Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): A Multi-site Cross-sectional Study

(The Multi-site Study)

New Information Collection Request

Supporting Statement Part A –

Justification

Principal Investigator: Marian Pavuk, MD, PhD
Title: Senior Epidemiologist, Environmental Epidemiology Branch
Email: fsh8@cdc.gov
Phone: 770-488-3671
Fax: 770-488-1541

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Glossary of Per- and Polyfluoroalkyl Substances

PFAS - Per- and Polyfluoroalkyl Substances to be Studied	
PFOA	perfluorooctanoic acid n-PFOA - linear isomer Sb-PFOA - serum branched isomer
PFOS	perfluorooctane sulfonic acid n-PFOS – linear isomer Sm-PFOS – serum branched
PFHxS	perfluorohexane sulfonic acid
PFOSA	perfluorooctane sulfonamide
Me-PFOSAA	2-(N-methyl-perfluorooctane sulfonamido) acetic acid
Et-PFOSAA	2-(N-ethyl-perfluorooctane sulfonamido) acetic acid
PFBS	perfluorobutane sulfonic acid
PFHpA	perfluoroheptanoic acid
PFNA	perfluorononanoic acid
PFDA	perfluorodecanoic acid
PFUnDA	perfluoroundecanoic acid
PFDoA	perfluorododecanoic acid

Part A. Justification

Goal of the study: The main goals of the research study are to examine potential associations between health outcomes and measured and historically reconstructed serum levels of PFAS. The ATSDR has awarded funds for seven research institutions to study PFAS at multiple sites around the country (the recipients).

Intended use of the resulting data: Recipients and the Agency for Toxic Substances and Disease Registry (ATSDR) will examine the association between PFAS compounds and lipids, renal function and kidney disease, thyroid hormones and disease, liver function and disease, glycemic parameters and diabetes, as well as immune response and function in both children and adults. In addition, recipients and ATSDR will investigate if PFAS are related to differences in sex hormones and sexual maturation, vaccine response, and neurobehavioral outcomes in children. In adults, additional outcomes of interest include cardiovascular disease, osteoarthritis, osteoporosis, endometriosis, and autoimmune disease.

Methods to be used to collect: Recipients will employ a cross-sectional design using a statistically based sampling of persons, where appropriate, from sites exposed to PFAS-contaminated drinking water based on pathways of exposure and water systems characterization at the individual sites.

Subpopulation to be studied: Study will enroll a sample of at least 9,100 participants (7,000 adults and 2,100 children, equally of both sexes). Adults will be 18 years or older, and children will be between 4-17 years of age at enrollment. Each cooperative agreement recipient will attempt to meet a target recruitment of 300 children and 1,000 adults.

How data will be analyzed: Study staff will calculate descriptive statistics to identify the presence and distribution of PFAS and effect biomarker analytes in the Multi-site Study participants. Statistical methods will include multiple linear regression of continuous effect biomarkers on continuous PFAS serum levels and categorized PFAS serum levels, and logistic regression of categorized effect biomarkers or disease prevalence on continuous and categorical PFAS serum levels. Study staff will use restricted cubic spline methods (or generalized additive models) for linear and logistic regression to obtain flexible, smoothed exposure-response curves. To identify risk factors that may act as confounders for a particular health outcome, the analysis will implement a "10% change in the effect estimate" rule.

A.1. Circumstances Making the Collection of Information Necessary

Per- and polyfluoroalkyl substances (PFAS) are a family of chemicals widely used in industrial applications and consumer products. A number of PFAS chemicals including perfluorooctane sulfonate (PFOS), perfluorooctanoate (PFOA), and perfluorohexane sulfonate (PFHxS) persist in the environment with serum half-lives in humans of 2 to 5 years. PFAS contamination of drinking water is widespread in the U.S. It is estimated that at least six million residents were served by 66 public water supplies that had at least one sample at or above the US EPA Lifetime Health Advisory for PFOA and PFOS (individually or combined) of 70 ng/L. Industrial facilities that manufacture or use PFAS have contaminated drinking water in surrounding communities in a number of states. In addition, PFAS chemicals including PFOS, PFOA, and PFHxS and others are also constituents in aqueous film-forming foam (AFFF), used to extinguish flammable liquid fires. Since the 1970s, military bases in the U.S. have used AFFF with PFAS constituents for firefighting training as well as to extinguish fires. At some military bases, AFFF use has resulted in the migration of PFAS chemicals through soils to ground water and/or surface water sources of drinking water for the bases and/or surrounding communities.

ATSDR and the Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health (NCEH) were mandated to conduct research on PFAS contamination in drinking water in Section 316 of the 2018 National Defense Authorization Act (Public Law 115-91) as amended by Section 315 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) (**Appendix A**).

ATSDR is requesting a three-year Paperwork Reduction Act (PRA) clearance for a new information collection request titled "Human Health Effects of Drinking Water Exposures to Per- and Polyfluoroalkyl Substances (PFAS): The Multi-site Study." The 60-day Federal Register Notice was published on April 23, 2019 (**Appendix B**) and is further discussed in **Section A.8**. ATSDR is funding this research under Notice of Funding Opportunity (NOFO) No. CDC-RFA-TS-19-002 (**Appendix C**). The cooperative agreement research recipients awarded under this NOFO are included in the protocol as **Attachment 1**.

A.2. Purpose and Use of the Information Collection

In 2017, the Agency for Toxic Substances and Disease Registry (ATSDR) conducted a feasibility assessment and literature review to identify candidate designs and health outcomes for

research on the health effects potentially related to PFAS exposure (**Appendix D**) (ATSDR 2017). Based on the feasibility assessment, ATSDR is currently conducting the Pease Study (OMB Control No. 0923-0061) as a proof-of-concept model for a Multi-site Study of PFAS health effects. Pease Study final response rates are not known as the study is ongoing, and recruitment is paused due to Covid-19. So far (with enrollment starting on Nov 4, 2019) about 20% of adults who participated in the biomonitoring in NH (termed "wave 1" recruitment) have enrolled in the Pease study (300 out of 1,500). We may still increase the number to be closer to the 40% response rate used for estimation purposes in **Section 12** as the recruitment is still ongoing till end of 2020.

