Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs)

New Information Collection Request

Supporting Statement Part A –

Justification

Project Officer:

Rachel Worley, PhD
Science Support Branch
Division of Community Health Investigations
Agency for Toxic Substances and Disease Registry
4770 Buford Hwy NE, MS F5
Atlanta, GA 30341
Phone: 770-488-1549
Fax: 770-488-1542
Email: RWorley@cdc.gov

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Part A. Justification

Goal of the study: The goal of this information collection request (ICR) is to address the requirements for completing exposure assessments (EAs) for per- or polyfluoroalkyl substances (PFAS) authorized in *Section 8006 of the Consolidated Appropriations Act, 2018*. The Agency for Toxic Substances and Disease Registry and the National Center for Environmental Health (ATSDR/NCEH) will use statistical methods to recruit respondents at a minimum of eight current or former domestic military installations known to have PFAS contamination in drinking water, groundwater or other water sources. Respondents may include both on-site and off-site residents. ATSDR will collect biological and environmental samples to evaluate exposure at the installations.

Intended use of the resulting data: The PFAS EAs will produce unbiased exposure prevalence estimates for each site and may identify some community-specific factors (e.g., activities, exposure sources) associated with higher population PFAS levels. The EAs will allow ATSDR/NCEH to provide exposure reduction recommendations, if necessary, to the community as well as to the individual respondents of the EA and to prioritize responses to communities based on the identified risks.

ATSDR/NCEH will not generalize the results of each EA beyond the defined boundaries of the investigation. The results of the EAs will also be used to inform a future health study on PFAS exposure.

Methods to be used to collect data: ATSDR will select respondents using one-stage cluster sampling methods from the identified military installations (e.g., list of telephone numbers, list of homes in the community). ATSDR will collect biological samples (serum and urine) from all respondents, although not all urine samples may be tested. ATSDR will also collect environmental samples (tap water and indoor dust) at a random 10 percent subset of households that report using tap water for drinking water. The EAs will be one-time sampling events.

Subpopulation to be studied: Eligible respondents include residents living on or near military installations with known PFAS water contamination that have lived in their home for at least one year and who are three years of age and older. To be eligible for environmental sampling, the household must report using tap water as a primary drinking water source.

How data will be analyzed: Accredited laboratories will analyze the biological and environmental samples for PFAS. Statisticians will conduct descriptive analyses and higher level statistical analyses of the EA information.

A.1 Circumstances Making the Collection of Information Necessary

Per- and polyfluoroalkyl substances (PFAS) are contaminants that have gained national prominence over the last decade. PFAS are a large group of man-made chemicals that have been used in industry and consumer products worldwide since the 1950s. Products containing PFAS include aqueous film-forming firefighting foam (AFFF), stain- and grease-resistant coatings, nonstick cookware, cleaning and personal care products, and paints, varnishes and sealants. Although some PFAS are no longer produced in the United States, many remain in the environment and may impact people's health.

Under Section 8006 of the Consolidated Appropriations Act, 2018, ATSDR is 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.

For each site, a statistically based, community sampling design will be used to determine:

- The distribution of PFAS serum concentrations in communities with exposures to PFAS in drinking water.
- PFAS urine concentrations from a subset of participants with exposures to PFAS in drinking water.
- PFAS concentrations in indoor dust and tap water samples from a subset of homes of participants in biological sampling.

A questionnaire will be administered to all participants to gather information to characterize each individual's exposure.

Blood and urine samples from EA participants will be analyzed to determine the distribution of PFAS levels in each community. Individual and aggregated community serum and urine concentrations will be compared to reference ranges from nationally representative data. Environmental samples will be analyzed to determine PFAS exposure concentrations and to provide insight into environmental determinants of biological PFAS concentrations across all included sites.

Each exposure assessment will include the following goals:

- **Provide a public health service to the community:** This investigation will provide information to community members about their PFAS body burden, including an assessment of how their PFAS concentrations compare to national reference populations. Each individual participant will receive a report containing their individual results in the context of the national reference population. The investigation will also provide

information about aggregate serum concentrations and exposure in the community from which participants are selected.

