

Evaluating the Association between Serum Concentrations of Per- and Polyfluoroalkyl Substances (PFAS) and Symptoms and Diagnoses of Selected Acute Viral Illnesses

OMB Control No. 0923-NEW

New Information Collection Request

Supporting Statement Part A –

Justification

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Part A. Justification

Goal of the study: To assess the association between serum-PFAS levels and self-reported frequency of various groups of symptoms of viral infection (as a marker for susceptibility to viral infections).

Intended use of the resulting data: The results of the study will be disseminated through abstracts, professional meeting presentations, and manuscripts for publication in peer reviewed journals.

Methods to be used to collect: Following the initial survey, ATSDR will administer surveys in four rounds spaced by 3 months (total of 5 rounds overall). Participants will be asked about symptoms prospectively, as well as COVID information prospectively and retrospectively (from January 2020, as this was the month when the first infection of coronavirus was reported in the US). Survey data will be linked to serum-PFAS measurements that have been previously collected and analyzed for ATSDR PFAS cohorts.

Subpopulation to be studied: The study will recruit from existing cohorts with known serum-PFAS concentrations including ATSDR's PFAS Exposure Assessment, PFAS Exposure Assessment Technical Tools (PEATT) pilot site participants, and Pease Study participants (potential n = 3,170; 2,800 adults and 370 children).

How data will be analyzed: Survival analysis will be used to assess associations between the previously collected serum-PFAS concentrations and incident viral infections for outcomes that are expected to occur only once during the follow-up period (e.g., diagnosis of COVID-19). Recurrent-event survival analysis, using the counting process approach, will be used for outcomes that are expected to occur multiple times during the follow-up period (e.g., upper respiratory illness). Models will control for potential confounders (e.g., age, gender, race/ethnicity) and account for clustering within households (in both types of analyses) and within individuals (in the recurrent events analysis). The analysis will be a within-community analysis to control for the local COVID-19 transmission level, combining information across communities.

A.1. Circumstances Making the Collection of Information Necessary

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a new two-year information collection request (ICR) titled *Evaluating the Association between Serum Concentrations of Per- and Polyfluoroalkyl Substances (PFAS) and Symptoms and Diagnoses of Selected Acute Viral Illnesses*. The ICR will examine the association between serum-PFAS levels and susceptibility to viral illnesses, including but not limited to the coronavirus disease 2019 (COVID-19). ATSDR, in partnership with the Centers for Disease Control and Prevention's National Center for Environmental Health (CDC/NCEH), is authorized to conduct this research study under the 1980 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the 1986 Superfund Amendments and Reauthorization Act (SARA) (42 U.S.C. 9601, 9604), and under the Public Health Service Act Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243), respectively (Attachment A).

Per- and polyfluoroalkyl substances (PFAS) are a large, diverse group of thousands of chemicals (Buck et al., 2011; Fromme, Tittlemier, Völkel, Wilhelm, & Twardella, 2009). They have been used extensively in a wide range of industrial and consumer applications (Fromme et al., 2009). Epidemiological studies have evaluated the associations between PFAS exposure and health effects in humans. Evidence from studies in occupationally exposed populations, residential populations exposed to higher levels of PFAS in drinking water, and studies in the general population suggest associations between PFAS and several health outcomes. Exposure to PFAS is nearly ubiquitous in the United States. Epidemiological studies suggest that PFAS exposure may impact the immune system and susceptibility to viral infections; however, there is little consistency in the results of studies on PFAS exposure and infectious disease. The COVID-19 pandemic presents a unique concern and opportunity to explore this association. If PFAS affect the immune system, it is possible that they could affect susceptibility to infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, or affect severity of COVID-19.

This study will recruit participants who have previously participated in an ATSDR-funded study that measured PFAS in serum –ATSDR PFAS Exposure Assessment (EA), PFAS Exposure Assessment Technical Tools (PEATT) pilot site participants, and Pease Study participants (potential n = 3,170) – to investigate possible associations between PFAS and respiratory viral infection in general, including but not limited to COVID-19. The cohorts had a substantial number of participants with high PFAS exposure, as well as a sufficient range of serum PFAS concentrations to allow examination of associations between the outcomes and PFAS serum concentrations across a wide range of PFAS exposures. Recruiting participants from these existing cohorts helps to minimize logistical challenges, maximizes the utility of data already collected, and takes advantage of existing serum PFAS measurements. This study will examine associations between PFAS exposure and susceptibility to a range of respiratory viral infections (e.g., flu), which would include COVID-19, as well as gastrointestinal viral infections (e.g.,

stomach flue). A previous study (Grandjean et al., 2020) provided preliminary evidence that elevated plasma perfluorobutanoic acid (PFBA) concentrations are associated with increased risk of more severe COVID-19 infection; however, this study was conducted in a population with low background-level exposures. Additional research on the topic is needed in populations with elevated exposures.

