ATSDR will collect urine samples pre- and post-activity. The urine samples will be analyzed for polyaromatic hydrocarbons and will also be archived in case of future development of new analytical methods for potential chemicals of interest.

The research study will screen a total of 220 participants for eligibility. The target sample size is 150 for synthetic turf field users and is 50 for the natural grass field users. The total burden hours for the research study is 184 hours among all of the 220 respondents. There is no cost to the respondents other than their time in the study.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Adult/Adolescent Field Users	Eligibility Screening Form	110	1	5/60
	Adult and Adolescent Questionnaire	100	1	30/60
	Exposure Measurement Form	100	1	20/60
Parents/Guardians of Youth/Child Field Users	Eligibility Screening Form	110	1	5/60
	Youth and Child Questionnaire	100	1	30/60
Youth/Child Field Users	Exposure Measurement Form	100	1	20/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

[60-Day–19–19ACF; Docket No. ATSDR–2019–0004]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ''Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): A multi-site cross-sectional study (The Multi-site Study).'' The purpose of this research is to use sound study methods to see if drinking water exposure to PFAS is related to health outcomes.

DATES: ATSDR must receive written comments on or before June 24, 2019.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2019–0004 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffery M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): A multi-site cross-sectional study (The Multi-site Study)—NEW—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

Per- and polyfluoroalkyl substances (PFAS) are a family of chemicals used in industrial applications and consumer products. PFAS contamination of drinking water is widespread in the U.S. Some estimates indicate that at least

sixty million residents were served by 66 public water supplies that had at least one sample at or above the US Environmental Protection Agency (EPA) Lifetime Health Advisory for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) (individually or combined), which is 70 nanograms per liter (ng/L) of water. Industrial facilities that manufacture or use PFAS have contaminated drinking water in surrounding communities in several states. In addition, PFOS, PFOA, perfluorohexane sulfonic acid (PFHxS) and other PFAS chemicals are constituents in aqueous film-forming foam (AFFF), used to extinguish flammable liquid fires. The use of AFFF at military bases and other sites may have 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 around the country.

In response to growing awareness of the extent of PFAS contamination across the U.S., the Section 316(a) of the 2018 National Defense Authorization Act (Pub. L. 115–91) authorized the Agency for Toxic Substances and Disease Registry (ATSDR) to conduct a study on the human health effects of PFAS contamination in drinking water. The existence of widespread contamination at many sites around the U.S. makes this a paramount effort in addressing the health effects of exposures to PFAS from contaminated drinking water. Consequently, ATSDR is requesting a three-year Paperwork Reduction Act (PRA) clearance for the Multi-site Study. The Multi-site Study will build on the preceding proof-of-concept study at the Pease International Tradeport in Portsmouth, New Hampshire.

ATSDR will conduct this research using a cooperative agreement titled ''Multi-site Study of the Health Implications of Exposure to PFAS-Contaminated Drinking Water'' (Notice of Funding Opportunity [NOFO] No. CDC–RFA–TS–19–002). The expected number of research recipients (*e.g.,* entities selected for funding) is six. The program will be administered by the CDC Extramural Research Program Office (ERPO) at the National Center for Injury Prevention and Control (NCIPC). The research under this cooperative agreement will be a two-part program. First, a mandatory core research protocol for all recipients is designed to aggregate data across all sites and designed to compare data between sites. Next, each recipient will have the option to propose additional investigator-initiated research questions and hypotheses related to the overall goals of this NOFO.

The main goal of this cross-sectional multi-site study is to evaluate associations between measured and reconstructed historic serum levels of PFAS including PFOA, PFOS, and PFHxS, and selected health outcomes. The health outcomes of interest include 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, the study will investigate PFAS differences in sex hormones and sexual maturation, vaccine response, and neurobehavioral outcomes in children. In adults, additional outcomes of interest include cardiovascular disease, osteoarthritis and osteoporosis, endometriosis, and autoimmune disease.

Under the cooperative agreement, each recipient shall propose candidate study sites at communities whose drinking water was impacted by AFFF use or by industrial PFAS emissions. Site selection will consider the documented levels of PFAS drinking water concentrations. The aim will be to include sites so that a wide range in PFAS exposures levels are included in the study. This will 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, to determine the period when the drinking water was contaminated, and to reconstruct historical PFAS contaminant concentrations.

For exposure estimation, participants will be categorized based on their measured serum concentration of PFAS compounds or on modeled estimated historical serum levels (*e.g.,* referent or low, medium, high). Measured and estimated PFAS serum levels will also be evaluated as continuous variables. At sites with prior PFAS biomonitoring data, the study will evaluate changes in PFAS concentration over time.