The main goal of the cross-sectional Multi-site Study is to evaluate potential associations between measured and historically reconstructed serum levels of PFAS including PFOA, PFOS, and PFHxS, and selected health outcomes as described below. Based on ATSDR's literature review of epidemiological studies of PFAS, the study will examine potential associations between PFAS compounds and lipids, glycemic parameters and diabetes liver function and disease renal function and kidney disease, thyroid hormones and disease, as well as immune response and function in both children and adults. In addition, the study will investigate differences in sex hormones and sexual maturation, vaccine response, and neurobehavioral outcomes in children as related to PFAS. In adults, additional outcomes of interest include cardiovascular disease, osteoarthritis and osteoporosis, endometriosis, and autoimmune disease.

The study will attempt to recruit a total of at least 2,100 children and 7,000 adults from communities exposed to PFAS-contaminated drinking water. Each award recipient will attempt to recruit 300 children and 1,000 adults. Sites include communities whose drinking water was impacted by AFFF use at military bases or by industrial PFAS releases. The selection process considered the levels of PFAS drinking water concentrations at a site, the size of the population exposed, the experience of the researchers in conducting drinking water epidemiological studies, and geographic coverage. A key aim was to select sites so that a wide range in PFAS exposures levels were included in the study in order to enable the evaluation of exposure-response trends including effects at the lower range of exposures. Ground water contaminant fate and transport models and water system distribution system models may be necessary to identify the areas with contaminated drinking water, determine the period when the drinking water was contaminated, and historically reconstruct PFAS contaminant concentrations. All pharmacokinetic (PK) models used to estimate historical serum PFAS concentrations will undergo peer review by physiologically based pharmacokinetic (PBPK) modeling and PFAS experts to ensure their applicability to human serum reconstruction. This applies to models that have already been published in the scientific literature, and models produced in-house by the recipients and/or ATSDR (see also **Supporting Statement B**).

A mandatory core research protocol for all recipients is designed to facilitate recruitment, data collection, and aggregate data across all sites.. If feasible, each award recipient shall identify and enumerate all households served by the contaminated drinking water supply in the selected community in order to recruit potential participants to meet the sample size requirements for children and adults.

- If the selected community is served by a PFAS-contaminated public water system, then the recipient will obtain a list of households served by the water purveyor from its billing records.
- If the community is served by contaminated private wells, then the recipient will obtain a list of households with contaminated wells from the local and/or state health and environmental agencies.

Statistical sampling methods (e.g., a two stage cluster sample) may be used for recruitment of study participants if all the affected households can be enumerated.

- If the PFAS drinking water concentrations vary widely across the community, then the recipient should consider using targeted sampling approaches including oversampling of areas with higher PFAS concentrations in order to ensure a sufficiently wide distribution of exposure levels among study participants to evaluate exposure-response trends.

If the enumeration of all households is not feasible, the recipient should consider the following approaches:

- If enumeration of all households is not feasible, or if participation rates are expected to be low, then the recipient should consider non-probabilistic sampling approaches such as “judgement” and “snowball” sampling approaches (Tyrer 2016).

In response to NOFO No. CDC-RFA-TS-19-002 (**Appendix C**) and following the guidelines in the multi-site study protocol, recipients developed detailed recruitment protocols specific for each site. Those were reviewed by external peer review and approved by ATSDR when awarding the cooperative agreement grants. Non-random approaches were included as options to site investigators, because association/etiologic studies (as opposed to descriptive studies like NHANES, for which estimation is targeted at individual variables rather than association parameters), selection bias results only when study participation is affected by both the exposure status and disease status (Hernan et al., 2004). The multi-site study is aimed at measuring exposure-disease associations, rather than estimating community-wide disease rates. Thus, non-random participation is only a concern if the two conditions for selection bias are met.

Investigators at five sites were able to enumerate the households and will proceed with statistically based sampling (or inviting all residents in the sampling frame area). However, as outlined above, the statistically representative sampling is needed for surveys generating normative data, such as quantifying exposures in the community (e.g. ATSDR Exposure Assessment), but not for ensuring the validity of studies of disease etiology (sic). Furthermore, the low response rates in communities - which are typical of studies of this nature - often preclude having meaningful probability samples.

- If the proposed efforts result in response rates below 15% after exhausting mail, phone, social media, and door to door attempts to contact (no more than 15 attempts total for selected household); the site will request ATSDR for deviation of the protocol and pursue non-probability sampling as described above.
- In addition, use of targeted sampling in high exposure area (e.g. private wells), and volunteers to complement site specific exposure scenarios at three of those five sites

Two remaining sites concluded that the statistically based sampling was not feasible and elected to use snowball/referral-based sampling and quota-based sampling methods.

- If the sites are unable to reach 60% of their recruitment goals using those techniques within one year of starting recruitment, they can request ATSDR to allow enrolling volunteers that meet study eligibility criteria.

All sites will fully document their methods and address how the final samples are likely to deviate from a true probability sample, drawing on relevant empirical data as feasible. Each site will make adjustments as needed to attain the required study size per guidelines above and in coordination with ATSDR. Site investigators will work diligently to document all steps of the process and will commit to the technical oversight and quality control through the established ATSDR Sampling and Recruitment Working Group (Supporting Statement B).

The primary issue in combining data from different sites is the sufficient comparability of the data in respect to conceptual framework and overall objectives of the study (Bangdiwala et al., 2018). Comparability will be ensured in this multi-site study by the implementation of common protocol that requires the same application of: a) eligibility criteria and characteristics; b) computer assisted interviews in study office (RedCap), c) outcomes of interest; d) sample collections/processing/storage procedures; e) timelines of implementation per funding mechanism; f) centralized laboratories for exposure; effect biomarker and clinical tests; g) data quality assurance and management through unified contract mechanism; and h) shared tools for staff training.

Meta-analysis is a well-known approach for obtaining common effect from several similar studies. In order to protect against bias in the pooled analyses, it may be necessary to adjust some pooled epidemiological models for study sites. For example, meta-analyses often use either indicator variables or random effects approaches to take into account differences across sites due to the effects of geographical location (i.e., the study site is likely to have direct effects on PFAS water concentrations and participation, as well as possible direct effects on some health outcomes). A weighted pooled estimate is obtained, considering the inverse of each study 's variance. Multi-level meta-regression or modeling structural relationship are further options in analyzing aggregated data (Bangdiwala et al., 2018; Basagana et al. 2016).

