

preserved. Accordingly, the recordkeeping requirement associated with these forms is contained in 17 CFR 404.4, which requires state member banks and uninsured state branches or state agencies of foreign banks, as well as other institutions, to retain these forms for three years after the financial institution notifies its ARA that it has ceased to function as a government securities broker or dealer. Although Treasury's recordkeeping requirement does not explicitly apply to foreign banks, Edge corporations, or commercial lending companies that are owned or controlled by foreign banks, the Board has the authority to "issue such rules and regulations with respect to transactions in government securities as may be necessary to prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade" (15 U.S.C. 78o-5(b)(3)(A)). Imposing a recordkeeping requirement on foreign banks, Edge corporations, and commercial lending companies owned or controlled by foreign banks is necessary for the public interest and protection of investors in order to ensure that the proper notification has been provided when these institutions are transacting in government securities (15 U.S.C. 78o-5(a)(1)(B)). In addition, the Board is authorized to impose a recordkeeping requirement on foreign banking organizations⁵ (12 U.S.C. 3108), on Edge corporations (12 U.S.C. 625), and on commercial lending companies that are owned or controlled by foreign banks (12 U.S.C. 3106, as applied through 12 U.S.C. 1844(c)).

The obligation to file the Form G-FIN and Form G-FINW with the Board, and the obligation for the government securities broker or dealer to retain a copy of the Form G-FIN and Form G-FINW, is mandatory for those financial institutions for which the Board serves as the ARA, unless the financial institution is exempt from the reporting requirement under Treasury's regulations. The filing of these forms and the records retention period is event-generated.

Under the Act, each ARA is instructed to make these forms available to the SEC, and the SEC is instructed to make the notices available to the public (15 U.S.C. 78o-5(a)(1)(B)(iii)). Thus, the information collected on Form G-FIN and Form G-FINW is ordinarily not treated as confidential. However, given

⁵ A foreign banking organization is a foreign bank that operates a branch, agency, or commercial lending company subsidiary in the United States; controls a bank in the United States; or controls an Edge corporation acquired after March 5, 1987; and any company of which the foreign bank is a subsidiary.

that Item 6 of Form G-FIN instructs the filer to attach copies of the confidential Form G-FIN-4, or if applicable, to attach copies of any previously filed confidential Form MSD-4 or confidential Form U-4, these attachments may be treated as confidential under exemptions 4 and/or 6 of the Freedom of Information Act, which protect, respectively, "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential" and information about individuals in "personnel and medical files and similar files" when the disclosure of such information "would constitute a clearly unwarranted invasion of personal privacy" (5 U.S.C. 552(b)(4) and 5 U.S.C. 552(b)(6)).

Current actions: On August 29, 2019, the Board published a notice in the **Federal Register** (84 FR 45491) requesting public comment for 60 days on the extension, with revision, of the Notice by Financial Institutions of Government Securities Broker or Government Securities Dealer Activities and the Notice by Financial Institutions of Termination of Activities as a Government Securities Broker or Government Securities Dealer (Form G-FIN and Form G-FINW). The changes proposed include revising the Form G-FIN and Form G-FINW to (1) require respondents to submit PDF versions of the forms and any attachments to a designated email address, and (2) to correct cross-references on the following forms: G-FIN-4, Form MSD-4, and Form U-4, which are incorporated by reference in Item 7 of the Form G-FIN. The comment period for this notice expired on October 28, 2019. One public comment was received, but it was outside the scope of the Board's review under the PRA.

Board of Governors of the Federal Reserve System, December 17, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

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BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day-20-19ACF]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for

Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled "Human Health Effects of Drinking Water Exposures to Per- and Polyfluoroalkyl Substances (PFAS): A Multi-site Cross-sectional Study (The Multi-site Study)" to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on April 23, 2019 to obtain comments from the public and affected agencies. ATSDR received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

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), as amended by Section 315 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115–232), authorized and appropriated funds for 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 across 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 builds on activities undertaken in preparing and conducting the data collection for the proof-of-concept study at the Pease International Tradeport in Portsmouth, New Hampshire (the Pease Study) (OMB Control No. 0923–0061; expiration date 08/31/2022). These activities included developing data management systems and community engagement materials, modifying the childhood neurobehavioral test battery, adjusting blood collection volume, and modifying data collection materials such as the

childhood questionnaire and medical records abstraction forms. Based on peer reviewer and OMB comments on the Pease Study, the Multi-site Study protocol now includes additional data analyses to address potential biases such as selection bias and confounding.

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). Seven research recipients have been selected: University of Colorado School of Public Health, Michigan State Department of Health and Human Services, Pennsylvania Department of Health and RTI International, Rutgers School of Public Health, Silent Spring Institute, SUNY at Albany and the New York State Department of Health, and the University of California at Irvine.

The Multi-site Study is designed to aggregate data across all recipient sites and is designed to compare data between sites. The main goal of this cross-sectional 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 proposed candidate study sites at communities whose drinking water was impacted by AFFF use or by industrial PFAS releases. Site selection considered the documented levels of PFAS drinking water concentrations. The aim was to include sites so that a wide range in PFAS exposures levels were 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 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.