Depending on the results of the investigation, ATSDR may make recommendations to further reduce exposure or conduct additional activities to better understand the impact of PFAS exposure on human health.

- **Generate information about pathways of exposures in the community:** Environmental sampling data will be combined with biological sampling results to generate information about the impact of drinking water and non-drinking water PFAS exposure pathways on PFAS body burden in each household or community.
- **Inform future studies to evaluate the impact of PFAS exposure on human health:** The results of these EAs will inform the design and implementation of the CDC Multi-site PFAS Health Study.
    - For example, exploration of indoor dust sampling and analysis may provide valuable insight into the utility of including indoor dust sampling in future PFAS studies.
    - Similarly, collection of paired serum and urine samples will provide information on relationships between PFAS concentrations measured in these media and may generate insight into the utility of measuring PFAS in urine in future health studies.
    - Additionally, measurement of PFAS in serum and urine will generate data that could potentially be used for validation and calibration of physiologically-based pharmacokinetic modeling tools in support of historical dose reconstruction for PFAS health studies.
    - Tracking information on recruitment outcomes and response rates will allow ATSDR to improve methodology for conducting statistically representative sampling in the future.

The Agency for Toxic Substances and Disease Registry and the National Center for Environmental Health (ATSDR/NCEH) are requesting a new three-year information collection request (ICR) titled *Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs)*. The ICR is needed to complete PFAS EAs authorized in *Section 8006 of the Consolidated Appropriations Act, 2018* (**Attachment 1a**).[1] This ICR will allow ATSDR/NCEH to fulfill the EA requirements of the Act at the military installations in a timely fashion. An additional 7 EAs (for a total of 15 EAs) may be completed as part of this three-year package at both Department of Defense (DoD) sites or at non-DoD locations, as appropriate.

The 60-day Federal Register Notice was published on 07/19/2018 (**Attachment 2**), and is further discussed in Section A.8. Supporting information for this Paperwork Reduction Act (PRA) ICR

[1] General ATSDR authorities to conduct EAs are found in 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 (**Attachment 1b**). NCEH is generally authorized under the *Public Health Service Act* to perform EAs related to public health (**Attachment 1c**).

is provided in **Attachments**, and the **PFAS EA Protocol with Appendices is provided as a separate document**.

A.2. Purpose and Use of the Information Collection

The primary objective of this ICR is to conduct EAs at no less than eight current or former domestic military installations that have or have had documented exposures to PFAS in drinking water. ATSDR has identified the eight locations and will conduct biological testing (PFAS in blood and urine) and environmental sampling (tap water and indoor dust at 10% of participant's homes) to determine whether exposure has occurred in the eight communities evaluated.

The following criteria were used to select the eight location for conducting the EAs. The ATSDR protocol has further information on the site selection process.

- Magnitude of exposure, as characterized by existing environmental data
- Estimated duration of exposure to PFAS-impacted drinking water
- Association with a current or former DoD facility
- Ability to characterize drinking water supply system, including ability to stratify exposed population into groups based on estimated exposure level
- Past PFAS biomonitoring events in the community as indication of need for additional exposure assessment
- Whether and how recently PFAS exposure mitigation has been implemented at the site

Listed in alphabetical order by county, the sites selected for PFAS exposure assessments are:

- Berkeley County, WV near Shepherd Field Air National Guard Base (Berkeley County)
- El Paso County, CO near Peterson Air Force Base (El Paso County)
- Fairbanks North Star Borough, AK near Eielson Air Force Base (Fairbanks North Star Borough)
- Hampden County, MA near Barnes Air National Guard Base (Hampden County)
- Lubbock County, TX near Reese Technology Center (Lubbock County)
- New Castle County, DE near New Castle Air National Guard Base (New Castle County)
- Orange County, NY near Stewart Air National Guard Base (Orange County)
- Spokane County, WA near Fairchild Air Force Base (Spokane County)

The EAs will be conducted using statistical recruitment. Thus, the EAs are designed to produce unbiased PFAS prevalence estimates for each community and to identify both person- and community-specific factors (e.g., activities, exposure sources) potentially associated with higher population exposure. The EAs will allow ATSDR/NCEH, as necessary, to provide public health recommendations to the community as well as to the individual respondents of the EA and to prioritize responses to communities based on the identified risks. ATSDR/NCEH will also use the EA findings to inform a future PFAS health study.

