

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

ATSDR Exposure Investigations (EI) Generic Information Collection Request
OMB No. 0923-0048

Attachment 2: Supporting Statement Part B

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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**

B. Collections of Information Employing Statistical Methods

Although no statistical methodology is used for the investigations, we will use this section of the submission to describe how the data are 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.

The purpose of the Decatur EI is to compare serum concentrations of perfluorinated compounds (PFCs) in residents of Morgan, Lawrence, and Limestone Counties, Alabama to national reference population (NHANES 2011-2012), to compare PFC-serum concentrations measured in individual participants to concentrations measured in 2010, to calculate biological half-life for each PFC species in order to improve understanding of pharmacokinetic behavior of these compounds in humans in this community, and to evaluate potential existence of non-drinking water PFC exposure pathways through physiologically-based pharmacokinetic (PBPK) modeling in this community.

This EI aims to evaluate changes in PFC-serum concentrations and thus, participant selection is specifically biased toward residents who participated in the 2010 EI, rather than statistical random selection methods used in research to generate or contribute to generalizable knowledge. Most EIs, including this one, are location-based. We estimate the potential respondent universe based on the number of residents who live in the Morgan, Lawrence, and Limestone County area and who participated in the 2010 EI.

B.2. Procedures for the Collection of Information

A list of questions, provided in Attachment 4, will be administered in person at the site of biological sample collection. Participants will be identified by recruiting from participants of the 2010 Decatur, AL EI. The EI team is identified by name along with qualifications or experience in conducting similar EIs.

ATSDR will contact all prior exposure investigation participants by phone to recruit them into the follow-up 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. Up to 155 participants will be recruited into the investigation. This will include children over the age of 12, pregnant women, and women of child-bearing age.

Participants in the investigation will be instructed to make an appointment at a blood collection center to have a blood sample drawn. 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. 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 provided to ATSDR.

Each participant will be asked to complete a short survey (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.

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. Samples 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

The Decatur, AL EI is a second exposure investigation that will be completed in response to recommendations made in the 2010 Decatur, AL Exposure Investigation report. Participants will be recruited from the population that participated in the 2010 EI.

For the Decatur, AL EI, we will be recruiting up to 155 participants including adults and children over the age of 12. In ATSDR's experience, getting sufficient numbers of participants has not been a problem since EI communities often request the testing before we arrive. We often achieve close to a 100% response rate. However, because we are interpreting each individual's response to his or her specific exposure and not attempting to determine population level exposures, we can interpret results without 100% participation.

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.