A.2. Purpose and Use of the Information Collection

The primary purpose of this information collection is to research the association between serum-PFAS and self-reported frequency of various groups of symptoms of viral infection (as a marker for susceptibility to viral infections). Scientific evidence suggests that PFAS exposure may be associated with immunological effects. This study aims to research this issue within vulnerable communities who have been exposed to PFAS through drinking water. This research can inform communication around this topic. Moreover, communities where ATSDR has existing relationships have been consistently asking about whether their PFAS exposure may lead to their increased susceptibility to COVID-19. This study will aim to answer these questions among those vulnerable communities.

In 2019 and 2020, ATSDR conducted statistically based biomonitoring PFAS exposure assessments (EAs) in eight communities that had documented exposures to PFAS in drinking water. ATSDR also supported two EAs that were designed to test the PFAS Exposure Assessment Technical Tools (PEATT). PFAS concentrations were measured in serum collected from EA and PEATT assessment participants, and a survey was administered to gather information to characterize each individual's exposure. These communities were investigated under "Per- or Polyfluoroalkyl Substances Exposure Assessments [PFAS EAs]" (OMB Control No. 0923-0059, expiration date 06/30/2022).

During the same period, ATSDR initiated a health study at the Pease International Tradeport that included measurement of PFAS serum levels and collection of information about individual exposures in participants under "Human Health Effects of Drinking Water Exposures to Per- and Polyfluoroalkyl Substances (PFAS) at Pease International Tradeport, Portsmouth, NH (The Pease Study)" (OMB Control No. 0923-0061, expiration date 08/31/2022).

This is a follow-up study that will recruit participants from the previous ATSDR-funded studies (detailed above) that measured PFAS in serum and who have given prior consent for additional contact from CDC/ATSDR (potential sample size for this study=3,170; 2,800 adults and 370 children). The cohorts had a substantial number of participants with high PFAS exposure, as well as a sufficient range of serum PFAS concentrations to allow examination of associations between the outcomes and PFAS serum concentrations across a wide range of PFAS exposures. CDC/ATSDR will invite participants to complete a new series of surveys to determine whether PFAS exposure increases susceptibility to viral infections, including, but not limited to COVID-19.

The objectives of the study are the following: (1) to examine the association between serum-PFAS collected through the EAs, PEATT assessments, and Pease Study and the frequency of occurrence of selected syndromes (combinations of self-reported symptoms), which will be

used as a proxy for viral infections; and (2) to examine the association between serum-PFAS collected through the EAs, PEATT assessments, and Pease Study and self-reported positive test results indicating specific viral infections.

The procedures for the collection of information are further described in Supporting Statement B, Section B.2 and in the Protocol.

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

For follow-up surveys, participants will have the option to complete a web-based survey via REDCap in lieu of a paper-based survey. Using REDCap will enable participants to complete and return each survey without the added task of returning it by mail. Additionally, the web-based version will include computer-generated skip patterns that will reduce the time burden associated with reading survey items that are not applicable to their case. We estimate that at least 75% of surveys will be received through the web-based platform.

We anticipate that using REDCap will reduce the time to complete each follow-up survey by 5 minutes. Therefore, if 75% of participants opt to use REDCap, we anticipate saving 760 participant hours across the 4 follow-up surveys. This is a total savings of \$14,500 for the study.

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

ATSDR has evaluated other federal agency initiatives to assess potential associations between PFAS and viral infections, including but not limited to COVID-19. This was done through literature scans and internet searches, discussions with other public health and environmental professionals, and attendance at meetings where other agencies have presented similar inquiries. Initiatives reviewed include an NIEHS grant to North Carolina as well as the Arizona HEROES and RECOVER studies. ATSDR has not identified any duplication in the present study of PFAS and viral infections.

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

This data collection will not involve small businesses.

A.6. Consequences of Collecting the Information Less Frequently

Participants will respond to the information collection quarterly over a period of 12-14 months. This frequency of data collection was selected to enable collection of information about participants' experience of symptoms throughout an entire year, to include the seasons for various types of respiratory infections. Moreover, the frequent surveys will make it easier for participants to recall their symptoms and other relevant information and decrease the potential for recall bias of symptoms associated with viral infections.