PFAS EA Information Collection and Sampling Steps: The ICR will allow ATSDR/NCEH to identify, recruit, consent and question eligible EA respondents. A protocol has been prepared that will be used for all EAs (**PFAS EA Protocol**).[2] The EAs will be conducted by trained ATSDR/NCEH staff and contractors. The steps in the information collection and sampling include:

1. A public meeting will be held within each EA community that will provide information on the EA process. A Community Event Evaluation Survey (**Appendix A1**) will be provided to the attendees to assess ATSDR's PFAS public health messaging, the EA enrollment process and to gauge local feelings toward the ATSDR PFAS EA project. The survey will help the EA team members adjust and enhance public health messaging and EA project information in real time.
2. Potentially eligible households within each EA community will be identified using one-stage cluster sampling **(PFAS EA Protocol**).
3. A recruitment letter and fact sheets will be sent to the randomly-selected households within the statistical sampling frame (**Appendix A2**).
4. All eligible people in the household will be invited to participate. Eligibility criteria (**Appendix A2**) include people that:
    a. Have lived in the home for one year or longer,
    b. Are aged 3 years or older, and
    c. Do not have a bleeding disorder that would preclude a blood draw.
5. A maximum of eight attempts will be made to recruit potential respondents by phone (**Appendix A3**).
6. If potential respondents are eligible and willing, an appointment to conduct the biological testing will be made during the phone call.
7. The Household Recruitment Phone Script (**Appendix A3**) also includes a question regarding whether the residents use tap water as a source of drinking water. After all respondents are identified for biological testing, households that were found to be eligible for environmental sampling (i.e., those that use tap water for drinking water) will be randomly selected and offered environmental sampling via a second phone call (**Appendix A4**). The environmental sampling will occur during the same time period that the biological testing will occur, but will be a separate appointment. The appointment for the environmental sampling will be made during the phone call.
8. Once respondents are identified, information will be sent to households confirming participation and providing urine collection supplies and instructions for urine collection

[2] As another resource, NCEH has developed a PFAS Exposure Assessment Technical Tool (PEATT) that provides a framework for state health departments to assess exposure to PFAS in drinking water by testing PFAS in serum (**Attachment 3**). ATSDR/NCEH has adapted the PEATT methodology for the **PFAS EA Protocol**, which is extended to assess PFAS in urine and in environmental media (drinking water and indoor dust).

and transport to the blood collection location. On the day of testing, a first morning urine sample will be brought to the centralized blood draw location and given to EA personnel.

9. At the centralized location, the respondents will be consented (**Appendices B1 to B4**), administered the appropriate questionnaire (**Appendices F1 and F2**) and a blood sample will be taken.
10. Environmental sampling will be conducted at the time scheduled with the respondents (10 percent of eligible households).

In addition to the forms cited above, the protocol includes:

1. The specific details of the statistically based recruitment design and sample size goals.
2. Sampling and analytical methods that will be used to determine levels of PFAS in biological and environmental samples.
    - A federal team leader with appropriate training will oversee all environmental and biological sampling.
    - Trained EA personnel and contractors, with assistance from federal, state and local partners, will collect samples and ship them directly to the appropriate laboratories for analysis.
    - Trained personnel, such as registered nurses (RNs), will collect biological samples and documentation and ship them directly to qualified laboratories for analysis.
    - ATSDR, NCEH, contractors, and partner states will prepare and implement appropriate Quality Assurance Plans as appropriate.
3. Individual test results with a written explanation of meaning will be provided by mail to the participants (**Appendix G – Results Letters**). Biological sampling results for individuals will be provided separately from environmental sampling results.
    - Following dissemination of individual results, an EA team member will be available to discuss individual questions by phone or email.
    - The EA team members will not have access to an individual's questionnaire responses. Therefore, responses to these questions cannot form the basis for feedback.
4. A Site Health and Safety plan for the EAs (**Appendix H**).
5. A Data Management Plan for the EAs (**Appendix I**).

A community report will be written detailing the results of the EA when completed. **Attachment 4** provides an example report from a previous ATSDR PFAS exposure investigation (EI).

