Supplemental Exposure Investigation (EI) at Select PFAS Exposure Assessment Sites

ATSDR Exposure Investigations (EI) Generic Information Collection Request
OMB No. 0923-0048
Expiration Date: 04/30/2022

Supporting Statement Part A

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Exposure Investigation Section
Office of Community Health and Hazard Assessment (OCHHA)
Agency for Toxic Substances and Disease Registry (ATSDR)

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Goal of the Exposure Investigation: Exposure Assessments (EAs) were completed at locations around the country in 2019 and 2020 to evaluate per- and polyfluoroalkyl substances (PFAS) body burden (serum and urine) in residents exposed to PFAS in drinking water. In a subset of participants' homes, samples of tap water and indoor dust were collected and analyzed for PFAS.

To better evaluate non-drinking water contributions to PFAS body burden, ATSDR and EPA are conducting this "Supplemental Exposure Investigation (EI) at Select Exposure Assessment Sites"" (called Environmental Sampling EI) to collect and analyze samples of various environmental media for PFAS. Both the EA and EI include administration of a questionnaire. This environmental sampling EI has three primary objectives:

1. Whether PFAS are detectable in various non-drinking water environmental media;
2. What the detectable levels of PFAS in environmental media are; and
3. Whether these detectable levels of PFAS may be associated with the existing measured body burden levels of PFAS identified during the EA.

Intended Use of the Resulting Data: The EA and environmental sampling EI questionnaire results will be used to better interpret the human exposure profile obtained during the EAs at the New Castle, DE and Hampton County, MA locations.

Federal and state regulations or guidelines are not available for PFAS in any of the media that will be sampled. Therefore, the results of the sampling can only be used to evaluate the presence or absence, and if detected, to identify the amount of PFAS that may be present in each of the sampled media. ATSDR Minimal Risk Levels (MRLs) are available for four PFAS (i.e., PFOA, PFOS, PFNA, PFHxS) and may be used to evaluate PFAS in appropriate media (e.g., soil).

The results of the serum testing available from the EAs will be evaluated using the results of the environmental sampling completed for this EI and the questionnaire results from both the EA and this environmental sampling EI. The results and conclusions from the environmental sampling EI will be released as a report for the general public as soon as is possible, and findings may be submitted for publication in the peer-reviewed scientific literature.

Methods to be Used to Collect: Environmental samples will be taken at the New Castle County, DE and Hampden County, MA EA locations. A maximum of 40 and 80 households will be sampled in New Castle County and Hampden County, respectively, which represent approximately 30% of the EA households at each location. All households will be sampled for indoor dust and will be administered a household and exposure questionnaire. In addition, 20 homes at each location will also be sampled for: indoor air, bulk dust (from a vacuum cleaner bag), indoor wipe samples, and soil. Personal exposure to PFAS will be evaluated by having one participant in each of the 20 households wear a silicone wristband. In addition, outdoor air samples will be taken at a central location within the community and samples of locally grown produce will be collected and analyzed for PFAS.

Subpopulation to be Studied: Participants of the EA at two of the locations, New Castle County, DE and Hampden County, MA, will be invited to participate in the EI. The results of the serum testing available from the EAs will be evaluated using the results of the environmental sampling completed for this EI and the questionnaire results from both the EA and this environmental sampling EI.

How Data will be Analyzed: The environmental samples will be analyzed by an accredited laboratory and the results provided to the EI team. The participants will be provided their individual results via a letter sent electronically or via US mail. A summary report for each location will be completed that will provide an analysis of the serum results from the EA using the results of the environmental sampling and questionnaires from the EA and this environmental sampling EI.

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

This data collection is being conducted using the Generic Information Collection Request mechanism of the Agency for Toxic Substances and Disease Registry (ATSDR) Exposure Investigations (EIs) – OMB Control No.0923-0048, expiration date 04/30/2022. The data collection for the environmental sampling EI aligns with the agency's mission.

The data collection is authorized by the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the "Superfund" Act, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986.