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

This request fully complies with the regulation 5 CFR 1320.5.

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 5, 2021 (Vol. 86. No. 63 pages 17600 – 17602) (Attachment B). ATSDR received 0 public comments and responded accordingly (Attachment B1).

- B. Prior to submission for Institutional Review Board (IRB) approval, the Protocol was reviewed through ATSDR’s external peer review process by 3 leading experts in the field:
 - a. Cheryl Stein, PhD, Research Associate Professor, Hassenfeld Children’s Hospital at NYU Langone
 - b. Amie DeWitt, PhD, DABT, Associate Professor, Brody School of Medicine, East Carolina University
 - c. Phillippe Grandjean, PhD, Adjunct Professor of Environmental Health, Harvard School of Environmental Health

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

Monetary incentives, including those as low as \$1, are associated with higher response rates compared with nonmonetary incentives (Cho, Johnson, & Vangeest, 2013). Incentives are justified for this study because there is a substantial reporting burden on participants. Participants will be asked to answer five surveys over 12-14 months. This frequency is important to lessen the potential for recall bias.

To encourage continued participation, ATSDR is offering incremental incentives to minimize loss to follow-up. Participants will be offered \$10 for each completed survey, plus an additional \$25 when all five surveys are returned, up to \$75 in total.

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

On 6/3/2021, the CDC Chief Privacy Officer reviewed this submission and has determined that the Privacy Act does apply. A Privacy Impact Assessment (PIA) was obtained. The submission date was 6/3/2021 (**Attachment C**).

The applicable Privacy Act System of Records Notice (SORN) is No. 09-19-0001, “Records of Persons Exposed or Potentially Exposed to Hazardous or Toxic Substances (retrievable by name or SSN).”

The following IIF Categories apply to this information collection (**Appendices A, B, C, C1, D, and D1 of the Protocol**):

- Name
- Date of Birth
- Mailing Address
- Phone Numbers
- Email Address

CDC/ATSDR uses the IIF only to contact respondents to obtain consent to participate and to conduct the surveys. All IIF and study data maintained by the agency will be managed by CDC/ATSDR and is subject to the CDC/ATSDR Comprehensive Record Control Schedule (CRCS), which contains authorized disposition instructions for CDC/ATSDR's administrative and program records.

Attachment E provides the Manual of Procedures (MOP) for this study, which includes the Rules of Behavior for Data Access and Use (Appendix A of Attachment E), Attachment F provides a Template for the Data Use Agreement for the CDC/ATSDR Data Set, and Attachment G provides the Data Management Plan for this study.

- The following individuals will have access to personal information in order to provide respondents with their personalized results: CDC/ATSDR employees and contractors.
- Data are treated in a private manner, unless otherwise compelled by law. Paper documents containing IIF are kept in locked file cabinets at CDC/ATSDR. Access to computer files is password-protected and access is limited to authorized personnel. All staff and contractors working on the project agree to safeguard the data and not to make unauthorized disclosures. Any data on laptops will be encrypted in accordance with information systems security requirements for safeguarding personally identifiable information. Data are safeguarded in accordance with applicable statutes. Responses in published reports are presented in aggregate form and no individuals are identified by name.
- CDC/ATSDR will implement a Data Management Plan for the data collected for the study per guidance
- CDC/ATSDR will implement a Security Plan that defines the process for handling security incidents. The system's team and the Office of the Chief Information Security Officer (OCISO) share the responsibilities for event monitoring and incident response. The EA team will direct reports of suspicious security or adverse privacy-related events to the CDC/ATSDR Information Systems Security officer (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.
- Respondents will be informed about the security measures for privacy protections in the consent form (see Appendix H, I, J). In addition, the respondents will be informed that their response is voluntary, and that they can discontinue participation at any time.

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

Federal Regulations for the Protection of Human Subjects (45 CFR 46) state that “*research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” The CDC/ATSDR Human Subjects Coordinator has determined that this study is a research activities and human subjects review by an Institutional Review Board (IRB) will be required (**Attachment D**).

The respondent will be informed that his or her response is voluntary. All consent forms include appropriate information from the Privacy Act including authority and purpose for collecting the data, with whom identifiable information will be shared, the voluntary nature of the information collection and the effect upon the respondent for not participating. The adult consent, parental permission, and child assent are provided in the protocol (**Appendix H, I, J**).

Adult Consent: Adults will be administered a consent form to participate in surveys (Appendix H).

Parental Permission: A parental permission form will be administered to parents of children aged 3-17 years (Appendix I).

