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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

[60Day-18-18AUZ; Docket No. ATSDR-2018-0008]

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) at Pease International Tradeport, Portsmouth, NH (The Pease 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 in this New Hampshire community.

DATES: ATSDR must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2018-0008 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, N.E., 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, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: 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) at Pease International Tradeport, Portsmouth, NH (The Pease Study) – NEW – Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

Per- and polyfluoroalkyl substances (PFAS) are a family of environmentally and biologically persistent chemicals used in industrial applications such as 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 bases and/or surrounding communities. In 2016, the U.S. Environmental Protection Agency (USEPA) issued a lifetime health advisory level of 0.07 total micrograms of perfluorooctanoate (PFOA) and perfluorooctane sulfonate (PFOS) combined per liter of drinking

water (µg/L). In response to growing awareness of the extent of PFAS contamination across the U.S., Section 8006 of the Consolidated Appropriations Act, 2018, 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.

In response, ATSDR is requesting a three-year Paperwork Reduction Act (PRA) clearance for the Pease Study, which will serve as a proof-of-concept model for a national multi-site study of PFAS health effects. The existence of a large body of state and local environmental monitoring and population blood testing data makes the Pease community in Portsmouth, NH, particularly suitable as ATSDR's initial PFAS research study site. From approximately 1970 until 1991, the Air Force used AFFF for firefighting and training at Pease Air Force Base. The base closed in 1991, and was converted to a large business and aviation industrial park in 1993, the Pease International Tradeport. In 2014, PFAS drinking water concentrations were detected (0.35 µg/L PFOA and 2.4 µg/L PFOS) at levels well above what was to become the USEPA lifetime health advisory level (0.07 µg/L PFOA/PFOS). In 2015-7, the New Hampshire Department of Health and Human Services (NH DHHS) offered a PFAS blood testing program to the community. The blood testing program showed that the Pease population had concentrations of some

types of PFAS that were two to three times higher than national estimates.

The Pease Study will be cross-sectional in design, drawing from a convenience sample of people with and without exposure to PFAS-contaminated drinking water from Pease. The main goals of the study are to: 1) evaluate the study procedures and methods to identify any issues that need to be addressed before embarking on a national multi-site study; and 2) examine associations between health outcomes and measured and historically reconstructed serum levels of PFAS. 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, ATSDR will investigate if PFAS is 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. Adults will be 18 years or older, and children will be 4-17 years of age at enrollment.

In total, ATSDR seeks to enroll 1,625 participants (1,100 adults and 525 children and their parents). Annualized estimates are 542 participants (367 adults and 175 children).

For the exposure group (n=1,350), ATSDR will enroll 1,000 adults and 350 children. Annualized estimates are 450 exposed participants (333 adults and 117 children). Eligible participants had to work at, live on, or attend childcare at the former Pease Air Force Base or the Pease International Tradeport, or live in a nearby home that was served by a PFAS-contaminated private well. Drinking water exposures must have occurred at some time between 2004 and May 2014, after which remediation of the public water supply occurred.

For the referent group (n=275), ATSDR will enroll 100 adults and 175 children. Annualized estimates are 92 referent participants (34 adults and 58 children). Eligible participants, never exposed to PFAS-contaminated drinking water from Pease, will come from other areas of Portsmouth, NH. Birth mothers of referent children likewise must never have had PFAS drinking water exposure.

ATSDR will recruit, screen for eligibility, and enroll in three waves. The exposure group will be recruited in Waves One and Two. ATSDR estimates that 90% of the exposure group will be enrolled in Wave 1 (n=1,215, or 405 per year), that is, will be past participants of the 2015-7 NH DHHS PFAS blood testing program. NH DHHS will assist ATSDR by sending out letters of invitation to its former blood testing program participants. To achieve the desired sample size, the other 10 percent of the

exposure group (n=135, or 45 per year) will be recruited in Wave 2. These will be people who were eligible for the PFAS blood testing program but did not take part. The referent group will be recruited in Wave Three (n=275, or 92 per year), which can occur concurrently with Wave 1 and Wave 2. Wave 2 and Wave 3 recruits will call to volunteer after ATSDR opens those waves to enrollment.

To restrict this study to drinking water exposures, any adult occupationally exposed to PFAS will not be eligible for the study (i.e. ever firefighters or in chemical manufacture). Likewise, children whose birth mothers were occupationally exposed will not be eligible. This restriction applies to both the exposure and the referent group. ATSDR assumes that 5% of the people who volunteer will not meet eligibility requirements. ATSDR will screen the 1,578 people from the NH DHHS PFAS blood testing program in Wave One (n=526 per year). ATSDR will screen at least 142 exposed people in Wave 2 (or 47 per year), and at least 289 unexposed people in Wave 3 (or 96 per year). This will require an annual time burden of 124 hours for eligibility screening.

At enrollment, ATSDR will obtain adult consent, parental permission, and child assent before data collection begins. Each child will enroll with a parent, who ideally will be the child's

birth mother, as ATSDR will ask details about the child's exposure, pregnancy, and breastfeeding history.

For each participant, ATSDR will take body measures, collect blood and urine samples for chemical and biomarker analysis, and administer a questionnaire on exposures and medical history. For purposes of burden estimation, ATSDR assumes that 20% of parents will also enroll as adults; therefore, 420 parents will take the child questionnaire long form (n=140 per year), while 105 parents will take the short form to reduce burden (n=35 per year). Parents and children will also complete assessments of the child's attention and behaviors. After eligibility screening, the annual time burden for participation in the study is 58 hours for adults and 208 hours for children and their parents.

ATSDR will ask for permission to compare adults' and children's medical histories with their medical records. ATSDR will also ask for permission to check children's school records to compare their behavioral assessment results. The annual time burden for medical and educational record abstraction is estimated to be 125 hours for adult records and 118 hours for children's records.

The total annualized time burden requested is 1,189 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)
Pease Study Participants	Wave One Eligibility Screening Script	526	1	10/60	88
	Wave Two Eligibility Screening Script	47	1	15/60	12
	Wave Three Eligibility Screening Script	96	1	15/60	24
	Appointment Reminder Telephone Script	542	1	5/60	45
	Update Contact Information Hardcopy Form	542	1	5/60	45
	Medication List	542	1	3/60	27
	Body and Blood Pressure Measures Form	542	1	5/60	45
	Blood Draw and Urine Collection Form	542	1	10/60	90
	Adult Questionnaire	367	1	30/60	184
	Child Questionnaire – Long Form	140	1	30/60	70
	Child Questionnaire – Short Form	35	1	15/60	9
	Parent Neurobehavioral Test Battery	175	1	15/60	44
	Child Neurobehavioral	175	1	90/60	263

	Test Battery				
Education Specialists	Child School Record Abstraction Form	15	12	20/60	60
Medical Record Specialists	Medical Record Abstraction Form - Adult	25	15	20/60	125
	Medical Record Abstraction Form - Child	25	7	20/60	58
Total					1,189

Jeffrey M. Zirger,

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