U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 6/9/22

Title:	PFAS Exposure Assessments
Project Id:	0900f3eb81caee53
Accession #:	NCEH-OCHHA-2/24/21-aee53
Project Contact:	Karen M Scruton
Organization:	NCEH/ATSDR/OCHHA
Status:	**Project In Progress : PRA Revision**
Intended Use:	**Project Determination**
Estimated Start Date:	06/30/2022
Estimated Completion Date:	06/30/2022
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0923-0059

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Environmental Sampling Non-Epi Aids Investigations	6/2/22	Davis_Stephanie I. (sgd8) CIO HSC
PRA: **PRA Applies**		6/2/22	Davis_Stephanie I. (sgd8) CIO OMB / PRA
ICRO: **PRA Applies**	OMB Approval date: 6/28/19 OMB Expiration date: 6/30/22	6/3/22	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Date Needed:	06/03/2022
Determination Start Date:	03/23/22
Description:	This is a 30-day FRN publication request for a revision of OMB Control No. 0923-0059, expiration date 06/30/2022. The 60-day FRN was published on 11/16/2021. Under Section 8006 of the Consolidated Appropriations Act, 2018, ATSDR conducted statistically based biomonitoring exposure assessments (EAs) at eight current or former domestic military installations with documented exposures to PFAS in drinking water. ATSDR is extending this PRA clearance to additional sites as they are identified. The EA protocol describes how these EAs will be conducted. For each site, a statistically based, community sampling design will be used to determine: - The distribution of PFAS serum concentrations in communities with recent or past exposures to PFAS in drinking water. - PFAS urine concentrations from a subset of participants with recent or past exposures to PFAS in drinking water. - PFAS concentrations in indoor dust and tap water samples from a subset of homes of participants in biological sampling. A questionnaire will be administered to all participants to gather information to characterize each individual's exposure. Blood and urine samples from EA participants will be analyzed to determine the distribution of PFAS levels in each community. Individual and aggregated community serum and urine concentrations will be compared to reference ranges from nationally representative data. Environmental samples will be analyzed to determine PFAS exposure concentrations and, in conjunction with questionnaire data, to provide insight into environmental contributors to biological PFAS concentrations across all included sites.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	Each exposure assessment will include the following goals: • Provide a public health service to the community: This investigation will provide information to community members about their PFAS body burden, including an assessment of how their PFAS concentrations compare to national reference populations. The investigation will also provide information about aggregate serum concentrations and exposure in the community from which participants are selected. Depending on the results of the investigation, ATSDR will make recommendations to further reduce exposure or conduct additional activities to better understand the impact of PFAS exposure on human health. • Generate information about pathways of exposures in the community: Environmental sampling data will be combined with biological sampling results to generate information about the impact of drinking water and some

	non-drinking water PFAS exposure pathways on PFAS body burden in each community. For example, environmental sampling data might allow investigators to assess the relative contribution of dust to PFAS exposure, but not necessarily other exposure sources such as foods. • Inform future studies to evaluate the impact of PFAS exposure on human health: The results of these EAs will inform the design and implementation of the CDC Multi-site PFAS Health Study. o For example, exploration of indoor dust sampling and analysis may provide valuable insight into the utility of including indoor dust sampling in future PFAS studies. o Similarly, collection of paired serum and urine samples will provide information on relationships between PFAS concentrations measured in these media and may generate insight into the utility of measuring PFAS in urine in future health studies. o Additionally, measurement of PFAS in serum and urine will generate data that could potentially be used for validation and calibration of physiologically-based pharmacokinetic modeling tools in support of historical dose reconstruction for PFAS health studies. o Tracking information on recruitment outcomes and response rates will allow ATSDR to improve methodology for conducting statistically representative sampling in the future.
Objective:	The objective of the project is to understand PFAS concentrations measured in blood and urine of participants in communities with known past exposure to PFAS in drinking water.
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
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 Populations to be Included/Represented:	General US Population ; Children ; Pregnant Women
Tags/Keywords:	Environmental Exposure
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:	Biomonitoring; Exposure Investigation; Individual Interviews (Qualitative)
Methods:	Households within a defined sample frame will be targeted for recruitment into the Exposure Assessments. Participants will schedule an appointment to provide blood and urine samples and answer an exposure questionnaire. A subset of participants will also be invited to participate in environmental sampling including drinking water and indoor dust sample collection from their household.

Collection of Info, Data or Biospecimen:	Data will be collected according to an OMB approved protocol. Households within a defined sample frame will be targeted for recruitment into the Exposure Assessments. Participants will schedule an appointment to provide blood and urine samples and answer an exposure questionnaire. A subset of participants will also be invited to participate in environmental sampling including drinking water and indoor dust sample collection from their household.
Expected Use of Findings/Results and their impact:	Individual blood and urine results will be provided to participants. Household environmental sampling results will be provided to each participant following laboratory analysis and quality assurance procedures, depending on when analytical methods become available. If a participant's blood or urine concentration level is higher than the 95th percentile reported in the National Health and Nutrition Examination Survey (NHANES) data, or if the participant's tap water sample is higher than either the EPA lifetime health advisory or a state value, that participant will be contacted sooner in order to facilitate rapid exposure source assessment and mitigation, as needed. If PFAS concentrations in tap water samples are higher than either the EPA lifetime health advisory or a state value, we will contact local water utilities and state drinking water officials to share this information. CDC/ATSDR intends to align communications with participants regarding water sampling concentrations with EPA's guidelines for use of the lifetime health advisory. The findings from each EA will be released as a report for the general public as soon as possible and aggregate findings will be submitted for publication in the peer-reviewed scientific literature. The findings of these EAs will inform design and implementation of current and future health studies that will be conducted by CDC/ATSDR in consultation with the National Institute of Environmental Health Sciences (NIEHS) and the US Department of Defense (DoD).
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)?	No
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding yet to be added .....

HSC Review

HSC Attributes

Environmental Sampling	Yes
Non-Epi Aids Investigations	Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No
Estimated number of study participants	

Population - Children	Protocol Page #:
Population - Minors	Protocol Page #:
Population - Prisoners	Protocol Page #:
Population - Pregnant Women	Protocol Page #:
Population - Emancipated Minors	Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

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	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
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 identfiable 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 & Staff

Institutions

Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Bradley Goodwin	10/15/2024	10/04/2024	10/05/2024		Co-Investigator	ylm5@cdc.gov	770-488-3795	OFFICE OF COMMUNITY HEALTH AND HAZARD ASSESSMENT
Karen Scruton	11/01/2024	05/01/2017	11/10/2024		Co-Investigator	isg3@cdc.gov	770-488-1325	OFFICE OF COMMUNITY HEALTH AND HAZARD ASSESSMENT

Data

DMP

Proposed Data Collection Start Date: 6/30/22

Proposed Data Collection End Date: 6/30/25

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL:

Data Use Contact: Hao Tian

Public Access Justification: Deidentified data will be shared with a data use agreement.

How Access Will Be Provided for Data: Reidentification risk will be conducted for any data use requests. Hao Tian will determine what data elements can be shared.

Plans for Archival and Long Term Preservation:

Spatiality

Country	State/Province	County/Region
United States	New York	Orange
United States	Colorado	El Paso
United States	Alaska	Fairbanks North Star

United States	Texas	Lubbock
United States	Washington	Spokane
United States	Delaware	New Castle
United States	West Virginia	Berkeley
United States	Massachusetts	Hampden

Dataset

Dataset Title	Dataset Description	Data Publisher/Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	06/03/2022	NOA 0923-0059 (2019)	Notice of Action	NOA 0923-0059_2019.pdf
	Davis_Stephanie I. (sgd8) CIO OMB / PRA	06/02/2022	30-day FRN and ICR files	Paperwork Reduction Act Form	0923-0059 PFAS EA 20220602 to ICRO.zip
	Davis_Stephanie I. (sgd8) CIO OMB / PRA	06/02/2022	Non-research protocol files for PRA revision ICR	Protocol	0923-0059 PFAS EA protocol 20220602 to ICRO.zip
	Scruton_Karen M. (isg3) CIO HSC	06/01/2022	Edited versions of protocol revisions	Protocol	protocol revision 6_1_22 edits.zip
	Scruton_Karen M. (isg3) CIO HSC	06/01/2022	edits to the OMB documents in response to OS comments	Paperwork Reduction Act Form	PFAS EA OMB forms edits6_1_22.zip
	Scruton_Karen	06/01/2022	Protocol and separated	Protocol	PFAS EA protocol and appendices_6_1_22.zip