Child Assent: Children aged 7 to 17 years will assent to participate in the study (Appendix J).

CDC/ATSDR will gather information that may be considered sensitive about individual characteristics (e.g., date of birth, height, weight). Additionally, participants will be asked to self-report any conditions that impact PFAS levels in the body and/or that impact the viral illnesses of interest. This information is needed to assist with the analysis. The protocol provides further discussion of the relevance of this information.

Social security numbers are not needed nor will be requested.

A.12. Estimates of Annualized Burden Hours and Costs

A. Estimates of Annualized Burden Hours

ATSDR will be conducting this study over a two-year period. The number of participants at each site will vary, but we expect most participants who provided consent for follow-up will participate in this study. The number of participants for completion of the consent forms and survey are as follows (2,800 adults aged 18 years and older; 92 children aged 3-6 years will not be responsible for assenting or filling out any forms; 278 children 7-17 years will provide assent for themselves and fill out forms with their parents assistance, if needed).

- Adult Initial Survey (Appendix A): Adults will be administered an initial survey at enrollment. The time associated with the adult initial survey is approximately 30 minutes, resulting in a burden of 700 hours annually.

- Adult Follow-up Survey: Adults will be administered four follow-up surveys over the course of a year.
 - Web-based (Appendix C1). The time associated with each follow-up survey is approximately 25 minutes, and we estimate that 75% of participants will opt for web-based surveys (n=2,100), resulting in a burden of 1,750 hours annually.
 - Paper-based (Appendix C). The time associated with each follow-up survey is approximately 30 minutes, and we estimate that 25% of participants will opt for paper-based surveys (n=700), resulting in a burden of 700 hours annually.
- Child Initial Survey (Appendix B): Parents will respond to the initial survey for children under the age of 7 years. Children aged 7 to 17 years can respond for themselves with parental assistance if needed. The time associated with the child initial survey is approximately 30 minutes, resulting in a burden of 93 hours annually.
- Child Follow-up Survey: Parents will respond to the four follow-up surveys for their children under the age of 7 years over the course of a year. Children aged 7 to 17 years can respond for themselves with parental assistance if needed.
 - Web-based (Appendix D1). The time associated with each follow-up survey is approximately 25 minutes, and we estimate that 75% of participants will opt for web-based surveys (n=278), resulting in a burden of 232 hours annually.
 - Paper-based (Appendix D). The time associated with each follow-up survey is approximately 30 minutes, and we estimate that 25% of participants will opt for paper-based surveys (n=93), resulting in a burden of 93 hours annually.
- Symptom Diary: (Appendix E): The paper-based or web-based diary will be provided to assist in tracking symptoms on a quarterly basis. The time associated with tracking and logging of adult symptoms is approximately twenty minutes per event, one event per month, for a total of four hours per year. The frequency of response is four times: between initial and first, first and second, second and third, and then third and fourth follow-up surveys.
 - Adult: Estimated burden of 5,600 hours annually.
 - Child: Estimated burden of 740 hours annually.

Type of Respondent	Form Name	Number of Respondents (Total/two-year period)	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Annual Burden (in hr)
Adults	Initial Survey - Adult (paper)	1400	1	30/60	700

	Follow up Survey - Adult (paper)	350	4	30/60	700
	Follow up Survey - Adult (REDCap)	1050	4	25/60	1750
	Symptom Diary - Adult	1400	1	4	5600
Children (7-17 years)	Initial Survey - Child (paper)	139	1	30/60	70
	Follow up Survey - Child (paper)	35	4	30/60	70
	Follow up Survey - Child (REDCap)	104	4	25/60	174
	Symptom Diary - Child	139	1	4	556
Parents of Children (3-6 years)	Initial Survey - Child (paper)	46	1	30/60	23
	Follow up Survey - Child (paper)	11	4	30/60	23
	Follow up Survey - Child (REDCap)	35	4	25/60	58
	Symptom Diary - Parent	46	1	4	184
Total					9,908

B. Annualized Cost to Respondents

The median hourly wage rate for adults (\$19.14) is based on the U.S. Department of Labor, Bureau of Labor Statistics' most current statistics for all occupations [May 2019 National Occupational Employment and Wage Estimates United States, online March 31, 2020 https://www.bls.gov/oes/current/oes_nat.htm]. The median hourly wage rate for parents responding for their children is assumed to be the same as for adults in the general population (\$19.14). The US minimum wage rate of \$7.25 set by the Department of Labor in 2019 will be applied for children, aged 7 to 17 years, who will respond for themselves with parental assistance, if needed (<https://www.dol.gov/whd/minwage/chart.htm>).