To aggregate pooled data effectively and to guide statistical approaches for pooled data analysis we will use formal tests of heterogeneity across study sites (Friedenreich, 1993). Standardized study sampling/recruitment protocols in itself might or might not prevent substantial heterogeneity in observed exposure-disease associations, but if such heterogeneity is observed, key features of the different sites that bear on comparability will be tabulated and examined by the study team (Supporting Statement B, Table B.5.2), with sensitivity analyses to consider the impact of excluding sites from some analyses based on those features (Roetzheim et al. 2012).

The recipient should consider requesting assistance from local and state health departments in its recruitment efforts. In addition, the recipient should engage community organizations to assist in conducting outreach about the study and recruitment of participants and consider establishing a community assistance panel ("CAP").

- The CAP can facilitate the involvement of the affected community in decisions related to outreach about the study, participant recruitment strategies, and study logistics.
- The CAP could also assist the recipient in the dissemination of study findings to the community.

The study will obtain blood samples from participants to measure PFAS serum levels and several effect biomarkers such as lipids, and thyroid, kidney, immune and liver function. The study will also obtain urine samples from participants to measure PFAS levels and kidney function biomarkers. The study will archive serum and urine samples in order to conduct analyses of additional PFAS chemicals and specific effect biomarkers. Adult participants and a parent of the child participant will complete a questionnaire that includes a residential history, medical history, occupational history and water consumption habits. The study will access medical and school records to confirm adverse health outcomes reported in the questionnaire. To facilitate access to these records, the recipient will reach out to local medical societies, the public school system and private schools to enlist their cooperation with the study.

Participants will be categorized based on the measured serum concentration of PFAS compounds or on modeled estimated historical serum levels (e.g., referent or low, medium, high). Estimated and measured PFAS serum levels will also be evaluated as continuous variables.

- At sites with preceding PFAS biomonitoring, the study will evaluate changes in PFAS concentration over time.
- The study will reconstruct historic serum PFAS concentrations by estimating half-lives and elimination rates as well as water contamination modeling to inform the PK or PBPK modeling.
- Historical serum PFAS reconstruction will enable the evaluation of exposure lags and vulnerable periods as well as statistical analyses that can control for confounding and reverse causation due to physiological factors.
- NCEH DLS will perform blood PFAS analyses for all Multi-site Study participants. Thus issues of inter-laboratory variability are avoided.

Clinical and health effect biomarkers measured in the study are described in the protocol in **Sections 3.7.1 for Children and 3.7.2. for Adults**. These analyses will also be performed by a centralized laboratory to avoid issue of inter-laboratory variability. The list of analytes for biochemical analyses of blood/serum samples is provided in Table A.2.1. These analytes are part of the biochemical analytical plan (**Attachment 2**) and will be tested as part of study hypotheses (protocol Section 2.5.2).

Urine samples will be collected from study participants for potential future analyses of PFAS or health biomarkers (not specified). Urine creatinine or urine specific gravity would be measured in connection with urine PFAS to adjust PFAS concentrations and present both adjusted and non-adjusted results. CDC IRB amendment for future urine biomarker analyses would need to be submitted.

Table A2.1. Biochemical analytes and health effect markers (Protocol Sections 3.7.1 Children and 3.7.2. Adults).

Biochemical Analyte	**Purpose of Testing**	**Children/Adults**
Total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL), and triglycerides	Higher or abnormal levels of lipids (e.g. hypercholesterolemia)	C/A
Uric acid, estimated glomerular filtration rate	Impaired renal function;	C/A

(eGFR)	hyperuricemia, lower estimated glomerular filtration rate (eGFR)	
Alanine transaminase (ALT), aspartate transaminase (AST), alkaline phosphatase (ALP), γ-glutamyltransferase (GGT), direct bilirubin, albumin	Liver function/damage	C/A
Cytokeratin-18 (CK-18; M60, M35)	Non-alcoholic fatty liver disease/steatohepatitis	C/A
Glucose, insulin, glycosylated hemoglobin (HbA1c), auto-antibodies (GAD-65 and IA-2), C-peptide, pro-insulin	Glycemic parameters, type 1 and type 2 diabetes	C/A
Thyroid stimulating hormone (TSH), total thyroxin (TT4), free thyroxin (FT4), Triiodothyronine (TT3), thyroglobulin antibody, thyroid peroxidase antibodies (TPO)	Thyroid function; hypo- and hyperthyroidism	C/A
Testosterone, estradiol, sex hormone-binding globulin (SHBG); insulin-like growth factor - 1 (IGF-1)	Differences in sex hormones, growth and sexual maturation	C
Immunoglobulins (IgG, IgA, IgE, and IgM)	Immune response; allergies (IgE)	C/A
Antibodies to rubella, mumps, and diphtheria vaccines	Lower antibody responses to rubella, mumps, and diphtheria vaccines	C
Rheumatoid factor, antinuclear antibodies (ANA)	Autoimmune disease	A
Cytokines and adipokines (interleukin 1-β (IL-1β), interleukin 6 (IL-6), interleukin 8 (IL-8), monocyte chemotactic protein-1 (MCP-1), tumor necrosis factor α (TNF-α), leptin, adiponectin, resistin, plasminogen activator inhibitor-1 (PAI-1); C reactive protein	Inflammation in chronic disease (e.g. heart disease, diabetes, liver disease)	A

In order to restrict this study to drinking water exposures, adults ever occupationally exposed to PFAS will not be eligible for the study (e.g., ever firefighters or ever worked in an industry using PFAS chemicals in its manufacturing process). Likewise, children whose birth mothers were occupationally exposed to PFAS will not be eligible. All health end points included in the multi-site study have sufficient power with the exclusion of those specifically discussed in the protocol, such as ulcerative colitis where sample size may be sufficient but not adequate if effect response is below OR=2.75 (**Section 3.31**, page 30 of the protocol).

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

ATSDR will use information technology for over 37 percent of the information collections each year through electronic means of information collection. The estimated percentages of total number of responses and total number of burden hours to be collected by electronic means are shown in **Table A.3.1**; where we estimate that 40.0 percent of responses will be by electronic means and 38.5 percent of time burden will be by electronic means.