	M. (isg3) CIO HSC		appendices - modified per OS comments		
	Scruton_Karen M. (isg3) CIO HSC	06/01/2022	OMB forms revised per OS comments	Paperwork Reduction Act Form	PFAS EA 0923-0059 OMB forms 6_1_22.zip
	Davis_Stephanie I. (sgd8) CIO HSC	03/31/2022	OS review of EA Protocol files	Protocol	0923-0059_protocol and appendices rev OS.zip
	Davis_Stephanie I. (sgd8) CIO HSC	03/31/2022	OS review of ICR files	Paperwork Reduction Act Form	0923-0059_30-day package rev OS.zip
	Scruton_Karen M. (isg3) Project Contact	03/23/2022	PFAS EA protocol and appendices modified based on lessons learned from the eight EAs	Protocol	0923-0059_protocol and appendices.zip
	Scruton_Karen M. (isg3) Project Contact	03/23/2022	OMB forms for the revision to 0923-0059 for the PFAS EAs	Paperwork Reduction Act Form	0923-0059_30-day package.zip
	Zirger_Jeffrey (wtj5) ICRO Reviewer	11/03/2021	NOA 0923-0059 (2019)	Notice of Action	0923-0059_2019.pdf
	Davis_Stephanie I. (sgd8) CIO HSC	11/02/2021	60-day FRN publication request package	Paperwork Reduction Act Form	PFAS EA Rev 0923-0059 to ICRO.zip
	Scruton_Karen M. (isg3) Project Contact	11/02/2021	Edited version of the submission forms	Paperwork Reduction Act Form	FRN request and form 0923-0059 edits.zip
	Scruton_Karen M. (isg3) Project Contact	11/02/2021	Clean version of submission forms and attachments in a zipped file	Paperwork Reduction Act Form	PFAS EA revision 0923-0059_clean.zip
	Davis_Stephanie I. (sgd8) CIO HSC	10/21/2021	OS comments of 60-day FRN package	Paperwork Reduction Act Form	PFAS EA 60D Files rev OS.zip
	Scruton_Karen M. (isg3) CIO HSC	10/20/2021	package modified per OS comments. The package reflects an extension of the original package	Paperwork Reduction Act Form	PFAS EA extension 0923-0059.zip
	Davis_Stephanie I. (sgd8) CIO HSC	10/06/2021	60D FRN request files with OS comments	Other	0923-0059 60D Files rev OS.zip
	Scruton_Karen	10/05/2021	OMB forms for 60-day FRN	Paperwork Reduction Act Form	FRN 60_day request 0923-0059_.zip

	M. (isg3) Project Contact				
	Scruton_Karen M. (isg3) Project Contact	09/20/2021	OMB forms for 60-day FRN	Paperwork Reduction Act Form	FRN 60_day request 0923-0059_.zip
	Davis_Stephanie I. (sgd8) CIO OMB / PRA	03/05/2021	Request for the 60-day FRN for extension/revision of the ICR for the PFAS EAs.	Paperwork Reduction Act Form	FRN 60_day request 0923-0059_.zip
	Davis_Stephanie I. (sgd8) CIO HSC	03/05/2021	Notice of Action for PFAS EAs, OMB Control No. 0923-0059, expiration date 06/30/2022	Notice of Action	NOA_0059_06242020.pdf
	Goodwin_Bradley (ylm5) Project Contact	02/26/2021	05/23/2018 - original non-research determination memo	HS Research Determination Memo	Att6 PFAS EA Research Determination 20180711.pdf
	Goodwin_Bradley (ylm5) Project Contact	02/24/2021	OMB forms in PRA package	Paperwork Reduction Act Form	0923-0059 PFAS EA OMB forms.zip