ATSDR Public Health Assessment Process and the Role of the Exposure Investigation

Previously, under Section 8006 of the Consolidated Appropriations Act, 2018, ATSDR was required to conduct statistically based biomonitoring exposure assessments (EAs) at "no less than eight current or former domestic military installations" that have or have had documented exposures to PFAS in drinking water. From 2019 to 2020, ATSDR conducted EAs in eight communities throughout the United States.

The intention of the EAs was to determine how exposure to PFAS in drinking water in communities nearby the military installations may have contributed to levels of PFAS in blood and urine of members of the community. In addition to blood and urine testing, tap water and indoor dust were also sampled in a subset of homes. A questionnaire to evaluate potential exposure to PFAS, resulting from water intake, use of consumer products and potential exposure in the workplace, was administered to both adults and children in each participating household.

Exposure to PFAS can result from exposure to both drinking water and non-drinking water sources. Although there is information indicating additional sources of exposure to PFAS, information on the contribution of these sources to PFAS body burden levels is sparse. To better evaluate non-drinking water sources of PFAS that result in contributions to PFAS body burden, ATSDR and EPA are conducting this supplemental Exposure Investigation at Select PFAS EA Sites (called environmental sampling EI).

All households will be sampled for indoor dust (filtered sample) and will be administered a household and exposure questionnaire. In addition, 20 homes at each location will also be sampled for: indoor air, bulk dust (from a vacuum cleaner bag), indoor wipe samples, and soil. Personal exposure to PFAS will be evaluated by having one participant in each of the 20 households wear a silicone wristband. In addition, outdoor air samples will be taken at a central location within the community and samples of locally grown produce will be collected and analyzed for PFAS. The results of the environmental sampling and the results of the questionnaires from both the EA and this environmental sampling EI will be used to better interpret the results of the serum sampling collected during the EA.

The Exposure Investigation Criteria and Recommendation Process

Four criteria must be met for the Exposure Investigation to be approved and conducted. If the answers to these questions indicate that an Exposure Investigation would allow ATSDR to make a better-informed public health call, the Office of Community Health and Hazard Assessment (OCHHA) EI Team may conduct agency-led EIs. At the EA sites, the responses to the four questions (provided below) indicated that an environmental sampling EI is warranted.

The EI Team from OCHHA and ATSDR Regions 1 and 3 will lead the investigation with input from EPA's Office of Research and Development (ORD).

Environmental Sampling Exposure Investigation (EI)

ATSDR was previously directed to conduct the EAs, and the environmental sampling EI was further funded by an Inter-agency Agreement with EPA to conduct environmental sampling at appropriate EA locations. This environmental sampling EI meets the criteria for completion of an EI. The four questions used to establish whether it was appropriate to conduct an environmental sampling EI for the selected EA site were as follows:

1. *Can an exposed population be identified?*

   Yes. Drinking water levels in the two EA communities were known to be above the EPA Health Advisory of 70 ppt (for the sum of PFOA and PFOS) at some point in the past. The serum samples analyzed for PFAS as part of the EA were compared to nationally representative data, specifically, to data collected by CDC as part of its National Health and Nutrition Examination Survey (NHANES) and the serum PFAS levels were found to be elevated above NHANES at all eight locations, including MA and DE, for several PFAS, primarily PFHxS, PFOS and/or PFOA. Low levels of PFAS were detected in few urine samples.

   PFAS may be present in drinking water as well as non-drinking water given that numerous consumer products used routinely in households may contain PFAS given PFAS's stain-, water- and grease-resistant properties.
   .
2. *Does a data gap exist that affects our ability to decide that a public health hazard exists?*
   Yes, very little is known about the levels of PFAS in non-drinking water environmental media that may contribute to the body burden of PFAS. Given that serum levels are available in the EA communities, sampling of non-drinking water sources of PFAS may better define potential exposure, resulting in better recommendations for reducing PFAS exposure.

3. *Can an Exposure Investigation address the data gap?*
   Yes. Environmental sampling, including media to evaluate indoor exposure (air, dust, wipe samples), outdoor exposure (soil), personal exposure (silicone wristbands) and exposure within the community (outdoor air in a central location and locally-grown produce) at the home will allow ATSDR to better interpret the serum PFAS results obtained during the EA.