The information to be collected during biological and environmental sampling events include:

- Demographic and residential history

- Occupational history
- Water source and household filtration system
- Age and activity patterns for respondents
- Basic health status information (e.g., kidney disease, pregnancy status) that will allow the individual blood results to be assessed for each respondent.
- Location of environmental samples taken, where appropriate

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

ATSDR/NCEH will interview respondents over the phone for the eligibility questionnaires and in-person for the consent forms and individual questionnaires. Consents and questionnaires will be completed in the field using Epi Info™ on secured computers. Sampling results, both biological and environmental, will be managed per the Data Management Plan (**Appendix I of the PFAS EA Protocol**).

ATSDR/NCEH computers comply with the HHS Standard 2008-0007.001S for encryption to safeguard information in identifiable form (IIF). That information will be stored in a secure database along with the laboratory and/or modeling 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 meetings that other 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.

This ICR differs from the projects cited above in that the EAs conducted using this ICR are intended to address data gaps regarding PFAS exposure at military installations.

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

The EA recruitment will focus on residential properties located at the military installations and is not expected to include any small businesses or other small entities.

A.6. Consequences of Collecting the Information Less Frequently

The EAs will be one-time sampling events.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on 07/19/2018, Vol. 83, No. 139, pp. 34135 (**Attachment 2**). ATSDR/NCEH received eight public comments related to this notice. The program responses to public comments are provided in **Attachment 2a**. The public comments are provided in **Attachments 2a1 through 2a8.**

B. For the PFAS EA effort, we consulted with Drs. Kyle Steenland from Emory University and Alan Ducatman from West Virginia University, both members of the C8 Science Panel.

   For additional information on female reproductive status and environmental health, we also consulted with Dr. Nathaniel DeNicola, Asst. Professor of Obstetrics and Gynecology, George Washington University School of Medicine and American Congress of Obstetricians and Gynecologists (ACOG) Environmental Health Expert and Liaison to

the American Academy of Pediatrics (AAP) Executive Council on Environmental Health (May 2019).

The PEATT (**Attachment 3**), which the **PFAS EA Protocol** is based upon, was reviewed by three state health departments – New York (Dr. Elizabeth Lewis-Michl), New Hampshire (Dr. Ben Chan), and Pennsylvania (Dr. Sharon Watkins). The state health departments were consulted during a state-focused PFAS Toolkit Review meeting in February of 2017.

We also consulted with Ekta Choudhary, PhD, MPH, NCEH project officer for the PEATT. Dr. Choudhary concurs that the methods are consistent with the PEATT methods and appropriate to conduct the PFAS EAs.

In addition, we consulted with Hao Tian, PhD, CIPP/G. Dr. Hao is leading NCEH/ATSDR's efforts to implement the open data policy. He is a Certified Information Privacy Professional (CIPP/G) and provides the agency with advice and recommendations on privacy protection for data sharing activities. Dr. Hao is the Data Manager and Privacy Officer for the PFAS EAs.

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

For PFAS EAs, ATSDR/NCEH will not provide any payment or gift to respondents.

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

On 10/01/2018, the CDC Chief Privacy Officer has determined that the Privacy Act does apply for PFAS EAs. The applicable Privacy Act System of Records Notice (SORN) is No. 09-19-0001, "Records of Persons Exposed or Potentially Exposed to Hazardous or Toxic Substances (retrievable by name or SSN). A Privacy Impact Assessment (PIA) was obtained. The submission date was 06/18/2018 (**Attachment 5).**

The following IIF Categories apply to this information collection (**Appendices B, F1 and F2 of the PFAS EA Protocol**):

- ❑ Name
- ❑ Date of Birth
- ❑ Mailing Address
- ❑ Phone Numbers
- ❑ Biological Specimens
- ❑ Email Address

ATSDR/NCEH will collect the minimum information needed to assess the laboratory data and to identify likely exposure scenarios. Once we conduct an EA, we will match the unique answers given by respondents with their laboratory results or environmental samples to determine

whether intervention is needed on an individual level. Thus, on one level, the information collection is *inherently person-specific.* On another level, the statistical sampling also allows ATSDR/NCEH to estimate *site-specific* population prevalence estimates for PFAS for the geographic extent of each EA.

ATSDR/NCEH uses the IIF only to contact respondents to obtain consent to participate, to conduct the survey, and to provide the results. All IIF and EA data maintained by the agency will be managed by ATSDR/NCEH and is subject to the ATSDR/NCEH Comprehensive Record Control Schedule (CRCS), which contains authorized disposition instructions for ATSDR/NCEH's administrative and program records. Attachment 6 provides a Template for the Data Use Agreement for the NCEH/ATSDR Data Set (Attachment 6a) and the Standard Operating Procedures (SOP) for Data Management for the PFAS EAs (Attachment 6b).

- The following individuals will have access to personal information in order to provide respondents with their personalized results: ATSDR/NCEH employees and contractors.
- Data are treated in a private manner, unless otherwise compelled by law. Paper documents containing IIF are kept in locked file cabinets at ATSDR/NCEH. Access to computer files is password-protected and access is limited to authorized personnel. All staff and contractors working on the project agree to safeguard the data and not to make unauthorized disclosures. Any data on laptops will be encrypted in accordance with information systems security requirements for safeguarding personally identifiable information. Data are safeguarded in accordance with applicable statutes. Responses in published reports are presented in aggregate form and no individuals are identified by name.
- ATSDR/NCEH will implement a Data Management Plan for the data collected for the EA per guidance (**Appendix I of the PFAS EA Protocol**).
- ATSDR/NCEH will implement a Security Plan that defines the process for handling security incidents. The system’s team and the Office of the Chief Information Security Officer (OCISO) share the responsibilities for event monitoring and incident response. The EA team will direct reports of suspicious security or adverse privacy-related events to the NCEH/ATSDR Information Systems Security officer (ISSO), CDC helpdesk, or to the CDC Incident Response team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

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

Federal Regulations for the 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." The NCEH/ATSDR Human Subjects Coordinator has determined that EAs are nonresearch activities and human subjects review by an Institutional Review Board (IRB) will not be required (**Attachment 7)**. ATSDR/NCEH will not recruit or test comparison populations; the results of the investigation are site-specific and applicable only to the respondents of the investigation and the exposed community.

ATSDR/NCEH does require that respondents in EAs be fully informed of the potential risks and benefits of their participation and that the privacy of the respondents' information be protected. All consent forms include 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. The adult consent, parental permission, child assent, and environmental sampling consent forms are provided in **Appendices B1 to B5 of the PFAS EA Protocol**. The results of the EAs are to be used to inform a PFAS health study. Therefore, the consent forms for the PFAS EAs will include a provision that will allow respondents to be recontacted for future study.

ATSDR/NCEH will gather information that may be considered sensitive about individual characteristics (e.g., gender, age, weight, ethnicity, and race) to assist with the assessment of the biological test results. For the PFAS EAs, respondents will be asked, but will not be excluded from the EA, if they self-report any conditions that impact PFAS levels in the body, including pregnancy and conditions associated with kidney function (e.g., kidney disease, diabetes, hepatitis C). This information is needed to assist in the assessment of a respondent's individual biological results . The PFAS EA protocol provides further discussion of the relevance of this information.

Social security numbers are not needed nor will be requested.

A.12. Estimates of Annualized Burden Hours and Costs

A. Estimates of Annualized Burden Hours

ATSDR/NCEH anticipates conducting 5 PFAS EAs each year over a period of three years. Per the NDAA, a minimum of 8 EAs are required, but it is estimated that an additional 7 military or non-military EAs may be completed within the three year period for a total of 15. The number of respondents per EA will vary, but we expect the number to average 395 respondents who will be recruited using statistical methods (see Supporting Statement B). The burden associated with the EAs include:

- Community Event Evaluation Survey: ATSDR/NCEH will hold a public meeting prior to the start of the EA at each EA location. A Community Event Evaluation Survey (**Appendix A1**) will be used as a way for the EA team to receive feedback from

prospective EA participants about ATSDR's PFAS public health messaging, the enrollment process, and to gauge local feelings toward the ATSDR PFAS EA project. It is assumed that approximately 250 community members will attend the public meeting that will be held to inform the community about the EA effort. Using a response rate of 65%, it is assumed that 163 community members will fill out the community event evaluation survey at each EA location and the survey will take approximately 5 minutes (815 members for 5 EAs). The resultant burden is 68 hours annually for 5 EAs.

- Household Eligibility Screener (**Appendix A3**): ATSDR/NCEH anticipates asking approximately 269 head-of-households, or someone who can make decisions about participation in the EA, to complete a 5-minute telephone script to identify 149 eligible households, assuming a household response rate of 85% and a general response rate of 65% (see **Supporting Statement B**). At the pilot sites, a within household response rate of 85% was achieved for households in which at least one person participated. To be eligible, the household residents must have lived in the home for at least one year. In addition, household members must be ≥3 years of age and not have a bleeding disorder, which would prevent a blood draw. The 269 head-of-households in would be administered the 5-minute questionnaire, resulting in a burden of 22 hours for each EA (112 hours annually for 5 EAs and 1,345 potential EA heads-of-households).
- Estimation of Number of EA Respondents by Age Group: Based on the criteria in the Household Recruitment Phone Script, the 149 households are assumed to provide the target sample size of 395 respondents per EA. All respondents will provide a serum and a urine sample. For five annual EAs, we estimate the number of respondents to be 1,975 (395*5).

  Based on 2017 Census estimates of average household size (2.5), and number of adults (1.9) and number of children under 18 years of age (0.6) in the household,[3] we are able to estimate the annual number of respondents by age group using the following: 76 percent (n=1,501) of respondents will be adults ≥18 years (1.9/2.5); and 24 percent (n=474) will be children (0.6/2.5). To further breakdown the number of parents who will respond for their child and the number of children who will respond for themselves, we again use Census estimates of children within households.[4] Children that will be eligible to participate in the EA are represented by children aged 3-11 years (50%) and 12-17 years (34%). Because 16 percent of the children in the household will be <3 years, and not eligible, and in order to achieve our sample size goals, we attribute their proportion equally to the two age groups [8 percent to both child groups; 58% for ages 3-11 years (275) and 42% for ages 12-17 years (199)].

[3] U.S. Census Bureau, Current Population Survey, March and Annual Social and Economic Supplements: Table HH-6. Average Population Per Household and Family: 1940 to Present.

[4] U.S. Census Bureau, Current Population Survey, 2017 Annual Social and Economic Supplement. Internet Release Date November 2017; Table C1. Household Relationship and Family Status of Children1 Under 18 Years, by Age and Sex: 2017

The number of participants for completion of the consent forms and questionnaire are as follows (children aged 3-11 years will not be responsible for filling out any forms alone):

		Participants	
Form	**Adults/Parents**	**Children 3-11 yr**	**Children 12-17 yr**
Biological Testing Tracking form	1,501	275	199
Adult Consent	1,501	NA	NA
Parental Permission	474	NA	NA
Assent	NA	NA	199
Questionnaire - Adult	1,501	NA	NA
Child Questionnaire –with assistance from adult	275	NA	NA
Child Questionnaire – completed by child	NA	NA	199

- Biological Testing Tracking: All participants, adults (1,501) and children (474), will be provided a biological testing tracking form when they sign in for the testing event. The form will ensure that all appropriate forms are completed and all biological samples are collected. The time associated with filling out the form as the participant moves between the various stations and the time needed to collect the biological samples is approximately 20 minutes, resulting in a burden of 658 hours annually for 5 EAs.
- Adult Consent for Biological Testing: Annually, 1,501 adults will be administered a consent form for testing of blood and urine for PFAS (**Appendix B2**). The consent form includes permission to store some biospecimens for future analysis and will include permission to recontact respondents for potential investigations or studies in the future. The time associated with administering the adult consent form is approximately 10 minutes, resulting in a burden of 250 hours annually for 5 EAs.
- Parental Permission Form for Biological Testing: A parental permission form will be administered to the parents of 474 children aged 3-17 years for testing of blood and urine for PFAS (**Appendix B3**). The parental permission form includes permission to store some biospecimens for future analysis and will include permission to recontact respondents for potential investigations or studies in the future. The time associated with administering the parental permission form is approximately 10 minutes resulting in a burden of 79 hours annually for 5 EAs.