Type of Respondent	Form Name	Number of Respondents (Total/two-year period)	Number of Responses per Respondent	Average Burden per Response	Total Annual Burden (in hr)	Hourly Wage Rate	Total Respondent Cost
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				(in hr)			
Adults	Initial Survey - Adult (paper)	1400	1	30/60	700	\$19.14	\$13,398
	Follow up Survey - Adult (paper)	350	4	30/60	700	\$19.14	\$13,398
	Follow up Survey - Adult (REDCap)	1050	4	25/60	1750	\$19.14	\$33,495
	Symptom Diary - Adult	1400	1	4	5600	\$19.14	\$107,184
Children (7-17 years)	Initial Survey - Child (paper)	139	1	30/60	70	\$7.25	\$508
	Follow up Survey - Child (paper)	35	4	30/60	70	\$7.25	\$508
	Follow up Survey - Child (REDCap)	104	4	25/60	174	\$7.25	\$1,262
	Symptom Diary - Children	139	1	4	556	\$7.25	\$4,031
Parents of Children (3-6 years)	Initial Survey - Child (paper)	46	1	30/60	23	\$19.14	\$440
	Follow up Survey - Child (paper)	11	4	30/60	23	\$19.14	\$440
	Follow up Survey - Child (REDCap)	35	4	25/60	58	\$19.14	\$1,110
	Symptom Diary - Parent	46	1	4	184	\$19.14	\$3,522
Total					9,908		\$179,296

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

There are no other total annual cost burden to respondents or record keepers.

A.14. Annualized Cost to the Federal Government

Total project estimated budget:

Project Title: CDC/ATSDR PFAS and Viral Infections Study	Total
LABOR	
Salaries & Wages and Fringe Benefits (1)	\$ 394,000

Contractor Support x 14 months (PM; Data Management; Logistics) (3)	\$ 50,000
Travel Costs	\$ 0
Total Labor	\$ 444,000
OTHER DIRECT COSTS (ODC)	
Printing (5 packages x 4,000 participants; 20 pages each x \$0.05/page) (2)	\$ 20,000
Mailing (5 packages x 4,000 participants; with 20,000 return envelopes \$2 each) (2)	\$ 80,000
Incentives (\$25 x 4,000 participants)	\$ 100,000
Total ODCs	\$ 200,000
GRAND TOTAL	\$644,000

NOTES:

- (1) One GS13 at 60% (\$114k), three GS14s at 20% (\$140k), two ORISE fellows (\$140k) (4)
- (2) Printing and mailing costs are based upon the “worst case scenario” assumption that 100% of participants will refuse to use RedCap and opt for paper questionnaires.
- (3) Contractor tasks:
 - Project management
 - Tracking/managing OMB review process
 - Tracking/managing IRB review process
 - Tracking/managing IT requirements (REDCap, text messaging service, data repository, etc...)
 - Scheduling meetings and taking meeting notes
 - Preparation of project communication materials (ppt slides, briefing materials, etc...)
 - Assisting with preparation of mailings (contractor to provide 25% support for this task)
 - Assisting with tracking responses (contractor to provide 25% support for this task)
 - Assisting with reminder follow ups (contractor to provide 25% support for this task)
 - Assisting with data entry (contractor to provide 25% support for this task)
- (4) ORISE Fellow tasks:
 - Preparation of mailings (fellows to provide 75% support for this task)
 - Tracking responses (fellows to provide 75% support for this task)
 - Coordination and implementation of reminder follow ups (fellows to provide 75% support for this task)
 - Data entry (fellows to provide 75% support for this task)

Total Cost: \$644,000

Number of years covered: 2

Annualized Cost: \$322,000

A.15. Explanation for Program Changes or Adjustments

This is a new ICR.

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

The following is the general schedule anticipated for this study.

Table A.16.1

Project Time Schedule	
Activity	Time Schedule
Letters sent to respondents	1–2 months after OMB approval
Information/Data collection	1–14 months after OMB approval
Complete field work	12–14 months after OMB approval
Validation	15–17 months after OMB approval
Analyses	15–24 months after OMB approval
Publication	24 months after OMB approval

Results Reporting

The results of the study will be disseminated through abstracts, professional meeting presentations and manuscripts for publication in peer reviewed journals.

We will share the aggregated results from this study through community-facing mechanisms. As the study findings are being finalized, the study team will work with ATSDR communications to develop a roll-out plan on how to best share these results with community members. This could potentially include a webinar for community members, distribution of fact sheets, or other mechanisms.

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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