4. *How will the Exposure Investigation results impact public health decision making?*
   The results of the environmental sampling and EI questionnaire will allow ATSDR to provide participants with better recommendations for reducing exposure to PFAS in non-drinking water sources.

Once the environmental sampling EI data collection and analysis are completed, a final EI report will be prepared for each community and the results will be presented to the communities in a public meeting.

A.2. Purpose and Use of Information Collection

The goals of this environmental sampling EI for at PFAS EA locations are to evaluate:

- Whether PFAS are detectable in various non-drinking water environmental media;
- What the detectable levels of PFAS are in environmental media; and
- Whether these detectable levels of PFAS may be associated with the existing measured body burdens of PFAS.

Data from the environmental sampling EI report may be used by public health professionals, environmental risk managers, and other decision makers in the communities that participate in the EI in determining the source and extent of PFAS exposure from non-drinking water sources. ATSDR will not generalize the results of each EA beyond the defined boundaries of the investigation. The results of the EAs may be used to inform a future health study on PFAS exposure.

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. Once we conduct an EI, we match the unique answers given by participants with their laboratory results or environmental samples to determine whether intervention is needed on an individual level. The information collection is therefore *inherently person- or location-specific.*

Data are treated to protect privacy; access to computer files is password-protected and access is limited to authorized EI personnel, including contractors. All staff working on the project agrees to safeguard the data and not to make unauthorized disclosures. Published reports may present responses in aggregate form and no individuals are identified by name.

A.3. Use of Improved Information Technology and Burden Reduction

ATSDR will provide appropriate consent/parental permission/assent forms and questionnaires to participants prior to the sample collection for completion prior to the sampling event. This is intended to allow EA participants to be included in the environmental sampling EI even if they are unable to be present in the home during the environmental sampling. After the sampling is completed, the information gathered from the questionnaire will be entered into Epi-Info to allow for evaluation of results.

A.4. Efforts to Identify Duplication and Use of Similar Information

ATSDR/NCEH has evaluated other agency initiatives to evaluate PFAS exposure through literature and internet searches, discussions with other public health and environmental professionals, and attendance at interagency, national, and international scientific meetings that other U.S. Federal agencies are asking or have asked similar questions about PFAS exposure.

The National Institute of Environmental Health Sciences (NIEHS) funds PFAS related projects, including grants led by Dr. Jane Hoppin (GenX biomonitoring in North Carolina: (https://tools.niehs.nih.gov/portfolio/index.cfm/portfolio/grantDetail/grant_number/R21ES029353); and Dr. John Adgate (blood sampling for PFAS in Colorado: (https://tools.niehs.nih.gov/portfolio/index.cfm/portfolio/grantDetail/grant_number/R21ES029394). These are the major PFAS projects being sponsored by NIEHS, but others may be available at: (https://tools.niehs.nih.gov/portfolio/index.cfm/portfolio/searchResults).

In addition, from 2005-2013, a C8 Science Panel carried out exposure and health studies in the Mid-Ohio Valley communities that had been potentially affected by the release of perfluorooctanoate acid (PFOA) (a.k.a. C8) to drinking water. The Panel has completed its work and no longer exists, but the effort concluded that there was a probable link between C8 exposure and health effects (http://www.c8sciencepanel.org/index.html). The panel published more than 40 peer-reviewed articles describing their findings.

The U.S. Food and Drug Administration (FDA) has been testing food for PFAS in the general food supply and in foods grown or produced in area with known PFAS contamination since 2019 as part of the Total Diet Study (TDS) (https://www.fda.gov/food/chemical-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure). When PFAS is detected in foods, the FDA conducts a safety assessment to evaluate whether the levels may present a potential human health concern.

This ICR differs from the projects cited above in that this environmental sampling EI is intended to address data gaps regarding non-drinking water exposures at PFAS EA sites located near military installations. Although the FDA continues to test PFAS in food within the U.S., locally grown food at the two EA locations will be tested to provide a more complete assessment of non-drinking water exposure to PFAS.

A.5. Impact on Small Businesses or Other Small Entities

Small businesses are not applicable since all the sampling will be residential.