- Child Assent Form for Biological Testing: Children aged 12 to 17 years (199) will assent to the testing of blood and urine for PFAS (**Appendix B4**). The assent form includes permission to store some biospecimens for future analysis and will include permission to recontact respondents for potential investigations or studies in the future. The time associated with administering the child assent form is approximately 10 minutes, resulting in a burden of 33 hours annually for 5 EAs.
- Adult Exposure Questionnaire for Biological and Environmental Testing: Annually, 1,501 adults will be administered an exposure questionnaire that includes questions associated with potential exposure to PFAS both inside and outside the home (e.g., work or school) (**Appendix F1**). In addition, the adult questionnaire also includes several questions associated with water use and flooring type. The time associated with administering the questionnaire and completing the biological sampling is approximately 30 minutes, resulting in a burden of 751 hours annually for 5 EAs.
- Parent Proxy for Child Exposure Questionnaire for Biological Testing: Annually, 275 parents will respond for their children, 3 to 11 years. They will be administered a child exposure questionnaire that includes questions associated with potential exposure to PFAS both inside and outside the home (e.g., school or daycare) (**Appendix F2**). In addition, the child questionnaire includes questions regarding playing in soil. The time associated with administering the questionnaire and completing the biological sampling is approximately 15 minutes for parents on behalf of their children, resulting in a burden of 69 hours annually for 5 EAs.
- Child Exposure Questionnaire for Biological Testing: Annually, 199 children will respond for themselves (age 12-17 years). Child respondents will be administered an exposure questionnaire that includes questions associated with potential exposure to PFAS both inside and outside the home (e.g., school or daycare) (**Appendix F2**). The time associated with administering the questionnaire and completing the biological sampling is approximately 15 minutes for children, resulting in a burden of 50 hours annually for 5 EAs.
- Household Recruitment Script for Environmental Testing: Assuming a 65 % participation rate, ATSDR/NCEH will administer a 5-minute recruitment script to 23 adult respondents in each EA who are already deemed eligible to take part in the biological testing, or 117 heads of households annually for 5 EAs (149/10*100/65*5) (**Appendix A4**). The time associated with the script is 5 minutes, resulting in a burden of 10 hours annually for 5 EAs.
- Consent for Environmental Testing: ATSDR/NCEH will recruit a 10 percent subset of households deemed eligible for the EA for testing of tap water and indoor dust samples; therefore, the desired number of households is 15 per EA, or 75 per year (149*10/100*5) (**Appendix B5**). The time associated with consenting to the environmental sampling is 10 minutes, resulting in a burden of 13 hours annually for 5 EAs.

- Environmental Sample Collection: ATSDR/NCEH will recruit a 10 percent subset of households deemed eligible for the EA for testing of tap water and indoor dust samples; therefore, the desired number of households is 15 per EA, or 75 per year (149*10/100*5) (**Appendix C2**). The time associated with conducting the environmental sampling and completing the collection form is 30 minutes, resulting in a burden of 38 hours annually for 5 EAs.

Table A.12.1: Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
EA Community Members	Community Event Evaluation Survey	815	1	5/60	68
EA Participants (all ages)	Biological Testing Tracking	1,975	1	20/60	658
EA Adults	Household Eligibility Screener	1,345	1	5/60	112
	Consent	1,501	1	10/60	250
	Exposure Questionnaire (Adult) for Biological and Environmental Testing	1,501	1	30/60	751
EA Parents	Parental Permission	474	1	10/60	79
	Exposure Questionnaire (Child) for Biological Testing (Parent Proxy)	275	1	15/60	69
EA Children	Assent	199	1	10/60	33
	Exposure Questionnaire (Child) for Biological	199	1	15/60	50

	Testing (Child completed)				
EA Heads-of-Households	Household Recruitment Script for Environmental Sampling	117	1	5/60	10
	Environmental Sampling Consent Form	75	1	10/60	13
	Environmental Sample Collection Form	75	1	30/60	38
Total					**2,131**

B. Annualized Cost to Respondents

The hourly wage rate for adults ($24.98) is based on the U.S. Department of Labor, Bureau of Labor Statistics' most current statistics for all occupations [May 2018 National Occupational Employment and Wage Estimates United States, online April 2,, 2019, https://www.bls.gov/oes/current/oes_nat.htm]. 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 2019 (https://www.dol.gov/whd/minwage/chart.htm).