Computer Assisted Telephone Interviews (CATIs) and Computer Assisted Personal Interviews (CAPIs) programmed into REDCap™[1]will reduce burden by incorporating computer-generated skip patterns and improve data quality by automating data entry. Also, ATSDR is offering the child questionnaire short form (**Attachment 15a**) to parents who will enroll as adults themselves. Responses to the short form will reduce duplication of effort and a parent's burden by half.

Screenshots of CATI and CAPI forms will be submitted to OMB as a non-substantive change request after PRA clearance for the Multi-site Study is granted, unless the CAPIs and CATIs are ready during OMB's review of the information collection request (ICR).

Table A.3.1. Information Collection by Electronic Means

Attachment No.	Form Name	Mode of Collection	No. Responses	Total Burden (in hours)
4	Eligibility Screening Script	CATI	7,982	1,330
8	Appointment Reminder Telephone Script	CATI	3,033	253
15	Child Questionnaire – Long Form	CAPI	560	280
15a	Child Questionnaire – Short Form	CAPI	140	35
16	Adult Questionnaire	CAPI	2,333	1,167
		Improved Technology Total	14,048	3,065
		Multi-site Study Total	35,100	7,960
		Improved Technology Percent	40.0%	38.5%

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

2005-2013

[1] https://www.cdc.gov/epiinfo/index.html

The most notable PFAS research in the U.S. to date was the C8 Health Project (see http://www.c8sciencepanel.org/). C8 is a trade name given to PFOA, manufactured in Parkersburg, WV. Extensive migration of C8 into the environment and subsequently into drinking water affected many people in the Mid-Ohio Valley in Ohio and in West Virginia. The purpose of the C8 Health Project was to collect health data from almost 70,000 Class Members of a lawsuit through written questionnaires and a battery of blood tests, including a test to measure PFOA and other PFAS compounds in the blood. As part of the Settlement Agreement, the C8 Science Panel released a series of "probable cause" reports linking C8 exposure to health outcomes. Given that the primary PFAS released by the chemical manufacturer was C8 (PFOA), the "probable link" to health outcomes are extremely informative for the Multi-site Study, but does not address all the PFAS constituents found in drinking water.

2017

In 2017 ATSDR conducted an extensive literature review for its Pease feasibility study (**Appendix D** - summarized on pages 14-15, and detailed beginning on page 77). The literature review focused on the epidemiological results for PFOA, PFOS and PFHxS. The purpose of the literature review was to identify the health-related endpoints that have been evaluated in at least one epidemiological study, and to assess the extent of the epidemiological research on the health effects of PFHxS and PFOS. The literature review was also used to derive sample size estimates for the Pease Study (OMB Control No. 0923-0061).

The literature review found that less information was available about the potential health effects of PFOS exposures, and very little information was available on the potential health effects of exposures to PFHxS. Because PFOS, PFHxS and other PFAS besides PFOA have occurred in the drinking water at contaminated sites around the country, epidemiological studies of populations at those sites have the potential to fill key knowledge gaps and address the community's concerns (**Appendix D**). ATSDR plans to analyze 14 serum PFAS in its biochemical analytical plan (**Attachment 2**).

2018

In efforts to increase cross-government coordination, ATSDR and NCEH/ATSDR senior leadership attended the PFAS National Leadership Summit, sponsored by U.S. EPA in Washington, D.C. on May 22-23, 2018 (see https://www.epa.gov/pfas/pfas-national-leadership-summit-and-engagement). During the summit, participants worked together to:

- Share information on ongoing efforts to characterize risks from PFAS and develop monitoring and treatment/cleanup techniques
- Identify specific near-term actions, beyond those already underway, that are needed to address challenges currently facing states and local communities

- Develop risk communication strategies that will help communities to address public concerns with PFAS

The list of confirmed organizations in attendance is found here: https://www.epa.gov/sites/production/files/2018-05/documents/pfas_summit_list_of_confirmed_organizations_5.22.18.pdf.

2019

Several modifications to the Multi-Site Study protocol and questionnaire were made based on work conducted in the preparation and conduction of data collection for the Pease Study. These modifications include:

- Modification of the childhood neurobehavioral test battery to ensure that each child on average will spend no more than 90 minutes to complete;
- Modification of the childhood questionnaire based on inter-governmental comments to the Pease Study questionnaire;
- Modification of the volume of blood to be collected from children and adults to ensure sufficient quantities for the clinical biomarker tests; and
- Inclusion of additional, quantitative bias analyses to the Multi-Site Study protocol based on peer reviewer and inter-governmental comments to the Pease Study protocol.

In addition, the data management system and community engagement strategy being used for the Pease Study have been adapted for use in the Multi-Site Study.

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

Medical practices and schools may be defined as small businesses or small entities.[2] The annual time burden for medical and educational record abstraction is estimated to be 2,490 hours. The portion of the time burden for medical and school record abstractions represents about 31 percent of the total hours requested (2,490/7,960 x 100).

The time to complete the school record abstraction form and the adult and child medical record abstraction forms is estimated to take 20 minutes per response. It is likely that the average time per response and the total number of record verifications will be less because:

[2] OMB FORM 83-I: A small entity may be (1) a small business which is deemed to be one that is independently owned and operated and that is not dominant in its field of operation; (2) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field; or (3) a small government jurisdiction which is a government of a city, county, town, township, school district, or special district with a population of less than 50,000.

- ATSDR anticipates that only a portion of children will have applicable education records of interest; however, once identified, it will be important that education specialists verify those that do.
- Most participants will report a smaller subset of the full complement of outcomes of interest on their questionnaire; therefore, medical record specialists will be able to find and abstract the medical outcomes within their practice specialties, and will not need to review patient records for every diagnosis or treatment on the list.

The number of outcomes of interest has been held to the absolute minimum required for the intended use of the research data. In order to reduce burden on, and if permitted by, the businesses or entities, ATSDR may offer to send trained study staff and contractors to assist in record abstraction.

A.6. Consequences of Collecting the Information Less Frequently

There are three types of respondents.

