

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

PROJECT TITLE: Perfluorinated Compound Biological Sampling in the Vicinity of Morgan, Lawrence, and Limestone Counties, Alabama

SITE LOCATION: Morgan, Lawrence and Limestone Counties, Alabama

REQUESTED BURDEN HOURS: 93

PROJECT SUMMARY

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| Principal Investigator(s): | <ul style="list-style-type: none"> • Rachel R. Worley (ATSDR Headquarters) • Bruce C. Tierney (ATSDR Headquarters) |
| Technical Assistance: | <ul style="list-style-type: none"> • Alabama Department of Environmental Management (ADEM) • EPA Region 4 • DLS/NCEH/ATSDR laboratory • Eastern Research Group (ERG) – contractor support • University of Georgia – Department of Veterinary Physiology and Pharmacology |
| Source of Request (state, petition, etc.): | Recommendations made in previous ATSDR Exposure Investigation (EI) report (Perfluorochemical Serum Sampling In the vicinity of Decatur, Alabama Morgan, Lawrence, and Limestone Counties, April 1, 2013). |
| Project Goals: | The goal of this EI is to conduct biological sampling in the vicinity of Morgan, Lawrence and Limestone Counties, Alabama, in order to collect blood and urine samples in order to determine how exposure to perfluorinated compounds (PFCs) have changed in this population since the previous 2010 EI. This exposure investigation will follow through on ATSDR recommendations from the previous EI and will provide the community with additional information about their site-specific exposures to PFCs. |
| Project Objectives: | <p>The exposed population in Morgan, Lawrence and Limestone Counties (AL) includes residents who live and work in a predominantly rural community. Many community members receive their drinking water from the East Lawrence/West Morgan public water supply system. The most current water data from this system indicates that this system has detectable levels of two PFC species; perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS).</p> <p>This project has four primary objectives:</p> <ul style="list-style-type: none"> • Compare current PFC-serum concentrations in the community to the national reference population (NHANES 2011-2012). • For each individual who also participated in the 2010 EI, compare current PFC serum concentrations to the concentration measured in 2010. |

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| | <ul style="list-style-type: none"> • Use paired serum and urine concentrations to calculate biological half-life for 12 PFC species to improve understanding of pharmacokinetic behavior of these compounds in humans in this community. • Evaluate potential existence of non-drinking water PFC exposure pathways (ex: soil exposure, contact with contaminated consumer products, ingestion of contaminated foods, inhalation) through physiologically-based pharmacokinetic (PBPK) modeling. |
| Environmental Sampling to be Completed: | None |
| Biological Sampling to be Completed: | ATSDR will conduct blood and urine tests for up to 155 volunteers (over age 12) from the exposed population. |
| Data Collection and Analysis Procedures: | <p><u>Recruitment of Participants:</u> Participants will be recruited based on the following prioritization:</p> <ul style="list-style-type: none"> • First Priority Target Group: Participants in the 2010 Exposure Investigation who continue to live in Morgan, Lawrence and Limestone Counties. • Second Priority Target Group: Participants in the 2010 Exposure Investigation who no longer live in Morgan, Lawrence and Limestone Counties. <p>ATSDR will target participants from the 2010 EI (155 residents) for recruitment into this investigation. ATSDR will contact all prior EI participants by phone to recruit them for this investigation. If telephone recruitment yields fewer than 75 participants, staff from ATSDR and local health agencies will hold a public meeting with the residents to attempt to recruit additional participants.</p> <p><u>Collection:</u></p> <ul style="list-style-type: none"> • All participants will be provided an assent/consent/parental permission form to sign (Attachment 3) and will be asked questions to allow a better interpretation of their results. The questionnaire to be used in the EI is attached (Attachment 4). • The human subjects documentation is provided in Attachment 5. The EI is not considered a research study; its primary intent is public health practice. The primary intent of this EI is to evaluate exposure to PFCs in the community. Collection of paired blood and urine samples will allow ATSDR staff to calculate biological half-life for each PFC species, thereby contributing to the broader scientific understanding of human exposures to PFCs in this community. The results of this EI are not intended to be generalized and are applicable only to the sampled participants • Participants in the investigation will be instructed to make two appointments – one to sign consent forms and receive urine collection materials and instructions, and a second to submit their urine sample, have a blood sample drawn, and complete |

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| | <p>a questionnaire.</p> <ul style="list-style-type: none"> • The blood samples will be obtained using certified phlebotomists at a designated location within the community. • ATSDR personnel will pack and ship all samples overnight to the NCEH or a contract laboratory from the sample collection site. • Urine samples will be collected by each participant at their home. Participants will be instructed to collect a complete first-morning void in a provided urine collection container on the morning of their scheduled blood testing appointment. The participant will be asked to note the time of collection and the time of their last urinary void prior to the collected urinary void on the urine collection log sheet. The urine container should be capped, sealed in a plastic bag, and placed in a refrigerator or cooler until collected by ATSDR at the blood collection appointment. • Each participant will be asked to complete a questionnaire (Attachment 4) to gather information on risk factors for exposure to PFCs through food pathways, contact with contaminated soil, or local well water use. Each participant will have their height, weight, and body fat percentage measured and recorded by an ATSDR staff person. <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 • The urine samples will be analyzed by AXYS Analytical Services Ltd (AXYS) using highly sensitive laboratory methods. • Given that PFCs are beginning to generate increased interest across the United States, de-identified data and samples from this investigation will be retained for potential additional analysis in the future. Consent and assent forms for sample and data retention are provided in attachment 3. |
| 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 expectations. |
| Other Ethical Concerns/Issues: | Blood will be drawn from children (older than 12 years) 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). Each appointment will take approximately 15 minutes per participant, and urine collection is expected to take no more than 5 minutes, for a total of 35 minutes per |

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| | <p>participant.</p> <ul style="list-style-type: none"> • The participants will be provided results of the blood and urine sampling within 6 months to one year of collection. • If concentrations in blood and/or urine are found at levels of health concern, participants will be contacted sooner. • 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 and urine results will be provided to participants within 6 months to one year of specimen collection. • If concentrations in blood and/or urine are found at levels of health concern, participants will be contacted sooner. • The EI report will be prepared, cleared and released as soon as possible. • Summary findings from the investigation will be submitted for publication in the peer-reviewed scientific literature. |
| Burden Hours Requested: | 93 hours (155 participants x 35 minutes per participant) |

ATTACHMENTS

1. Supporting Statement A
2. Supporting Statement B
3. Decatur EI Assent/Consent/Parental Permission Forms
 - a. Adult Consent Form (≥ 18 years of age)
 - b. Adult Consent Form for Sample Storage (≥ 18 years of age)
 - c. Assent Form for Children (12 - < 18 Years)
 - d. Assent Form for Children for Sample Storage (12 - < 18 Years)
 - e. Parental Permission Form for Children (12 - < 18 Years) Participating in Investigation
 - f. Parental Permission Form for Sample Storage for Children (12 - < 18 Years) Participating in Investigation
4. Decatur EI Questionnaire
5. Decatur EI Human Subjects Research Determination Form
6. Decatur EI Sample Results Letters
7. Example of Prior Exposure Investigation Final Report