Project Determination

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

Project ID:	0900f3eb81c58b2f
Accession #:	NCEH-TSET-12/15/20-58b2f
Project Contact:	Melanie Buser
Organization:	NCEH/ATSDR/OIA/TS/TSET
Status:	Project In Progress : PRA Revision
Intended Use:	Project Determination
Estimated Start Date:	09/01/21
Estimated Completion Date:	09/30/23
CDC/ATSDR HRPO/IRB Protocol#:	7360
OMB Control#:	No OMB Control Number issued

Description

Priority

Standard

Determination Start Date

12/02/21

Description

The proposed study will assess the association between PFAS exposure with symptoms of and susceptibility to viral infections using data from existing exposure assessment and Pease Study cohorts who have existing PFAS serum measurements and who have given prior consent for additional contact from CDC/ATSDR. Data will be collected through a series of surveys.

IMS/CIO/Epi-Aid/Chemical Exposure Submission

IMS Activation Name

Select the primary priority of the project

Select the secondary priority(s) of the project

Select the task force associated with the response

CIO Emergency Response Name

Not selected

Epi-Aid Name

Not selected

Assessment of Chemical Exposure Name

Not selected

Goals/Purpose

Assess the association between PFAS serum levels and self-reported frequency of various groups of symptoms of viral infections (as a marker for susceptibility to viral infections). An environmental scan revealed no known projects with similar data collection activities in the 12 communities include in this study. All IMS task force leads were contacted, and no additional data collection activities are planned at this time for these 12 communities.

Objective

The objectives of this study are the following: (1) examine the association between serum-PFAS collected through the PFAS exposure assessments (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) 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.

Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and/or decreasing disparities?

No

Project does not incorporate elements of health equity science

Measuring Disparities

Not selected

Studying Social Determinants of Health (SDOH)

Not selected

Assessing Impact

Not selected

Methods to Improve Health Equity Research and Practice

Not selected

Other

Not selected

Activities or Tasks

New Collection of Information, Data, or Biospecimens; Research with Humans

Target Population to be Included/Represented

General US Population; Children; Adult 18-24 years; Older adults > 64 years

Tags/Keywords

PFAS; SARS Virus; COVID-19; Infection; Influenza, Human; Environmental; Environmental Issues

CDC's Role

Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided; CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens; CDC employees will participate as co-authors in presentation(s) or publication(s)

Method Categories

Prospective Cohort Study; Survey

Methods

Surveys (delivered by mail or online), conducted in 4 rounds spaced by 3 months following the initial paper survey (i.e., 5 total surveys – 4 follow-up plus initial). 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). This study will collect survey information 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. Survey data will be linked to PFAS serum measurements that have been previously collected and analyzed through ATSDR PFAS studies. Statisticians have been consulted on power calculations and have reviewed all proposed statistical methods. Diagnosis criteria for various syndromes has been aligned with established definitions. Methods proposed in this study follow current CDC guidance for best practices, and data collection is standardized across sites. Data collection instruments have undergone pilot testing. The protocol has undergone external peer review with 3 leading experts in this field. It has gone through cross-clearance with 2 CDC centers (NCIRD and NCEZID) as well as with the JIC.

Collection of Info, Data, or Bio specimens

Information on viral symptoms will be collected via survey. PII will be collected, so the survey data can be linked to the serum-PFAS levels previously collected. Our target population includes: ATSDR PFAS Exposure Assessment Participants, PEATT pilot site participants, and Pease Study Participants (potential n = 3,170, 2,800 adults and 370 children, 4 to <18 years of age). Because we are linking the survey data from this proposed study to previously collected serum data, no additional biological samples will need to be collected. We are also asking participants to keep a symptom diary in order to help participants better recall symptoms they experience, close contact they may have with suspected COVID cases, and vaccinations during the 3 month time periods in between surveys. we estimate that participants will take about an hour total in between each survey, or 4 hours total over the course of the study The estimated time burden is: 5 Surveys: 3,170

participants * 0.5 hours * 5 surveys = 7,925 hours Symptom diary: 3,170 participants * 4 hours = 12,680 hours

Expected Use of Findings/Results and their impact

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

Could Individuals potentially be identified based on Information Collected?

Yes

Will PII be captured (including coded data)?

Yes

Does CDC have access to the Identifiers (including coded data)?

Yes

Is this project covered by an Assurance of Confidentiality?

No

Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?

Yes

Is there a formal written agreement prohibiting the release of identifiers?

