Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs)

OMB Control No. 0923-0059 (Exp. Date 06/30/2022)

Information Collection Request –Revision

Supporting Statement Part A –

Justification

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Part A. Justification

Goal of the study: The goal of this revision information collection request (ICR) is to complete up to nine additional exposure assessments (EAs) for per- or polyfluoroalkyl substances (PFAS) over the next three years. ATSDR/NCEH completed eight EAs from 2019 to 2020. This revision ICR will include modifications to the recruitment strategy and questionnaire, based on lessons learned from the eight EAs.

Intended use of the resulting data: The PFAS EAs will produce unbiased exposure prevalence estimates for each site and will identify community-specific factors (e.g., activities, exposure sources) associated with higher population PFAS levels. The EAs will allow ATSDR/NCEH 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 not generalize the results of each EA beyond the defined boundaries of the investigation. The results of the EAs may also be used to inform future health studies on PFAS exposure.

Methods to be used to collect data: ATSDR will select respondents using one-stage cluster sampling methods from selected DoD or non-DoD locations known to have PFAS contamination in drinking water, groundwater, or other water sources (e.g., list of telephone numbers, list of homes in the community). ATSDR will collect biological samples (serum and urine) from all respondents. ATSDR will also collect environmental samples (tap water and indoor dust) at a random 10% 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 at or near DoD or non-DoD locations with known PFAS water contamination. They must live in their home for at least one year prior to the PFAS being mitigated from the water, must be three years of age and older, and must not have a blood disorder that would preclude a blood draw. 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.

The Agency for Toxic Substances and Disease Registry (ATSDR) and the National Center for Environmental Health (NCEH) are requesting a three-year Paperwork Reduction Act (PRA) revision information collection request (ICR) titled *Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs)* (OMB Control No. 0923-0059, exp. date 6/30/2022).

Under Section 8006 of the Consolidated Appropriations Act, 2018, ATSDR, in collaboration with NCEH, conducted statistically based biomonitoring exposure assessments (EAs) at "…eight current or former domestic military installations…" that had documented human exposures to PFAS in drinking water. This current revision ICR allows for up to nine additional EAs to be conducted for another three years at either Department of Defense (DoD) or non-DoD locations.

For each site, a statistically based, community sampling design is 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 is administered to all participants to gather information to characterize each individual's exposure.

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

Each EA includes the following goals:

- **Provide a public health service to the community:** This investigation provides 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 receives an interpretation of what their individual results mean. The investigation also provides information about aggregate serum concentrations and exposure in the community from which participants are selected.

Depending on the results of the investigation, ATSDR/NCEH makes 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 are 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 community.
- **Inform future studies to evaluate the impact of PFAS exposure on human health:** The results of these EAs may inform the design of new or existing health studies.

Under this revision ICR, up to three EAs per year will be conducted using lessons learned from the initial eight EAs. Briefly, protocol revisions include modifications to the protocol recruitment strategies, such as increasing in the number of letters of invitation per EA due to low response rates observed, allowing options to conduct door-to-door recruitment and telephone questionnaires when warranted, and modifying water intake questions to evaluate exposure that may have occurred when PFAS was present in the water. These revisions are detailed in **Section A.15**.

ATSDR/NCEH are requesting a total of 8,735 respondents per year which reflects an increase of 184 respondents compared to the previously approved 8,551 respondents in 2019. In addition, the agencies are requesting a total time burden of 1,535 hours per year. This reflects a decrease of 596 hours compared to the previously approved 2,131 hours in 2019.

The authorizing legislation for this ICR is provided in **Attachment 1**. The 60-day Federal Register Notice was published on 11/16/2021 (**Attachment 2**) and is further discussed in **Section A.8**. Supporting information for this ICR is provided in **Attachments**, while the **Appendices** are indexed in accordance with the **PFAS EA Protocol**.

A.2. Purpose and Use of the Information Collection

The primary objective of this ICR is to conduct up to nine EAs at DoD or non-DoD locations known to have PFAS in drinking water, groundwater or any other sources of water. The locations of the EAs will be chosen based on the following criteria:

- 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

The nine additional EAs will again 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 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 may also use the EA findings to inform a future PFAS health study.

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. Questionnaires may be administered in-person or by phone. 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**).

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 have 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).

This ICR differs from the projects cited above in that the original EAs were intended to address data gaps regarding PFAS exposure at military installations. The revision is intended to conduct PFAS EAs at both DoD and non-DoD sites, as appropriate.