Table A.12.2. Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per Response (In hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
EA Community Members	Community Event Evaluation Survey	815	1	5/60	68	$24.98	$1,696.56
EA Participants (all ages)	Biological Testing Tracking	1,975	1	20/60	658	$20.72	$13,640.67
EA Adults	Household Eligibility Screener	1,345	1	5/60	112	$24.98	$2,799.84
	Consent	1,501	1	10/60	250	$24.98	$6,249.16

	Exposure Questionnaire (Adult) for Biological and Environmental Testing	1,501	1	30/60	751	$24.98	$18,747.49
EA Parents	Parental Permission	474	1	10/60	79	$24.98	$1,973.42
	Exposure Questionnaire (Child) for Biological Testing (Parent Proxy)	275	1	15/60	69	$24.98	$1,717.38
EA Children	Assent	199	1	10/60	33	$7.25	$240.46
	Exposure Questionnaire (Child) for Biological Testing (Child completed)	199	1	15/60	50	$7.25	$360.69
EA Heads-of-Households	Household Recruitment Script for Environmental Sampling	117	1	5/60	10	$24.98	$243.56
	Environmental Sampling Consent Form	75	1	10/60	13	$24.98	$312.25
	Environmental Sample Collection Form	75	1	30/60	38	$24.98	$936.75
TOTAL							**$48,918.22**

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

There are no other total annual cost burden to respondents or record keepers.

A.14. Annualized Cost to the Federal Government

Costs for ATSDR/NCEH personnel and contractors are estimated based on experience with Exposure Investigation activities under *ATSDR Exposure Investigations* (OMB Control No. 0923-0048, expiration date 03/31/2019; updated package approved with an expiration date of 04/30/2022). EIs are similar to EAs in that ATSDR will take biological and/or environmental samples to fill data gaps at a site.

ATSDR/NCEH anticipates that the annual budget for EAs for the next three years may be approximately $3,500,000 (i.e., assuming approximately $700,000 for each of the 5 EAs per year). This includes 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 ICR.

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

ATSDR/NCEH will provide a project time schedule for each EA in the protocol which will depend on the sampled biological and environmental media. The following is the general schedule anticipated for the PFAS EAs.

Table A.16.1

Project Time Schedule	
Activity	Time Schedule
Start of Data Collection	1 months after OMB approval
Field Work	1—6 months after OMB approval
Analysis	6—12 months after OMB approval
Respond to Respondents	12—15 months after OMB approval
Written Report	15—24 months after OMB approval

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

The display of the OMB expiration date is appropriate.

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

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

List of Attachments and Protocol Appendices

Attachment 1. Authorizing Legislation
- 1a: Authorizing Legislation for PFAS Exposure Assessment
- 1b: Authorizing Legislation for ATSDR
- 1c: Authorizing Legislation for NCEH

Attachment 2. 60-day Federal Register Notice
- 2a. Program Responses to Public Comments
  - 2a1-8. Public Comments

Attachment 3. PFAS Exposure Assessment Technical Tool (PEATT)
Attachment 4. Example Exposure Investigation Report for PFAS
Attachment 5: Privacy Impact Assessment
Attachment 6: Data Use Agreement Template and SOP for Data Management
- 6a: Data Use Agreement Template
- 6b. SOP for Data Management

Attachment 7. Research Determination

<u>PFAS Exposure Assessment Protocol and Appendices</u>
Appendix A: Community Event Evaluation Survey, Recruitment Letter and Phone Script
Appendix B: Privacy Act Statement, Consent, Parental Permission and Assent Forms and PFAS EA Biological Testing Tracking Form
Appendix C: Sample Collection Logs
Appendix D: Chain of Custody Forms
Appendix E: Urine Collection Instructions
Appendix F: Questionnaire
Appendix G: Results Letters
Appendix H: Site Health and Safety Plan
Appendix I: Data Management Plan