- The Multi-site Study participants (7,000/3 = 2,333, adults per year and 2,100/3 = 700 children and their parents per year) will respond to the information collection once.
- ATSDR is requesting two types of record abstractions to verify children's behavioral assessments and to verify adults' and children's self-reported medical histories. The basis for these estimates comes from and are consistent with the Pease study and were derived from the total number of projected enrolled persons (adults and children) for all sites combined per year. The number of school districts and medical offices was also estimated based on site information available and averaged for all sites. We estimate the following:
    - Across school districts, ATSDR estimates up to 30 school administrators will each receive 23 requests for school record abstractions, and 48 education specialists will each abstract up to 15 student records per year.).
    - Across medical practices, ATSDR estimates up to 70 medical office administrators will each receive 43 requests for medical record abstraction, and 150 medical record specialists will each abstract 16 adult records (1,000/ year) and 50 pediatric record specialists up to 14 (700/year) child medical records per year.
    - To reduce burden on school districts and medical practices, ATSDR may send trained study staff and contractors to assist with this effort.

If the collection is not conducted or is conducted less frequently, the validity of the study results, by relying on self-reported outcomes alone, will be subject to recall bias. Therefore, records verification at the estimated frequency is needed to address and to understand the extent of this potential source of bias.

There are no technical or legal obstacles to reducing burden.

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

The following special circumstance(s) apply to this information collection. We are requiring the following:

- Education specialists and medical records specialists will report information to the agency/recipients more often than quarterly because of the number of Multi-site Study participants for whom records will be abstracted.
    - Justification for reporting frequency greater than quarterly is provided in **Sections A.5** and **A.6**.
- If feasible, the recipient shall identify and enumerate all households served by the contaminated drinking water supply in the selected community in order to recruit potential participants to meet the sample size requirements for children and adults.
    - If the selected community is served by a PFAS-contaminated public water system, then the recipient will obtain a list of households served by the water purveyor from its billing records.
    - If the community is served by contaminated private wells, then the recipient will obtain a list of households with contaminated wells from the local and/or state health and environmental agencies.
- Statistical sampling methods (e.g., a two-stage cluster sample) shall be used for recruitment of study participants if all the affected households can be enumerated.
    - If the PFAS drinking water concentrations vary widely across the community, then the recipient should consider using targeted sampling approaches including oversampling of areas with higher PFAS concentrations in order to ensure a sufficiently wide distribution of exposure levels among study participants to evaluate exposure-response trends.
    - If enumeration of all households is not feasible, or if participation rates are expected to be low, then the recipient should consider non-probabilistic sampling approaches such as “judgement” and “snowballing” sampling approaches (Tyrer 2016).

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 April 23, 2019, Vol. 84, No. 78, pp. 16857-9 (**Appendix B**). ATSDR received 2 non-substantive comments and replied with a standard ATSDR response (**Appendix B1**).

B. The following persons outside and inside the agency were consulted (**Attachment 1**).

Table A.8.1. ATSDR External Consultations, 2018

Name	Title	Affiliation	Phone	Email/Date of Consultation
OUTSIDE CONSULTANTS				
Pease Community Assistance Panel (CAP)	see https://www.atsdr.cdc.gov/sites/pease/cap.html			Ongoing since 2016
External Peer Reviewers	Fall2018 - per CERCLA requirements for research, thee independent peer reviewers			
Matthew P. Longnecker, MD, ScD	Consultant	Ramboll Group A/S Consultants	(919) 765-8029	mlongnecker@ramboll.com 05/31/2018
Mark Strynar, PhD	Physical Scientist	US EPA National Research Exposure Laboratory (NERL)	(919) 541-3706	strynar.mark@epa.gov 09/06/2018
ACADEMIC INSTITUTIONS				
Kyle Steenland, PhD	Professor, Epidemiologist	Emory University	(404) 712-8277	nsteenl@sph.emory.edu 03/27/2018
Elsie M. Sunderland, PhD	Associate Professor	Harvard University	(617) 496-0858	ems@seas.harvard.edu 05/10/2018
Alan Ducatman, MD, MSc	Professor	West Virginia University	(304) 293-3693	aducatman@hsc.wvu.edu 05/17/2018
Philippe Grandjean, MD, DMSc	Professor; Adjunct Professor	University of Southern Denmark; Harvard University	617-384-8907	pgrand@hsph.harvard.edu 10/11/2018

Table A.8.2. Ongoing Consultations within CDC/ATSDR, 2018-9

Name	Title	Affiliation	Phone	Email
Antonia Calafat, PhD	Chief	NCEH Organic Analytical Toxicology Branch, Division of Laboratory Sciences (OATB/DLS)	(770) 488-7891	aic7@cdc.gov
Matthew Maenner	Epidemiologist	NCBDDD Division Of Congenital And Developmental Disorders (DCDD) Developmental Disabilities Branch (DDB)	(404) 498-3072	xde8@cdc.gov
NCEH/ATSDR PFAS Steering Committee				
Patrick Breysse, PhD, Chair		NCEH/ATSDR Director	(770) 488-0604	pjb7@cdc.gov

Donna Knutson, PhD*	NCEH/ATSDR Deputy Director	(770) 488-0673	dbk2@cdc.gov
Yulia Carroll, MD*	NCEH/ATSDR Associate Director for Science, Acting	(770) 488-3912	eya3@cdc.gov
Pamela Protzel-Berman, PhD, MPH	NCEH/ATSDR Associate Director for Policy	(770) 488-3016	pxp5@cdc.gov
Christopher Reh, PhD, MS	ATSDR Associate Director	(404) 498-5977	cer2@cdc.gov
Heather Bair-Brake, DVM, MS	NCEH/ATSDR Associate Director for Communications	(404) 639-3323	hhb9@cdc.gov
James Pirkle, MD	Director, NCEH Division of Laboratory Sciences (DLS)	(770) 488-7950	jlp1@cdc.gov
Angela Ragin, PhD	Deputy Associate Director, ATSDR	(770) 488-3807	atr0@cdc.gov
*No longer in this capacity			

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

As a token of thanks for participation, ATSDR will offer gift cards according to the following schedule:

- $25 for body and blood pressure measures, and for blood and urine collection;
- $25 for completed questionnaire; and
- $25 for child/parent completion of the neurobehavioral test battery.

If all parts of the study are completed, adult participants will receive $50 and each child and his or her parent will receive $75 in gift cards.

