Project Determination

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

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| --- | --- |
| **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 |
|  |  |

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| --- |
| 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 |
| Yes |
| IMS Activation Name |
| 2019 Novel Coronavirus Response |
| Select the primary priority of the project |
| Transmission of SARS-CoV-2 |
| Select the secondary priority(s) of the project |
| COVID-19 disease detection, burden, and impact |
| Select the task force associated with the response |
| Epidemiology and Surveillance |
| CIO Emergency Response Name |
|
 Not selected
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| 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 |
|
 Yes
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| Measuring Disparities |
|
 Not selected
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| 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 &lt;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 | Budget Amount |
| CDC Contract | Guidehouse Contract Support - $700,000 | GS00F045DA | 2020 | 1 | 700000.00 |

| ****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
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|
 2a - Collection of blood from healthy, non-pregnant adults; below volume and frequency limits, minimally invasive
  |
|
 No Selection
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|
 2b - Collection of blood from other adults and children; below volume and frequency limits, minimally invasive
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|
 No Selection
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|

 3 - Prospective noninvasive collection of biological specimens for research purposes

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 No Selection
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 4 - Collection of data through routine, noninvasive procedures, involving no general anesthesia, sedation, x-rays, or microwaves
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 No Selection
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 5 - Research that uses previously collected materials

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|
 No Selection
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 6 - Collection of data from voice, video, digital, or image recordings made for research purposes

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 No Selection
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 7 - Research that uses interview, program evaluation, human factors, or quality assurance methods

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 Yes
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| 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** | **Page: 10** |
| Population - Minors |
| **Allowed** | **Page: 10** |
| Population - Prisoners |
| **Excluded** | **Page:**  |
| Population - Pregnant Women |
| **Allowed** | **Page: 10,H** |
| Population - Emancipated Minors |
| **N/A** | **Page:**  |
| 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
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 Page: G,H,I,J |
| Comprehension tool is provided |
|
 No Selection
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| 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
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| 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 |  | 11/12/2024 |  | Co-Investigator | aiw1@cdc.gov | 404-498-0057 | HEALTH STUDIES |
| ArthurWendel | 06/03/2022 | 10/28/2024 |  |  | Co-Investigator | dvq6@cdc.gov | 206-553-0454 | WESTERN SECTION REGION 10 |
| MelanieBuser | 10/07/2024 |  | 12/22/2023 |  | Principal Investigator | wyf9@cdc.gov | 770-488-3311 | SCIENTIFIC EVALUATION TEAM |
| MichelleZeager | 08/14/2023 |  | 08/18/2023 |  | Co-Investigator | pqr5@cdc.gov | 404-498-3959 | EXPOSURE INVESTIGATIONS TEAM |
| RachelRogers | 06/17/2022 | 01/08/2024 |  |  | Co-Investigator | idz7@cdc.gov | 770-488-1549 | EXPOSURE INVESTIGATIONS TEAM |

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| --- | --- |
| ****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: Requires HRPO Review | Non-Exempt Human Subjects Research when CDC is engaged: CDC IRB Review 45 CFR 46 subpart A (and as appropriate subparts B, C, and D) and OHRP 2008 Engagement Guidances  | 12/09/21 | Abel\_Jason A. (jza5) CIO HSC |
|
 PRA: PRA Applies |  | 12/10/21 | Abel\_Jason A. (jza5) CIO OMB / PRA |
|
 HRPO: HRPO/IRB Approves |
 HRPO/IRB Approval date: 12/16/21

 IRB Expiration date: 11/14/22 | 12/16/21 | Vann\_Jerrell A. (jiv4) HRPO Reviewer |
|
 ICRO: PRA Applies |
 OMB Approval date: 12/10/21

 OMB Expiration date: 12/31/99 | 12/10/21 | Zirger\_Jeffrey (wtj5) ICRO Reviewer |