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

The EA recruitment will focus on residential properties 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. There are no legal obstacles to reduce the burden.

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 08/13/2021, Vol. 86, No. 218, pp. 63390 (**Attachment 2**). ATSDR/NCEH received one public comment related to this notice. The program responses to public comments are provided in **Attachment 2a.**

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.

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.

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 05/09/2022, 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 (**Attachment 5).**

The following IIF Categories apply to this information collection (**Appendices B, F1, and F2**):

❑ 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 CDC Scientific and Research Project Record Schedule, which contains authorized disposition instructions for ATSDR/NCEH's scientific records.

- The following individuals will have access to personal information in order to provide respondents with their personalized results: ATSDR/NCEH employees and contractors.
- Sunshine Laws may apply in some states where an EA is conducted. Sunshine Laws require openness in government, which may result in personal identification being accessible by the general public. For the EAs, federal privacy laws will take precedence.
- 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**).
- 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 non-research activities and human subjects review by an Institutional Review Board (IRB) will not be required (**Attachment 6)**.

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 B6**. 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 will only be used to assist in the assessment of a respondent's individual biological results.

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

Eight EAs were completed in 2019 to 2020, and an additional seven EAs, conducted at either DoD or non-DoD locations, were permitted but not conducted. Under this revision ICR, ATSDR/NCEH anticipate conducting three PFAS EAs each year over a period of three years, for a maximum of nine EAs. The number of respondents per EA will vary, but we expect the number to average 379 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 five minutes (489 members for three EAs). The resultant burden is 41 hours annually for three EAs.

- Biological Testing Tracking: All participants, adults (864) and children (273), will be provided a biological testing tracking form when they sign in for the testing event **(Appendix B6)**. 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 379 hours annually for three EAs.
- Household Eligibility Screener: ATSDR/NCEH anticipate asking approximately 1,520 head-of-households per EA to complete a 5-minute telephone script (**Appendix A3**) to identify 152 eligible households, assuming a response rate of 10% (see **Supporting Statement B**). To be eligible, the household residents must have lived in the home for at least one year prior to removal of PFAS from the drinking water. In addition, household members must be ≥3 years of age and not have a bleeding disorder, which would preclude a blood draw. The 1,520 head-of-households per EA would be administered the five-minute questionnaire, resulting in a burden of 127 hours for each EA (380 hours annually for three EAs and 4,560 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 152 households are assumed to provide the target sample size of 379 respondents per EA. All respondents will provide a serum and a urine sample. For three annual EAs, we estimate the number of respondents to be 1,137 (379*3).

  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,[1] we are able to estimate the annual number of respondents by age group using the following: 76% (n=864) of respondents will be adults ≥18 years (1.9/2.5); and 24% (n=273) 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.[2] 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% 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

[1] 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.

[2] 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

age groups [8% to both child groups; 58% for ages 3-11 years (158) and 42% for ages 12-17 years (115)].

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 12-17 yr**
Consent	864	NA
Parental Permission	273	NA
Assent	NA	115
Questionnaire - Adult	864	NA
Child Questionnaire – with assistance from adult	158	NA
Child Questionnaire – completed by child	NA	115

- Adult Consent for Biological Testing: Annually, 864 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 144 hours annually for three EAs.
- Parental Permission Form for Biological Testing: A parental permission form will be administered to the parents of 273 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 46 hours annually for three EAs.
- Child Assent Form for Biological Testing: Children aged 12 to 17 years will assent to the testing of blood and urine for PFAS (115) (**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 adult consent form is approximately 10 minutes, resulting in a burden of 19 hours annually for three EAs.
- Adult Exposure Questionnaire for Biological and Environmental Testing:

Annually, 864 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 432 hours annually for three EAs.