A.6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection in the summer of 2021. There are no legal obstacles to reduce the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this data collection. The data collection will fully comply with the guidelines of 5 CFR 1320.5 and will be voluntary.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This data collection is being conducted using the Generic Information Collection mechanism for Exposure Investigations – OMB Control No. 0923-0048 (expiration date: 4/30/2022). A 60-day Federal Register Notice was published in the *Federal Register*, Vol. 83, No. 215 on Tuesday, November 6, 2018. No comments were received.

ATSDR is conducting this EI in collaboration with ATSDR Regions 1 and 3 and with EPA Office of Research and Development (ORD).

A.9. Explanation of Any Payment or Gift to Respondents

ATSDR will provide a payment to participants to show appreciation for the time it will take to allow ATSDR to conduct the environmental sampling. A gift card will be provided when the sampling is conducted: $20 per household per appointment. Those homes that have the additional robust sampling requiring two appointments will receive a total of $40 for participating.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The ATSDR/NCEH Information Systems Security Officer (ISSO) has determined that the Privacy Act does apply for the "Supplemental Exposure Investigation (EI) at Select Exposure Assessment Sites" (called Environmental Sampling EI). The relevant Privacy Act System of Records Notice (SORN) for this EI is Privacy Act System Notice 09-19-0001, Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances (HHS/ATSDR). A Privacy Act Statement is included in the consent package (Attachment 9).

Data obtained during the environmental sampling EI will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. The EI will comply with all appropriate federal and state requirements.

A.10.1. Privacy Impact Assessment Information

The environmental sampling EI at the PFAS EA sites will involve up to 120 EA households: 40 in New Castle County, DE and 80 in Hampden County, MA. ATSDR provides participants with information on the EI process and what it can and cannot determine. Recruitment materials, including an invitation to participate letter and fact sheet, phone scripts to allow ATSDR to identify participants who may be scheduled for the robust sampling and an appointment reminder letter are provided in Attachment 8. After providing the participants this information, ATSDR will ask for consent/parental permission/assent to participate in the EI (forms in Attachments 10, 11, 12, and 13). Participation is completely voluntary; participants can stop participating in the EI at any time.

Overview of the Data Collection System

The primary objective of the information collected for the environmental sampling EI is to assess non-drinking water exposure to PFAS. Data obtained during this environmental sampling EI will include analytical measures of PFAS in various environmental media that will provide information to better interpret the PFAS EA serum results.

The data collection system for this EI will be characterized by the following:

1. Who will use the EI Data Collection System?
   The OCHHA EI Team, including ATSDR regional personnel, along with EPA ORD will use the Data Collection System to collect and analyze PFAS in various environmental media at the New Castle County, DE and Hampden County, MA EA locations.

2. Who can be included as part of the EI Generic Clearance?
   EI participants for the environmental sampling EI are identified as EA participants from the New Castle County, DE and Hampden Country, MA EA locations.

3. What types of questions may be asked as part of the EI Generic Clearance?
   For the environmental sampling EI, environmental media will be sampled and questions relating to water intake, household condition, use of consumer products containing PFAS and dietary intake are included in the questionnaire. Attachments 14, 15 and 16 provide the household and personal exposure questionnaires that will be used for the environmental sampling EI.

Items of Information to be Collected

Collecting identifying information is necessary to facilitate personal contact with participants, to obtain their consent to participate and to provide them with results. The information is also used by ATSDR to better interpret the results of the serum sampling that was completed during the PFAS EA. Data is treated in a private manner, unless otherwise compelled by law.

ATSDR collects contact information (e.g., name, address, phone number, email address) to provide the participant with their individual results. General information, which includes age/date of birth, race, gender, etc., will also be collected.

ATSDR will administer two questionnaires: a household questionnaire and a personal exposure questionnaire (Attachments 14, 15 and 16). The household questionnaire includes questions regarding characteristics of the home and the use of products that may contain PFAS. The personal exposure questionnaire includes questions regarding personal exposure such as water use, time spent outdoors and dietary intake off locally grown produce and convenience food. Only questions needed to determine the extent of exposure in a particular situation will be asked.

Participants will be provided their individual environmental sampling results and a final report will be produced and provided to the communities.

