home

5C. Protect Your Family from Lead in Your Yard

5D. Safe Gardening in Lead-Contaminated Soil

5E. Pregnancy and Lead: Stay Healthy During Pregnancy

1. Privacy Impact Assessment Form
2. JNC EI Protocol (and Pertinent Appendices)

Appendix A: Background

Appendix C: Fact Sheets and Recruitment Material

C1. Exposure Investigation Fact Sheet

C2. Newton County Recruitment Flyer

C3. Jasper County Recruitment Flyer

C4. Social Media Recruitment Content

 Appendix D: ATSDR Privacy Act Statement, Consent, Permission and Assent Forms

D1. ATSDR Privacy Act Statement

D2. ATSDR Adult Consent Form for Blood Testing

D3. ATSDR Parental Permission Form for Blood Testing (child under )

  D4. ATSDR Child Assent Form for Blood Testing (minor non-participant)

D5. EPA Consent Form

D6. MDHHS Consent Form

Appendix E: ATSDR Data Collection Forms

E1. ATSDR JNC EI Questionnaire

E2. ATSDR Biological Testing Tracking Form

Appendix F: Environmental Sampling Protocols

Appendix G: Health and Safety Plan

Appendix H: Sample Results Letter to Participants

 H1. ATSDR Results Letter

 H2. EPA Sample Results Letter

Appendix I: Data Collection Forms Used by Partnering Agencies

I1. Home Schematic (Form 100)

 I2. Interior Environmental Paint Assessment (Form 110)

 I3. External Environmental Paint Assessment (Form 120)

I4. Dust Wipe Collection (Form 200)

I5. Soil Composite Sample Collection (Form 300)

I6. Private Well Water Collection (Form 400)

I7. Public Water Kitchen Tap Collection (Form 500)