Trained study staff will document provision of gift cards on the hard copy form (**Attachment 12**). As part of the exit procedures, the participant will sign this form to document receiving the gift card.

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

Privacy Act Determination: On July 29, 2019, the CDC Chief Privacy Officer reviewed this submission and determined that the Privacy Act does apply (**Appendix E**).

The applicable Privacy Act System of Records Notices (SORN) are

- No. SORN 09-19-0001 ATSDR "Record of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances." ATSDR will file and retrieve Information in identifiable Form (IIF) by the name of the individual and Social Security Number.
- No. SORN 09-20-0136 "Epidemiologic Studies and Surveillance of Disease Problems." NCEH will file and retrieve IIF by the name of the individual and Study ID number.

The following IIF Categories apply to this information collection. Further discussion on the collection of Social Security Number (SSN) is found in **Section A.11**:

❑ Name
❑ Date of Birth
❑ Social Security Number (SSN)
❑ Mailing Address
❑ Phone Numbers
❑ Medical Information and Notes
❑ Biological Specimens
❑ Email Address
❑ Education Records
❑ Military Status
❑ Employment Status

Safeguards: The following special safeguards are provided to protect the records from inadvertent disclosure:

- Authorized Users: A database security package is in place for CDC's technology infrastructure to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access to records is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of ATSDR or its contractors, as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.
- Physical Safeguards: Logbooks and other source data are maintained in locked cabinets in locked rooms, and security guard service in buildings provide personnel screening of visitors. Access to CDC facilities housing technology infrastructure is controlled by a cardkey system. The facilities are protected by an automatic sprinkler system, numerous automatic sensors (e.g., water, heat, smoke, etc.) are installed, and a proper mix of portable fire extinguishers is located throughout the facility. The system is backed up on a nightly basis with copies of the files stored off site in a secure fireproof safe. Computer workstations, lockable personal computers, and automated records are located in secured areas.
- Procedural Safeguards: Protection for computerized records includes programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures and secure off-site or cloud storage is available for backup files.

Retention and Disposal**:** Records are retained and disposed of in accordance with the CDC Records Control Schedule (B-321) and the ATSDR Comprehensive Records Control Schedule (B-

371). Current CDC and ATSDR procedures allow the system manager to keep the records for 20 years unless needed for further study. Retention periods vary depending on the type of record. Source documents for records are disposed of when no longer needed in the study as determined by the system manager, and as provided in the signed consent form, as appropriate.

Privacy Impact Assessment: ATSDR will collect, maintain, and disseminate IIF in flat files stored in encrypted share drive. The CDC NCEH Division of Environmental Health Science and Practice (DEHSP) Lead Poisoning Prevention and Environmental Health Tracking Branch (LPPEHTB) will receive files from forms that do not collect IIF. The NCEH/ATSDR Information Systems Security Officer (ISSO) has determined that a full Privacy Impact Assessment (PIA) is required. The submission date was July 15 and the approval date was July 29, 2019 (**Appendix E**).

The system's Security Plan defines the process for handling security incidents. The system's team and OCISO share the responsibilities for event monitoring and incident response. All incidents involving a suspected or confirmed breach of IIF must be reported to OCISO according to the policy titled "OCISO/CDC Standard for Responding to Breaches of Personally Identifiable Information (PII)." The team will direct reports of suspicious security or adverse privacy-related events to the NCEH/ATSDR 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.

The participant will be informed about the security measures for privacy protections. The advisement on privacy protections is contained in the consent information (**Attachment 7b**) and the study fact sheet (**Attachment 7c**). Additionally, information is contained in the protocol, specifically in the Manual of Procedures **(Attachment 12).**

- The participant will be informed that, under the requirements of the 2016 21st Century Cures Act and Section 301 of the Public Health Service Act, the research is covered under a 301(d) Certificate of Confidentiality (CoC) (**Attachment 7b** and **Appendix F**).
- The ATSDR plans for data ownership and data sharing are found in the **Multi-site Study Protocol** (**Section 3.8.5**) and in **Appendix G**. Advisement is provided to the participant in **Attachment 7b**.
    - Coded research datasets and specimens will be available to ATSDR study investigators listed in **Attachment 1**.
        - Coding with a study ID means that datasets and specimens are still identifiable to investigators.

- ATSDR will produce coded datasets by removing the following: name, SSN, date of birth, address, former address(es), phone number, and date of completion of the blood draw and questionnaire.
    - SSN will be collected at enrollment for linkage to medical records and school records. Once the linkage has occurred, the SSN will be kept with other PII in a separate access restricted secure database. ATSDR may use SSN for tracking and tracing Multi-site Study participants for future studies.
    - Date of birth will be collected at enrollment (**Attachment 4**). It will be used to verify age eligibility. The participant's age, in years, will be used in data analysis file because it is a necessary variable in exposure and health outcome analyses.
- Specimen collection tubes provided to performing laboratories will be coded with study ID only.
- ATSDR PIs will maintain the identifying links as described in the consent information (**Attachments 7b&7c**):
    - To report results for the Multi-site Study and any future research studies, if necessary, by ATSDR.
    - To recontact Multi-site Study participants to take part in future research studies.

o Release of de-identified data to outside investigators must be approved by ATSDR. A data use agreement (DUA) will be prepared, detailing the condition of use of the data and proposed analyses for each outside project. The DUA condition of use will specify that ATSDR will not release the link between the study IDs and the participants' PII to the outside researchers. Through the DUA, the data are no longer coded, but are effectively de-identified to the outside researchers. The DUA will also specify that:

- After the approved project with the outside researchers is completed, further or secondary analyses of electronic datasets can only be undertaken with additional approval(s) from ATSDR.
- Written confirmation of understanding the conditions of use will be required from the lead scientist and institution. Copies of statistical code and datasets used in statistical analyses by the outside investigators will be kept by ATSDR.

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

The Multi-site Study has been determined to be non-exempt human subjects research under 45 CFR 46. The CDC IRB approval memo is found in **Appendix F**.

The Certificate of Confidentiality (CoC) approval also is found in **Appendix F**. A CoC is covers this research because the Multi-site Study will collect sensitive identifiable information from the study participants, including school records and medical records. ATSDR considers school and medical records verification necessary to maximize the quality and accuracy of the study results; otherwise, reliance on self-reported outcomes alone would be subject to recall bias. The participants will be asked to consent for ATSDR to access these records during the informed consent process, and the participant will be informed that his or her response is voluntary (**Attachments 7b&7c**).