- Parent Proxy for Child Exposure Questionnaire for Biological Testing: Annually, 158 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 40 hours annually for three EAs.
- Child Exposure Questionnaire for Biological Testing: Annually, 115 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 29 hours annually for three 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 70 heads of households annually for three EAs (152/10*100/65*3) (**Appendix A4**). The time associated with the script is five minutes, resulting in a burden of six hours annually for three EAs.
- Consent for Environmental Testing: ATSDR/NCEH will recruit a 10% 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 45 per year (152*10/100*3) (**Appendix B5**). The time associated with consenting to the environmental sampling is 10 minutes, resulting in a burden of eight hours annually for three EAs.
- Environmental Sample Collection: ATSDR/NCEH will recruit a 10% 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 45 per year (152*10/100*3) (**Appendix C2**). The time associated with conducting the environmental sampling and completing the collection form is 15 minutes, resulting in a burden of 11 hours annually for three 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	489	1	5/60	41
EA Participants (all ages)	Biological Testing Tracking	1,137	1	20/60	379
EA Adults	Household Eligibility Screener	4,560	1	5/60	380
	Consent	864	1	10/60	144
	Exposure Questionnaire (Adult) for Biological and Environmental Testing	864	1	30/60	432
EA Parents	Parental Permission	273	1	10/60	46
	Exposure Questionnaire (Child) for Biological Testing (Parent Proxy)	158	1	15/60	40
EA Children	Assent	115	1	10/60	19
	Exposure Questionnaire (Child) for Biological Testing (Child completed)	115	1	15/60	29
EA Heads-of-Households	Household Recruitment Script for	70	1	5/60	6

	Environmental Sampling				
	Environmental Sampling Consent Form	45	1	10/60	8
	Environmental Sample Collection Form	45	1	15/60	11
Total					**1,535**

B. Annualized Cost to Respondents

The hourly wage rate for adults ($28.01) is based on the U.S. Department of Labor, Bureau of Labor Statistics' most current statistics for all occupations [May 2021 National Occupational Employment and Wage Estimates United States, online May 31, 2022, 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 since 2009 (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	489	1	5/60	41	$28.01	$1,148.41
EA Participants (all ages)	Biological Testing Tracking	1,137	1	20/60	379	$28.01	10,615.79
EA Adults	Household Eligibility Screener	4,560	1	5/60	380	$28.01	$10,643.80
	Consent	864	1	10/60	144	$28.01	$4,033.44
	Exposure Questionnair	864	1	30/60	432	$28.01	$12,100.32

	e (Adult) for Biological and Environmental Testing						
EA Parents	Parental Permission	273	1	10/60	46	$28.01	$1,288.46
	Exposure Questionnaire (Child) for Biological Testing (Parent Proxy)	158	1	15/60	40	$28.01	$1,120.40
EA Children	Assent	115	1	10/60	19	$7.25	$137.75
	Exposure Questionnaire (Child) for Biological Testing (Child completed)	115	1	15/60	29	$7.25	$210.25
EA Heads-of-Households	Household Recruitment Script for Environmental Sampling	70	1	5/60	6	$28.01	$168.06
	Environmental Sampling Consent Form	45	1	10/60	8	$28.01	$224.08
	Environmental Sample Collection Form	45	1	15/60	11	$28.01	$308.11
TOTAL							**$41,998.87**

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

There are no other total annual cost burdens 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 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 $2,100,000 (i.e., assuming approximately $700,000 for each of the three 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 revision ICR. Changes to the protocol were made as a result of lessons learned from eight EAs that were completed in 2019 and 2020. The changes reflect modifications in recruitment strategy, administration of questionnaires, and data collection forms, and additions and deletions of other protocol appendices.

Protocol Modifications (outlined in **Appendix K**):

- Recruitment strategy modifications
    - The expected response rate to letters of invitation was initially assumed to be 65%. In practice, the agencies observed much lower response rates of 10% in EA communities. Thus, using a 10% response rate, ATSDR/NCEH estimates the number of invitation letters to mail out is more realistically 3,000 per EA community.
    - Recruitment was initially solely based on mailing recruitment letters and follow-up phone calls. Due to the low response rate observed, ATSDR/NCEH is adding door-to-door recruitment as an option whenever warranted.
- Questionnaire administration
    - Questionnaires were initially to be administered in-person during home visits. With the emergence of COVID-19, safety modifications to the EA protocol (**Appendix J**) allowed administering questionnaires by phone. ATSDR/NCEH is adding this as an option whenever warranted.
- Supplemental documents for data management are added to **Appendix I**.
    - NCEH/ATSDR Data Use Agreement Template (**Appendix I2**).
    - Standard Operating Procedures (SOPs) for Data Management (**Appendix I3**)
- Form modifications:

- Questionnaire Modifications (**Appendices F1 and F2**): Below is a crosswalk table showing where questions are added or modified. These questionnaire modifications are not expected to affect the estimated average burden per response, which remains 30 minutes per adult questionnaire (**Appendix F1**) and 15 minutes per child questionnaire (**Appendix F2**).