An example of a completed Exposure Investigation is provided as Attachment 4 and the final environmental sampling EI Protocol is provided as Attachment 5.

Sharing and Purpose of Collected Information

The information collected for the environmental sampling EI will be used to evaluate potential non-drinking water exposure to PFAS at Exposure Assessment sites. Deidentified information will be shared with US EPA and other federal, state, and local public health agencies as appropriate. Participants will be notified of their individual results and an EI report will be prepared that will present the results of the investigation to the MA and DE Exposure Assessment communities.

Securing of Collected Information

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. Once we conduct an EI, we match the unique answers given by participants with their environmental samples to determine whether intervention is needed on an individual level. The information collection is therefore *inherently person- or location-specific.*

Data are treated to protect privacy; access to computer files is password-protected and access is limited to authorized EI personnel, including contractors. All staff working on the project agree

to safeguard the data and not to make unauthorized disclosures. Published reports may present responses in aggregate form and no individuals are identified by name.

Data are treated in a private manner, unless otherwise compelled by law. Paper documents containing personal identifiers are kept in locked file cabinets at ATSDR. ATSDR computers comply with the HHS Standard 2008-0007.001S for encryption in accordance with information systems security requirements for safeguarding personally identifiable information. Access to computer files is password-protected and access is limited to authorized EI personnel. That information is stored in a secure database along with the laboratory results.

Applicability of the Privacy Act

A. The Privacy Act is applicable. The applicable System of Records Notice (SORN) is No. 09-19-0001, "Records of Persons Exposed or Potentially Exposed to Hazardous or Toxic Substances."

B. Identifying information such as name, address, phone number and email are collected. ATSDR uses the information only to contact respondents. Identifying information is necessary to facilitate the personal contact with respondents to conduct the questionnaire, to obtain consent to participate, and to provide them their results.

All identifying information maintained by the agency will be managed by ATSDR and is subject to the ATSDR Comprehensive Record Control Schedule (CRCS), B-371, which contains authorized disposition instructions for ATSDR's administrative and program records.

C. Respondent Consent –ATSDR will require that environmental sampling EI participants be fully informed of the potential risks and benefits of their participation and that the privacy of the participants' information will be protected. The consent/parental permission/assent forms for the environmental sampling EI include all appropriate information from the Privacy Act including authority and purpose for collecting the data, with whom identifiable information will be shared, the voluntary nature of the information collection and the effect upon the respondent for not participating (Attachment 9). State laws requiring openness in government will be followed as appropriate. The environmental sampling EI will comply with all appropriate requirements.

D. Voluntary Nature - Respondents are told that their participation in the EI is voluntary and they may refuse to answer any of the questions.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Federal Regulations for Protection of Human Subjects (45 CFR 46) state that "*research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." In contrast, this EI is intended to be a systematic investigation but is not designed to develop or contribute to generalizable knowledge. The environmental sampling EI is a non-research activity and human subjects review by an Institutional Review Board (IRB) is not required. The primary intent of the EI is to provide or improve a public health program or service for the community. The EI was reviewed by the NCEH/ATSDR Human Subjects Coordinator (Attachment 3).

For the EAs, ATSDR gathered information about individual characteristics (e.g., gender, age, ethnicity, and race) to assist with interpretation for environmental samples. For example, the individual's laboratory results were compared to similar ethnicity and race results in the *National Report on Human Exposure to Environmental Chemicals* (http://www.cdc.gov/exposurereport/). Beyond that, questions of a sensitive nature were not asked.

For this environmental sampling EI, we will not ask questions on symptoms, medical outcomes, or drug and medication use.

Social security numbers are not needed nor will they be requested.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.1. Estimates of Annualized Burden Hours

The estimate for burden hours for the environmental sampling EI is based on similar EIs that the EI team has conducted in the past. The time burden per respondent will vary based on the participant's role in the sampling.

Participants at the two former EA locations are represented as follows:

- In MA, there were 459 participants (410 adults and 49 children – 10% children) with an average household of 1.8 persons
- In DE, there were 214 participants (203 adults and 11 children – 5% children) with an average household of 1.6 persons

For the estimation of burden hours, we will assume there would be 2 people in the household, with 10% of the households having a child as the second resident. Therefore, if there are 120 additional people in the households, we estimate that 108 of them will be adults and 12 will be children (assume 6 children younger than 12 years old, and 6 children between 12 and 17 years old).

The first activity that is associated with burden hours is recruitment screening. An invitation letter will be sent to all households that participated in the Exposure Assessment and they are

asked to call and make an appointment (Attachment 6). The time they are anticipated to spend on the phone to sign up for the sampling is estimated to take 10 minutes for each of the 120 total households that will be included in the EI (80 in MA and 40 in DE). We are recruiting on a first-come, first-serve basis so we do not anticipate speaking to all EA participants. Attachment 7 includes two recruitment scripts: one for people who call to make an appointment and one for those contacted by ATSDR if additional participants are needed. Both scripts contain the same information. The estimated total burden is 20 hours for this activity.

There are two additional phases of the EI that will incur burden hours: 1) completion of appropriate questionnaires and 2) time needed to conduct the sampling.

1. **Completion of Questionnaires**: All household members that provided a blood sample during the Exposure Assessment will be eligible to be included in the EI. The appropriate consents and questionnaires will be identified when the sampling appointment is made and the forms will be mailed to the household with the appointment verification letter. The participants will be asked to fill the forms out prior to the sampling, which will allow household participants that are not present at the home during the sampling to be included in the EI. The questionnaires will be filled out as follows:
    a. One adult participant that provided a blood sample during the EA will be identified and their burden associated with completion of questionnaires will be calculated as follows (estimated burden of 30 minutes per participant, 60 hours total for 120 participants):
        - Complete the household questionnaire, that applies to all members of the household, (15 minutes), and
        - Complete the personal exposure questionnaire (adult) (15 minutes).
        - Of these 120 adult participants, 80 will be asked to consent to and be present for dust only sampling in their household (1 hour), while 40 will be asked to consent to and to be present for robust household sampling (4 hours). See the description of the household sampling strategy below.
    b. Other adults (assumed 108 persons) that provided a blood sample during the Exposure Assessment will have burden associated with the completion of the personal exposure questionnaire (adult)(estimated at 15 minutes per participant, resulting in a total burden of 27 hours total for 108 participants):
    c. Children in the household (assume 6 children aged 12 to 17 years old) that provided a blood sample during the Exposure Assessment will have burden associated with completing the personal exposure questionnaire (child) (estimated burden of 15 minutes per child, resulting in a total burden of 1.5 hours).
    d. Parents of children younger than 12 years old (assume 6 children) that provided a blood sample during the Exposure Assessment will assist their child with completing the personal exposure questionnaire (child) (estimated burden of 15 min per child, resulting in a total burden of 1.5 hours).

2. **Completion of Sampling at Exposure Assessment Households**: ATSDR will conduct environmental sampling at 80 households at the Hampden County, MA Exposure Assessment location and 40 households at the New Castle Country, DE Exposure Assessment location. A filtered dust sample will be taken at all homes and 20 homes at each location will also have additional environmental sampling performed (robust sampling). The following burden hours are associated with each type of sampling (estimated burden hours of 1 to 4 hours per person for a total of 80 to 160 hours):
    a. **Completion of filtered dust sample**: At the households where only a filtered dust sample will be taken, the total burden is 60 minutes or 1 hour, which includes the participant remaining in the home while the dust sampling is completed (estimated burden of 1 hour for 80 homes results in a total burden of 80 hours).
    b. **Robust environmental sampling**: In addition to the filtered dust sample, ATSDR will conduct additional robust environmental sampling, including a bulk dust sample, indoor air, wipes samples, soil and silicone wristbands, at 20 homes at each location. Two appointments will be needed at the 20 homes since both the indoor air and silicone wristbands require a 7-day collection period. The burden associated with this sample collection is 4 hours per household, which includes two, 2-hour appointments, one week apart for an estimated total of 160 hours for the 40 homes.

The estimate annualized burden hours, by person and activity, is provided below. The total burden estimated to complete the environmental sampling EI sites is 351 hours.