A portion of participants may view diagnoses of medical conditions that may affect employability or insurability (e.g., heart disease, cancer) as sensitive, as well as special education status, developmental disabilities, occupation, race, and ethnicity data (**Attachments 15, 15a, and 16**). Accidental disclosure, when linked to a person's identity, such as the medications list (**Attachment 11**) or medical records abstraction forms (**Attachment 17a&17b**) may be sufficient to discern a participant's health history. Accidental disclosure of school records abstraction forms (**Attachment 18c**) may be damaging to a child's reputation and social standing. For all these reasons, all study staff and contractors will be trained to understand the need, and the regulations set aside, to protect the privacy and confidentiality of participants' private information (**Attachment 12**).

As stated in **Section A.10**, ATSDR wishes to collect SSNs. ATSDR provides each participant with information in the Privacy Act Statement (**Attachment 7b1**), including: 1) the statute which authorizes ATSDR to solicit the SSN; 2) how the SSN will be used; and 3) that the respondent's disclosure of the SSN is voluntary.

A.12. Estimates of Annualized Burden Hours and Costs

For sites with a contaminated public water supply, the recipient will request a list of residences served by the water purveyor (**Multi-site Study Protocol Attachment 3c**). The information requested will include the name of the person on the residential account and the street address of the residence. The recipient will also request information from the water purveyor on the distribution system characteristics, in particular, whether the PFAS concentrations can be

assumed to be relatively uniform throughout the system or whether the system had specific areas with substantially higher or lower PFAS concentrations. If uniform PFAS concentrations can be assumed, then a random sample of households may be conducted and recruitment letters mailed to these households. If the system has specific areas with substantially higher PFAS concentrations, then households in these areas will be targeted (oversampled) for recruitment letters.

For sites with contaminated private wells, the recipient will request information on the impacted residences and the results of PFAS sampling of their private wells from the state and/or local health and environmental agencies (**Multi-site Study Protocol Attachment 3d**). Sampling will target households based on the magnitude of the PFAS concentrations in their private wells – i.e., wells with higher concentrations will be oversampled if necessary to ensure a sufficiently wide range of exposure levels. For example, it is not unusual to have a large number of private wells with detectable PFAS contamination below EPA's lifetime health advisory levels for PFOA and PFOS, with only a small percentage having PFAS levels considerably above EPA's lifetime health advisory.

The annual time burden for the collection of water records by the recipients is estimated to be 189 hours.

In total, ATSDR seeks to enroll approximately 9,100 participants in the MSS (7,000 adults and 2,100 children and their parents). Annualized estimates are 3,033 participants (2,333 adults and 700 children). The exact number of enrolled participants at specific sites may increase or decrease slightly but should not exceed the 9,100 participants, when combined across sites. Recruitment letters will provide a phone number to call for information about the study. The recipient will screen potential recruits using an eligibility screening script (**Attachment 4**). Assuming a 95 percent eligibility rate and a 40 percent response rate, we estimate that the recipients will screen 7,982 people (6,140 adults and 1,842 children) across all sites in order to recruit the target sample size of 3,033 participants (2,333 adults and 700 children) per year. Trained study staff will use the recruitment tracking form (**Attachment 6**) to track recruitment success and to calculate non-response bias. At enrollment, recipients will obtain adult consent, parental permission, and child assent before data collection begins (**Attachment 7b**).

Each child will enroll with a parent, who ideally will be the child's birth mother, as the recipients will ask details about the child's exposure, pregnancy, and breastfeeding history **(Attachment 15&15a).** For each participant, recipients will take body measures, collect blood and urine samples for chemical and biomarker analysis (**Attachments 13 & 14**), and administer a questionnaire on exposures and medical history (**Attachment 15, 15a & 16**).

For purposes of burden estimation, ATSDR assumes that 20 percent of parents (n=140 per year) will also enroll as adults and can take the child short form questionnaire (**Attachment 15a**); therefore, 560 parents will take the child long form questionnaire (**Attachment 15**). Trained

professionals will administer neurobehavioral assessments of the child's attention and behaviors to parents and children (n=700).

The annual time burden for information collection for multi-site participants is estimated to be 5,454 hours.

To facilitate access to medical and school records, each recipient will reach out to local medical societies, the public school system, and private schools, to enlist their cooperation with the study. Recipients will ask for permission to abstract adults' and children's medical records from approximately 70 medical practices across all sites per year (**Attachment 17**). Across medical practices, ATSDR estimates up to 150 adult and 50 pediatric medical record specialists will each abstract up to 16 and 14 medical records in each age group per year (**Attachments 17a &17b**).

Recipients will also ask for permission to check children's school records to compare their behavioral assessment results from approximately 30 school administrations across all sites per year (**Attachment 18b**). Across all sites, ATSDR estimates up to 48 education specialists will each abstract 15 student records per year (**Attachment 18c**).

The annual time burden for medical and educational record abstraction is estimated to be 2,490 hours.

Table A.12.1. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Public Water Purveyors	Drinking Water Information Collection Form	14	1	10	140
Environmental Protection Agencies	Drinking Water Information Collection Form	7	1	7	49
7Multi-site Study Participants	Eligibility Screening Script	7,982	1	10/60	1,330
	Appointment Reminder Telephone Script	3,033	1	5/60	253
	Update Contact Information Hardcopy Form	3,033	1	5/60	253
	Medication List	3,033	1	3/60	152
	Body and Blood Pressure Measures Form	3,033	1	5/60	253
	Blood Draw and Urine Collection Form	3,033	1	10/60	506
	Adult Questionnaire	2,333	1	30/60	1,167
	Child Questionnaire – Long Form	560	1	30/60	280
	Child Questionnaire –	140	1	15/60	35

	Short Form				
	Parent Neurobehavioral Test Battery	700	1	15/60	175
	Child Neurobehavioral Test Battery	700	1	90/60	1,050
Medical Office Administrators	Request for Medical Record Abstraction	70	43	20/60	1003
Medical Record Specialists	Medical Record Abstraction Form - Adult	150	16	20/60	800
	Medical Record Abstraction Form - Child	50	14	20/60	233
School Administrators	Request for Child School Record Abstraction	30	23	20/60	230
Education Specialists	Child School Record Abstraction Form	48	15	20/60	240
Total					8,149

Estimates of the annualized cost to respondents were based on the Department of Labor "May 2018 National Occupational Employment and Wage Estimates, United States" (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).