Table A.15.1 Questionnaire Modifications

Appendix F1. Adult Questionnaire	
2019	2022
Q12 - During the time you lived in a home served by the water source identified above, on average how many 8-oz cups of water or beverages prepared with tap water did you drink while at home per day?	**Q12 -** During the time you lived in a home served by the water source identified above, on average how many 8-oz cups of water or beverages prepared with tap water did you drink while at home per day *BEFORE the PFAS was mitigated from the water*?
Appendix F2. Child Questionnaire	
Q6 - How many 8-oz cups of tap water or beverages prepared with tap water *do* you drink per day at home? o _ _ _ (8-oz cups) o Don't drink tap water o Don't know o Refused to answer **Note**: 1 cup = 8-oz; 2 cups = 1 pint (16-oz); 4 cups = 1 quart (32-oz); 16 cups = 1 Gallon (128-oz)	**Q6 -** How many 8-oz cups of tap water or beverages prepared with tap water *did* you drink per day at home *BEFORE the PFAS was mitigated from the water*? o _ _ _ (8-oz cups) o Don't drink tap water o Don't know o Refused to answer **Note**: 1 cup = 8-oz; 2 cups = 1 pint (16-oz); 4 cups = 1 quart (32-oz); 16 cups = 1 Gallon (128-oz)
	Insert New Q7 - How many 8-oz cups of tap water or beverages prepared with tap water do you currently drink per day at home? o _ _ _ (8-oz cups) o Don't drink tap water o Don't know o Refused to answer **Note**: 1 cup = 8-oz; 2 cups = 1 pint (16-oz); 4 cups = 1 quart (32-oz); 16 cups = 1 Gallon (128-oz)
Q12 - Did you drink formula reconstituted with tap water as an infant? o Yes **If Yes**, for how long? ____ (months) o No o Don't know	**Q13 -** Did you drink formula reconstituted with tap water as an infant *BEFORE the PFAS was mitigated from the water*? o Yes **If Yes**, for how long? ____ (months) o No o Don't know

o Refused to answer o Not Applicable	o Refused to answer o Not Applicable

ICR Changes Based on the Reduced Number of EAs Requested per Year:

- In 2019, ATSDR/NCEH received PRA clearance for up to five EAs per year (15 over three years). Under this revision ICR, ATSDR/NCEH are requesting PRA clearance for up to three EAs per year (nine over three years).
- The total number of respondents requested per year is 8,735, which reflects an increase of 184 respondents compared to the previously approved 8,551 respondents in 2019. This difference is due to the increased number of recruitment letters needed based on a response rate of 10% (based on the eight completed EAs) instead of 65%.
- The agencies are requesting a total time burden of 1,535 hours per year. This reflects a decrease of 596 hours compared to the previously approved 2,131 hours in 2019.
- The table below shows the net changes of respondents and burden hours by form.

Table A.15.2. Modification of Requested Number of Respondents and Burden Hours

Type of Respondents	Form Name	No. of Respondents		Net Change in No. Respondents Requested	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours		Net Change in Burden Hours Requested
		2019	2022				2019	2022	
EA Community Members	Community Event Evaluation Survey	815	489	-326	1	5/60	68	41	-27
EA Participants (all ages)	Biological Testing Tracking	1,975	1,137	-838	1	20/60	658	379	-279
EA Adults	Household Eligibility Screener	1,345	4,560	3215	1	5/60	112	380	268
	Consent	1,501	864	-637	1	10/60	250	144	-106
	Exposure Questionnaire	1,501	864	-637	1	30/60	751	432	-319

	(Adult) for Biological and Environmental Testing								
EA Parents	Parental Permission	474	273	-201	1	10/60	79	46	-33
	Exposure Questionnaire (Child) for Biological Testing (Parent Proxy)	275	158	-117	1	15/60	69	40	-29
EA Children	Assent	199	115	-84	1	10/60	33	19	-14
	Exposure Questionnaire (Child) for Biological Testing (Child completed)	199	115	-84	1	15/60	50	29	-21
EA Heads-of-Households	Household Recruitment Script for Environmental Sampling	117	70	-47	1	5/60	10	6	-4
	Environmental Sampling Consent Form	75	45	-30	1	10/60	13	8	-5
	Environm	75	45	-30	1	30/60	38	11	-27

	ental Sample Collectio n Form								
Total		**8,551**	**8,735**	**184**			**2,131**	**1,535**	**-596**

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.