Estimated Annualized Burden Hours

Type of Respondents	Name of Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (In Hours)
EI Adult Participants making appointment	Household Recruitment Script	120	1	10/60	20
EI Adult Participants – signing consent for self and household sampling (dust only)	Household Questionnaire	80	1	15/60	20
	Personal Exposure Questionnaire (Adult)	80	1	15/60	20
	Environmental Sampling Collection Form (dust	80	1	1	80

	only)				
EI Adult Participants – signing consent for self and household sampling (robust sampling)	Household Questionnaire	40	1	15/60	10
	Personal Exposure Questionnaire (Adult)	40	1	15/60	10
	Environmental Sampling Collection Form (robust sampling)	40	2	2	160
EI Adult Participant – signing consent for self only	Personal Exposure Questionnaire (Adult)	108	1	15/60	27
EI Child Participants (12 – 17 years of age)	Personal Exposure Questionnaire (Child)	6	1	15/60	2
Parents of EI Child Participants (less than 12 years of age)	Personal Exposure Questionnaire (Child)	6	1	15/60	2
Total					351

A.12.2. Annualized Cost to Respondents

Using a mean hourly rate of $27.07/hr. for all occupations, the annualized cost to respondents for the hour burdens for the collection of information is $9,444.77. The hourly wage rate is based on the U.S. Department of Labor, Bureau of Labor Statistics' most current statistics [May 2020 National Occupational Employment and Wage Estimates United States, http://www.bls.gov/oes/current/oes_nat.htm#00-0000]. The hourly wage rate for children is assumed to be the US minimum wage rate of $7.25 set by the Department of Labor in 2009 (https://www.dol.gov/general/topic/wages/minimumwage)

Estimated Annualized Burden Costs

Type of Respondents	Name of Form	No. of Respon	No. of Respon	Averag e	Total Burden	Hourly Wage	Total Respondent

		dents	ses per Respondent	Burden per Response (in hours)	(In Hours)	Rate	Costs
EI Adult Participants making appointment	Household Recruitment Script	120	1	10/60	20	$27.07	$541.40
EI Adult Participants – signing consent for self and household sampling (dust only)	Household Questionnaire	80	1	15/60	20	$27.07	$541.40
	Personal Exposure Questionnaire (Adult)	80	1	15/60	20	$27.07	$541.40
	Environmental Sampling Collection Form (dust only)	80	1	1	80	$27.07	$2,165.60
EI Adult Participants – signing consent for self and household sampling (robust sampling)	Household Questionnaire	40	1	15/60	10	$27.07	$270.70
	Personal Exposure Questionnaire (Adult)	40	1	15/60	10	$27.07	$270.70
	Environmental Sampling Collection Form (robust sampling)	40	2	2	160	$27.07	$4,331.20
EI Adult EI Participant – signing consent for self only	Personal Exposure Questionnaire (Adult)	108	1	15/60	27	$27.07	$730.89
EI Child Participants (12 – 17 years of age)	Personal Exposure Questionnaire (Child)	6	1	15/60	2	$7.25	$10.88
Parents of EI Child Participants (less than 12 years of age)	Personal Exposure Questionnaire (Child)	6	1	15/60	2	$27.07	$40.61
Total							$9,444.77

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the participants other than their time to participate in the EI.

A.14. Annualized Cost to the Government

Costs for ATSDR personnel and contractors are estimated based on experience with Exposure Investigation activities under *ATSDR Exposure Investigations* (OMB Control No. 0923-0048, expiration date 04/30/2022).

This Exposure Investigation is being conducted using an Interagency Agreement (IAA) with the U.S. Environmental Protection Agency (EPA) that provides a budget of approximately $950,000 for completion of the Exposure Investigation, which includes costs associated with FTEs (including benefits); contractors; travel; per diem; and laboratory, supplies, and equipment costs.

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

A.16.1 Project Time Schedule

The project Time Schedule for the environmental sampling EI is as follows:

Activity	**Time Schedule**
Start of data collection and field work	2 weeks after OMB approval
Time to conduct the field work	2 months after OMB approval
Laboratory analysis	5-6 months after OMB approval
Respond to participants	9 months after OMB approval
Written report released	TBD - based on clearance process

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not requesting an exemption.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification for Paperwork Reduction Act.