No

Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award
CDC Contract	Guidehouse Contract Support - $700,000	GS00F045DA	2020	1

HSC Review

Suggested level of IRB Review

Expedited review is suggested

Yes

1a - Study of drugs not requiring Investigational New Drug exemption from FDA

No Selection

1b - Study of medical devices not requiring Investigational Device Exemption from FDA

No Selection

2a - Collection of blood from healthy, non-pregnant adults; below volume and frequency limits, minimally invasive

No Selection

2b - Collection of blood from other adults and children; below volume and frequency limits, minimally invasive

HSC Review

Suggested level of IRB Review

No Selection

3 - Prospective noninvasive collection of biological specimens for research purposes

No Selection

4 - Collection of data through routine, noninvasive procedures, involving no general anesthesia, sedation, x-rays, or microwaves

No Selection

5 - Research that uses previously collected materials

No Selection

6 - Collection of data from voice, video, digital, or image recordings made for research purposes

No Selection

7 - Research that uses interview, program evaluation, human factors, or quality assurance methods

Yes

Controversial or Sensitive Topics

The study addresses a controversial or sensitive topic

Yes

Controversial or Sensitive Topic Rationale

COVID-19 and human PFAS exposures

HSC Attributes

Data Collected Under a Previous Protocol

Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office

Yes

Estimated number of study participants

4075

Population - Children

Allowed	

Population - Minors

Regulation and Policy

Population - Prisoners	
Population - Pregnant Women	
Population - Emancipated Minors	
Suggested level of risk to subjects	
Minimal	
Do you anticipate this project will be exempt research or non-exempt research	
Non-Exempt	
Requested consent process waivers	
Informed consent for adults	
No Selection	
Children capable of providing assent	
No Selection	
Parental permission	
No Selection	
Alteration of authorization under HIPPA Privacy Rule	
No Selection	
Requested Waivers of Documentation of Informed Consent	
Informed consent for adults	
No Selection	
Children capable of providing assent	
No Selection	
Parental permission	
No Selection	
Consent process shown in an understandable language	
Reading level has been estimated	
Yes	Page: G,H,I,J

Regulation and Policy

Comprehension tool is provided	
No Selection	
Short form is provided	
No Selection	
Translation planned or performed	
No Selection	

Clinical Trial

Involves human participants	
Yes	
Assigned to an intervention	
No Selection	
Evaluate the effect of the intervention	
No Selection	
Evaluation of a health related biomedical or behavioral outcome	
Yes	
Registerable clinical trial	
No Selection	

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	
No Selection	
Human genetic testing is planned now or in the future	
No Selection	
Involves long-term storage of identifiable biological specimens	
No Selection	
Involves a drug, biologic, or device	
No Selection	
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	
No Selection	

Institutions

Institution	FWA #	FWA Exp. Date	IRB Title	IRB Exp. Date	Funding #
Centers for Disease Control & Prevention	FWA00001413	07/30/26			

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization / Institution
AndreaWinquist	12/05/2021				Co-Investigator	aiw1@cdc.gov	404-498-0057	HEALTH STUDIES
ArthurWendel	06/03/2022				Co-Investigator	dvq6@cdc.gov	206-553-0454	WESTERN SECTION REGION 10
MelanieBuser	10/07/2024				Principal Investigator	wyf9@cdc.gov	770-488-3311	SCIENTIFIC EVALUATION TEAM
MichelleZeager	08/14/2023				Co-Investigator	pqr5@cdc.gov	404-498-3959	EXPOSURE INVESTIGATIONS TEAM
RachelRogers	06/17/2022				Co-Investigator	idz7@cdc.gov	770-488-1549	EXPOSURE INVESTIGATIONS TEAM

DMP

Proposed Data Collection Start Date	09/01/21
Proposed Data Collection End Date	09/30/22
Proposed Public Access Level	Non-Public, Restricted
Reason for not Releasing the Data	Removal of identifiers renders the remaining data of no value
Data Use Type	Data Sharing Agreement
Data Use Type Data Use Type URL	

Data Use Contact	
Public Access justification	Survey data collected through this study will be linked to serum samples collected from EA cohort participants. This cohort data is not sharable due to a data sharing agreement, so the current study will be limited for public access as well.
How Access Will Be Provided for Data	PII data will be maintained in a separate database that will be linked to the survey data and serum samples through random number assignment. Access to this information will be limited to the immediate team members.
Plans for archival and long-term preservation of the data	

Spatiality (Geographic Location)

Country	State/Province	County/Region
United States	Massachusetts	Hampden
United States	West Virginia	Berkeley
United States	Delaware	New Castle
United States	Washington	Spokane
United States	Texas	Lubbock
United States	Alaska	Fairbanks North Star
United States	Colorado	El Paso
United States	New York	Orange
United States	Pennsylvania	Bucks
United States	Pennsylvania	Montgomery
United States	New York	Suffolk
United States	New Hampshire	Rockingham

Determinations

Determination	Justification	Completed	Entered By & Role
HSC:		12/09/21	Abel_Jason A. (jza5) CIO HSC
PRA:		12/10/21	Abel_Jason A. (jza5) CIO OMB / PRA
HRPO:	HRPO/IRB Approval date: 12/16/21 IRB Expiration date: 11/14/22	12/16/21	Vann_Jerrell A. (jiv4) HRPO Reviewer
ICRO:	OMB Approval date: 12/10/21 OMB Expiration date: 12/31/99	12/10/21	Zirger_Jeffrey (wtj5) ICRO Reviewer