ATSDR used the following occupation codes and hourly wage estimates to represent each respondent type in the burden table.

Table A.12.2. Mean Hourly Wages for Respondent Types

Respondent Type	Occupation Code	Occupation Title	Mean Hourly Wage
Public Water Purveyors	51-8031	Water and Wastewater Treatment Plant and System Operators	$23.79
Environmental Protection Agencies	19-4091	Environmental Science and Protection Technicians, Including Health	$24.21
Multi-site Study Participants	00-0000	All Occupations	$24.98
School Administrators	11-9030	Education Administrators	$46.65
Education Specialists	25-9099	Education, Training, and Library Workers, All Other	$22.44
Medical Office Administrators	11-9111	Medical and Health Services Managers	$54.68
Medical Record Specialists	29-2071	Medical Records and Health Information Technicians	$21.16

Table A.12.3. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Responde	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs

			nt				
Public Water Purveyors	Request Letter for Public Water System	14	1	10	140	$23.79	$3330.60
Environmental Protection Agencies	Request Letter for Water Testing Data	7	1	7	49	$24.21	$1,186.29
Multi-site Study Participants	Eligibility Screening Script	7,982	1	10/60	1,330	$24.98	$33,231.73
	Appointment Reminder Telephone Script	3,033	1	5/60	253	$24.98	$6,313.70
	Update Contact Information Hardcopy Form	3,033	1	5/60	253	$24.98	$6,313.70
	Medication List	3,033	1	3/60	152	$24.98	$3,788.22
	Body and Blood Pressure Measures Form	3,033	1	5/60	253	$24.98	$6,313.70
	Blood Draw and Urine Collection Form	3,033	1	10/60	506	$24.98	$12,627.39
	Adult Questionnaire	2,333	1	30/60	1,167	$24.98	$29,139.17
	Child Questionnaire – Long Form	560	1	30/60	280	$24.98	$6,994.40
	Child Questionnaire – Short Form	140	1	15/60	35	$24.98	$874.30
	Parent Neurobehavioral Test Battery	700	1	15/60	175	$24.98	$4,371.50
	Child Neurobehavioral Test Battery	700	1	90/60	1,050	$24.98	$26,229.00
Medical Office Administrators	Request for Medical Record Abstraction	70	43	20/60	1,003	$54.68	$54,862.27
Medical Record Specialists	Medical Record Abstraction Form - Adult	150	16	20/60	800	$21.16	$16,928
	Medical Record Abstraction Form - Child	50	14	20/60	233	$21.16	$4,937.33
School Administrators	Request for Child School Record Abstraction	30	23	20/60	230	$46.65	$10,729.50
Education	Child School	48	15	20/60	240	$22.44	$5385.60

Specialists	Record Abstraction Form						
Total							$233,556.40

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

There are no required capital and start-up costs to respondents or record keepers for the Multi-site Study. In addition, there are no cost requirements for operation, maintenance, and purchase of equipment or services for respondents or record keepers.

A.14. Annualized Cost to the Federal Government

Pursuant to PL 115-91 and PL 115-232 (**Appendix A**), ATSDR received funds from the Department of Defense to conduct the research on the health effects of PFAS in drinking water. The annualized cost of the Multi-site Study is $7,379,581.70. This estimate was based on the following table:

Table A.14.1. Annual Estimated Costs to the Federal Government

Staff	GS Level	Salary	% FTE	$ Cost
Study co-PI; Technical Officer	14	$140,765	50	$70,382.50
Study co-PI, Technical Officer	14	$140,765	70	$98,535.50
Project Officer, Health Scientist	12	$87,332	85	$74,232.20
Associate Service Fellow	11	$72,863	50	$36,431.50
Other Costs				$ Cost
Cooperative agreements (includes data and sample collection, historical water concentration reconstruction of PFAS exposure)				$7,000,000.00
Travel				$100,000
				$7,379,581.70

A.15. Explanation for Program Changes or Adjustments

This is a new information collection request.

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

The 2018 National Defense Authorization Act (NDAA) (PL 115-91) was enacted on 12/12/2017 and serves as a guide for the scope of the study (**Appendix A1**). It specifies that "not later than 5 years after the date of enactment of this Act (or 7 years after such date of enactment after providing notice to the appropriate congressional committees of the need for the delay)," that ATSDR is to complete such study and make any appropriate recommendations; and submit a report to the appropriate congressional committees on the results of such study.

Therefore, ATSDR aims to complete the data collection by the end of 2022 (no more than 3 years), and to complete data analysis and reports by the end of 2024 (5 years).

Table A.16.1. Project Time Schedule

If unforeseen delays occur, ATSDR may submit an extension or revision ICR, making the time to complete the report to Congress a total of 7 years.

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.

References

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List of Appendices

Multi-site Study Protocol and Attachments

Attachment 11. Medication List
Attachment 12. Manual of Procedures
Attachment 13. Body and Blood Pressure Measures Form
Attachment 14. Blood Draw and Urine Collection Form
Attachment 15. Child Questionnaire – Long Form
Attachment 15a. Child Questionnaire – Short Form
Attachment 16. Adult Questionnaire
Attachment 17. Request for Medical Record Abstraction
Attachment 17a. Medical Record Abstraction Form - Adult
Attachment 17b. Medical Record Abstraction Form - Child
Attachment 18. Child/Parent Neurobehavioral Test Battery
Attachment 18a. NBT Time Estimation Table, by Age in Years
Attachment 18b. Request for Child School Record Abstraction
Attachment 18c. Child School Record Abstraction Form
Attachment 19. Body and Blood Pressure Measurements Report
Attachment 20. Advance Reporting Script for Clinical Tests
Attachment 20a. Advance Clinical Test Report Tracking Form
Attachment 20b. Letter Report of Critical Values
Attachment 21. Clinical Test Results Report
Attachment 22. PFAS Results Report
Attachment 22a. ATSDR PFAS Factsheet