Each recipient shall reconstruct historic serum PFAS concentrations. This may be done by estimating half-lives and elimination rates as well as by water contamination modeling to inform pharmacokinetic (PK) or physiologically based pharmacokinetic (PBPK) models. 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.

Each recipient shall identify and enumerate all households served by the contaminated drinking water supply in the selected community to recruit potential participants and 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—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 can consider non-probabilistic sampling approaches such as ''judgment'' and ''snowball'' sampling approaches.

The recipients 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 could provide comments on any additional investigator-initiated research questions and hypotheses and 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.

In total, ATSDR seeks to enroll at least 8,000 participants (6,000 adults and 2,000 children and their parents) from communities exposed to PFAS-contaminated drinking water over the first three years of the five-year cooperative agreement program. Annualized estimates are 2,667 participants (2,000 adults and 667 children). To restrict this study to drinking water exposures, adults occupationally exposed to PFAS will not be eligible for the study (*e.g.,* ever firefighters or ever workers in an

industry using PFAS chemicals in its manufacturing process). Likewise, children whose birth mothers were occupationally exposed will not be eligible. ATSDR assumes that 5 percent of the people who volunteer will not meet eligibility requirements; therefore, a total of 8,400 people will be screened. To complete the data collection in three years, annualized estimates for eligibility screening are 2,800 people (2,100 adults and 700 children) and an annual time burden of 467 hours. The recipients will provide appointment reminder calls for each eligible person who agrees to be enrolled (n = 2,667 per year) for a time burden of 222 hours per year.

At enrollment, each recipient will obtain adult consent, parental permission, and child assent before data collection begins. For each participant, the recipient will take body measures, collect blood samples to measure PFAS serum levels and several effect biomarkers such as lipids, and thyroid, kidney, immune and liver function. The recipient will also obtain urine samples from participants to measure PFAS levels and kidney function biomarkers. The study will archive leftover serum and urine samples for additional analyses of PFAS chemicals and specific effect biomarkers. The National Center for Environmental Health (NCEH) laboratory will perform blood and urine PFAS analyses for all Multi-site Study participants. Thus, issues of inter-laboratory variability for exposure measures will be eliminated.

Adult participants and a parent of child participants will complete a questionnaire that includes residential history, medical history, occupational history, and water consumption habits (n=2,000 adults and 667 children per year). Ideally, the parent will be the child's birth mother, as ATSDR will ask details about the child's exposure, pregnancy, and breastfeeding history.

For purposes of time burden estimation, ATSDR assumes that 20 percent of parents will also enroll as adults and can take the child short form questionnaire (n=133 per year); therefore, 534 parents will take the child long form questionnaire per year. Parents and children, with administration by trained professionals, will also complete neurobehavioral assessments of the child's attention and behaviors (n=667 per year).

To facilitate access to medical and school records, each recipient will reach out to local medical societies, public school systems, and private schools, to enlist their cooperation with the study. The recipient will ask for permission to abstract participants' medical records to confirm self-reported health outcomes. The recipient will also seek permission to abstract and compare children's school records to their behavioral assessment results. Based on ATSDR's experience from the Pease proof of concept study, ATSDR estimates that it will take 48 education specialists and 150 adult and 50 pediatric medical record specialists to complete record abstractions across all study sites. Given the goal to enroll at least 2,000 adults and 667 children per year, the annual time burden for medical and educational record abstraction is estimated to be 1,091 hours.

The total annualized time burden requested is 5,269 hours. There is no cost to the respondents other than their time.

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)
Multi-site Study Participants	Eligibility Screening Script	2,800	1	10/60	467
	Appointment Reminder Telephone Script	2,667	1	5/60	222
	Update Contact Information Hardcopy Form	2,667	1	5/60	222
	Medication List	2,667	1	3/60	133
	Body and Blood Pressure Measures Form	2,667	1	5/60	222
	Blood Draw and Urine Collection Form	2,667	1	10/60	444
	Adult Questionnaire	2,000	1	30/60	1,000
	Child Questionnaire—Long Form	537	1	30/60	268
	Child Questionnaire—Short Form	133	1	15/60	33
	Parent Neurobehavioral Test Battery	667	1	15/60	167
	Child Neurobehavioral Test Battery	667	1	90/60	1,000
Education Specialists	Child School Record Abstraction Form	48	14	20/60	224
Medical Record Specialists	Medical Record Abstraction Form—Adult	150	13	20/60	650
	Medical Record Abstraction Form—Child	50	13	20/60	217
Total					5,269

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–19–0457; Docket No. CDC–2019–0032]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Aggregate Reports for Tuberculosis Program Evaluation. The goal of the study is to allow CDC to collect and monitor indicators for key program activities, such as finding tuberculosis infections in recent contacts of cases