If feasible, 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 their recruitment efforts. In addition, the recipients 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 approximately 9,100 participants (7,000 adults and 2,100 children and their parents) from communities exposed to PFAS-contaminated drinking water over the first three years of the five-year cooperative agreement program. In total, each recipient will attempt to meet a target recruitment of 1,000 adults and 300 children. Annualized estimates are 3,033 participants (2,333 adults and 700 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.

Assuming a 95 percent eligibility rate and a 40 percent response rate, ATSDR estimates that the recipients will screen 7,982 people (6,140 adults and 1,842 children) each year across all sites in order to recruit the target sample size of 3,033 participants (2,333 adults and 700

children), using an annual time burden of 1,330 hours. The recipients will provide appointment reminder calls for each eligible person who agrees to be enrolled (n=3,033 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=3,033 adults and 700 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 (n=140 per year) will also enroll as adults and can take the child short

form questionnaire; therefore, 560 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=700 per year). The time burden for responding to questionnaires is 1,482 hours, and for neurobehavioral assessments is 1,225, 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 Study (OMB Control No. 0923-0061; expiration date 08/31/2022), ATSDR estimates that it will take 30 school administrators, 48 education specialists, 70 medical office administrators, and 150 adult and 50 pediatric medical record specialists to complete record abstractions across all study sites. The annual time burden for medical and educational record abstraction is estimated to be 2,490 hours.

The total annualized time burden requested is 7,960 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)
Multi-site Study Participants	Eligibility Screening Script	7,982	1	10/60
	Appointment Reminder Telephone Script	3,033	1	5/60
	Update Contact Information Hardcopy Form	3,033	1	5/60
	Medication List	3,033	1	3/60
	Body and Blood Pressure Measures Form ...	3,033	1	5/60
	Blood Draw and Urine Collection Form	3,033	1	10/60
	Adult Questionnaire	2,333	1	30/60
	Child Questionnaire—Long Form	560	1	30/60
	Child Questionnaire—Short Form	140	1	15/60
	Parent Neurobehavioral Test Battery	700	1	15/60
	Child Neurobehavioral Test Battery	700	1	90/60
	Medical Office Administrators	Request for Medical Record Abstraction	70	43
Medical Record Specialists	Medical Record Abstraction Form—Adult	150	16	20/60
	Medical Record Abstraction Form—Child	50	14	20/60
School Administrators	Request for Child School Record Abstraction	30	23	20/60
Education Specialists	Child School Record Abstraction Form	48	15	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

[60Day-20-0057; Docket No. ATSDR-19-0009]

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 "APPLETREE Performance Measures," which ATSDR will use to manage its next three-year cooperative agreement program under Notice of Funding Opportunity (NOFO) No. CDC-RFA-TS20-2001.

DATES: ATSDR must receive written comments on or before February 21, 2020.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2019-0009 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 Jeffrey 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

APPLETREE Performance Measures (OMB Control No. 0923-0057, Exp. 07/31/2020)—Revision—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) seeks to build and sustain the capacity to evaluate exposures to hazardous waste across the country. Releases from hazardous waste sites are a major source of harmful

exposures in homes, schools, workplaces, and communities. These exposures are often complex and may be difficult to identify and control. Hazardous waste sites may involve various toxic substances, exposure pathways, and health impacts. ATSDR's primary goal is to keep communities safe from harmful exposures and related diseases. To accomplish this goal, the agency works closely with partnering agencies to evaluate exposures at hazardous waste sites, educate communities, and seek new ways to better protect public health.

ATSDR's Partnership to Promote Local Efforts to Reduce Environmental Exposure (APPLETREE) Program is critical to ATSDR's success in accomplishing its mission in communities nationwide. ATSDR's recipients will use APPLETREE funding to advance ATSDR's primary goal of keeping communities safe from harmful environmental exposures and related diseases. APPLETREE gives recipients the resources to build their capacity to assess and respond to site-specific issues involving human exposure to hazardous substances in the environment. APPLETREE helps recipients identify exposure pathways at specific sites; educate affected communities about site contamination and potential health effects; make recommendations to prevent exposure; review health outcome data to evaluate potential links between site contaminants and community health outcomes. APPLETREE facilitates the implementation of state-level programs to ensure that potential early care and education facilities are in areas free from harmful environmental exposures. It also encourages recipients in the innovation of progressive public health interventions that prevent exposures to environmental contamination. Because of APPLETREE recipients' local connections and partnerships, community engagement and implementation of recommendations is improved. This program is authorized under Sections 104(i)(15) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986 [42 U.S.C. 9604(i)(15)].

Under the next three-year APPLETREE cooperative agreement (NOFO No. CDC-RFA-TS20-2001), eligible applicants include federally recognized American Indian/Alaska Native tribal governments; American Indian/Alaska native tribally designated organizations; political subdivisions of states (in consultation with states); and