Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–10, Atlanta, Georgia 30329–4027, Telephone: (404) 639–0390; Email Address: *ACDirector@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Advisory Committee to the Director (ACD), CDC, shall advise the Secretary, HHS, and the Director, CDC, on policy and broad strategies that will enable CDC to fulfill its mission of protecting health through health promotion, prevention, and preparedness. The committee recommends ways to prioritize CDC's activities, improve results, and address health disparities. It also provides guidance to help CDC work more effectively with its various private and public sector constituents to make health protection a practical reality.

M*atters To Be Considered:* The agenda will include discussions on CDC's current work and priorities as they relate to health equity and data and surveillance recommendations to the Department of Health and Human Services and CDC Director. The agenda also includes a laboratory workgroup update with recommended action steps to the full ACD Committee, along with an update on the public health infrastructure grant. Agenda items are subject to change as priorities dictate.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–00408 Filed 1–10–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–IP–23–001, Public Health Epidemiology, Prevention and Control of Influenza and Other Respiratory Pathogens in China, RFA–IP–23–004, Developing, Implementing, and Evaluating Protocols to Increase Routine Adult Immunization Coverage Among Persons Who are Incarcerated, and RFA–IP–23–005, Approach to Adult Vaccine Counseling.

Date: April 11–12, 2023.

Time: 10 a.m.–5 p.m., EDT.

Place: Teleconference, Centers for Disease Control and Prevention, Room 1077, 8 Corporate Boulevard, Atlanta, Georgia 30329.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC, 1600 Clifton Road NE, Mailstop US8–1, Atlanta, Georgia 30329–4027; Telephone: (404) 718–8833; Email: *GAnderson@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–00242 Filed 1–10–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day–23–0063; Docket No. ATSDR–2022–0007]

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 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 March 13, 2023.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2022–0007 by either of the following methods:

• *Federal eRulemaking Portal: www.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 H21–8, Atlanta, Georgia 30329.

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

Please note: Submit all comments through the Federal eRulemaking portal (*www.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 H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7118; 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;

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; and

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) (OMB Control No. 0923–0063, Exp. 5/31/2023)—Revision—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year revision of the Paperwork Reduction Act (PRA) information collection request (ICR) titled ''Human Health Effects of Drinking Water Exposures to Per- and Polyfluoroalkyl Substances (PFAS): A Multi-site Cross-sectional Study (The Multi-site Study)'' (OMB Control No. 0923–0063, Exp. Date 05/31/2023).

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 60 million residents were served by 66 public water supplies that had at least one sample at or above the U.S. 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., 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), first authorized and appropriated funds for ATSDR to conduct this 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. Currently, the study is funded through section 337 of the William M. (Mac) Thornberry National Defense Authorization Act for fiscal years 2019 through 2023 (Pub. L. 116–283).

The Multi-site Study builds on research methods and activities developed for the proof-of-concept study at the Pease International Tradeport in Portsmouth, New Hampshire (the Pease Study) (OMB Control No. 0923–0061, Discontinued 08/31/2022). These methods and 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.

ATSDR is conducting this cooperative research program under Notice of Funding Opportunity (NOFO) No. CDC–RFA–TS–19–002, titled ''Multi-site Study of the Health Implications of Exposure to PFAS-Contaminated Drinking Water.'' The seven research recipients are 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.

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.

The Multi-site Study is designed to aggregate data across all recipient 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.

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 is reconstructing historic serum PFAS concentrations. This is being 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. Over the first three years of the five-year cooperative agreement program, the recipients have prepared working group support documents describing the methods used by sites for the historical reconstruction and for the whole consortium for the PBPK modeling. Both documents that are undergoing external peer review as required by ATSDR.

If feasible, each recipient is identifying and enumerating 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. ATSDR estimates that up to 14 public water purveyors will spend ten hours each to retrieve lists of households they serve per year (n=140 hours total). 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. ATSDR estimates that up to seven environmental protection agencies will spend seven hours each to retrieve lists of households with contaminated private wells per year (n=49 hours total).

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 can use 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 cumulatively enroll approximately 9,100 participants (7,000 adults and 2,100 children and their parents) from communities exposed to PFAS-contaminated drinking water. 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). Over the first three years of the five-year cooperative agreement program, the recipients have enrolled over 3,000 adults and over 300 children (as of 11/17/2022). The enrollment of children has been especially challenging during and following major closures and access to schools and other educational facilities due to the COVID–19 pandemic.

To restrict this study to drinking water exposures, adults occupationally exposed to PFAS are not 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% eligibility rate and a 40% 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. Recipients 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% 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 verify participants' medical conditions to confirm self-reported health outcomes. Recipients will also seek permission to obtain information from the children's school records to supplement their behavioral assessment results. Based on ATSDR's experience from the Pease Study (OMB Control No. 0923–0061, Discontinued 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 health condition and school information verification and abstractions across all study sites. The annual time burden for medical and educational record abstraction is estimated to be 2,490 hours.

ATSDR is revising and updating portions of the protocol related to PFAS analytes. ATSDR has no plans to revise the previously approved data collection forms, nor the annual number of burden hours (n=8,149), respondents (n=27,949), and responses (n=35,121). 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)
Public Water Purveyors	Drinking Water Information Collection Form.	14	1	10	140
Environmental Protection Agencies.	Drinking Water Information Collection Form.	7	1	7	49
Multi-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—Short Form	140	1	15/60	35
	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	1,003
Medical Records 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

Jeffrey M. Zirger,

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

[FR Doc. 2023–00333 Filed 1–10–23; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–3351]

Authorization of Emergency Use of an In Vitro Diagnostic Device in Response to an Outbreak of Mpox; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of mpox. FDA has issued an Authorization for an in vitro diagnostic device as requested by Life Technologies Corporation (a part of Thermo Fisher Scientific Inc.). The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to the FD&C Act, subject to terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of December 13, 2022.

ADDRESSES: Submit written requests for a single copy of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive