Exposure Assessment Protocol: Biological and Environmental Sampling of Per- and Polyfluoroalkyl Substances (PFAS)

Funded and Sponsored by
Agency for Toxic Substances and Disease Registry (ATSDR)
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Abbreviations and Acronyms

11Cl-PF3OUdS	11-chloroeicosafluoro-3-oxaundecane-1-sulfonic acid
9Cl-PF3ONS	9-chlorohexadecafluoro-3-oxanone-1-sulfonic acid
ALT	Alanine aminotransferase
ATSDR	Agency for Toxic Substances and Disease Registry
DCHI	Division of Community Health Investigations
DE	Design effect
dL	Deciliter
DoD	US Department of Defense
DONA	4,8-dioxa-3H-perfluorononanoic acid
EA	Exposure Assessment
EPA	Environmental Protection Agency
EtFOSAA	N-ethyl perfluorooctanesulfonamidoacetic acid
FRB	Field reagent blank
FtS 8:2	fluorotelomer sulfonic acid 8:2
FtS 6:2	fluorotelomer sulfonic acid 6:2
FtS 4:2	fluorotelomer sulfonic acid 4:2
g	Gram
GGT	Gamma-glutamyl transferase
HDL	High density lipoprotein
HFPO-DA (GenX)	hexafluoropropylene oxide dimer acid
ICC	intra-cluster correlation coefficient
L	Liter
LDL	Low density lipoprotein
LOD	Limit of detection
MeFOSAA	N-methyl perfluorooctanesulfonamidoacetic acid
Mg	Milligrams
mL	Milliliter
MRL	Minimum risk level
n-PFOA	ammonium perfluorooctanoate
n-PFOS	sodium perfluoro-1-octanesulfonate
NCEH	National Center for Environmental Health

NDAA	National Defense Authorization Act
Ng	Nanogram
NHANES	National Health and Nutrition Examination Survey
NIEHS	National Institute of Environmental Health Sciences
PFAS	Per- and polyfluoroalkyl substances
PFBA	perfluorobutanoic acid
PFBS	perfluorobutane sulfonic acid
PFDA	perfluorodecanoic acid
PFDS	perfluorodecane sulfonic acid
PFDoA	perfluorododecanoic acid
PFHpA	perfluoroheptanoic acid
PFHpS	perfluoroheptane sulfonic acid
PFHxA	perfluorohexanoic acid
PFHxS	perfluorohexane sulfonic acid
PFNA	perfluorononanoic acid
PFNS	perfluorononane sulfonic acid
PFOA	perfluorooctanoic acid
PFOS	perfluorooctane sulfonic acid
PFOSA	perfluorooctane sulfonamide
PFPeA	perfluoropentanoic acid
PFPeS	perfluoropentane sulfonic acid
PFTA	perfluorotetradecanoic acid
PFTrA	perfluorotridecanoic acid
PFUnA	perfluoroundecanoic acid
Sb-PFOA	mixture of perfluoro-5-methylheptanoic acid isomers
Sm-PFOS	mixture of sodium perfluoro-5-methylheptane sulfonate isomers

This protocol has been updated to reflect changes necessary to compete the Exposure Assessments during the Covid-19 pandemic. Appropriate safety precautions, including the use of all appropriate personal protective equipment (PPE), will be implemented to keep the EA team and participants safe during the EA process. Appendix J, the PFAS EA Restart Plan, has been included that outlines the additional procedures that will be implemented during recruitment, field work and community meetings to ensure that the EAs are completed in compliance with CDC and state requirements. https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-covid-19-client-interaction.html for non-COVID-19

The activities that will be modified include:

- **Holding virtual community meetings, including the kickoff meeting and the presentation of results. Small group (less than 10 participants) may be held as needed following applicable local, state and CDC guidelines in place at the time of the meeting.**
- **Ensuring that social distancing and the use of PPE are employed to comply with CDC and state guidelines during door-to-door recruitment.**
- **Adding information to the recruitment letter to reassure potential EA participants that all state and CDC guidelines will be in place during the EA testing.**
- **Asking participants about their and their family's health/COVID-19-status during their appointment reminder phone call and prior to beginning the testing process.**
- **Monitoring the temperature of EA team members (CDC/ATSDR and contractor staff) twice daily and taking participant's temperatures prior to entering the EA testing facility.**
- **Administering the exposure questionnaire over the phone instead of at the testing facility to reduce exposure time: consent form administration and collection of biological samples will occur at the testing location.**

These changes are provided in modified Appendices and scripts.

Project Overview

Title

Biological and Environmental Sampling of Per- and Polyfluoroalkyl Substances (PFAS)

Protocol Summary

Under Section 8006 of the Consolidated Appropriations Act, 2018, ATSDR is required to conduct statistically based biomonitoring exposure assessments (EAs) at "no less than eight current or former domestic military installations" that have or have had documented exposures to PFAS in drinking water. This 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.

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.

  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.

  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.

  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.

  Tracking information on recruitment outcomes and response rates will allow ATSDR to improve methodology for conducting statistically representative sampling in the future.

Participating Agencies/Contractors

Institution	Role
Agency for Toxic Substances and Disease Registry	Sponsoring Agency, Funding Agency
Centers for Disease Control and Prevention	Collaborating Agency
Eastern Research Group	Contractor
Abt Associates	Contractor

Conflicts of Interest

The investigators report no conflicts of interest that would prevent them from objectively carrying out the investigation.

Introduction

Literature Review

PFAS are a large family of chemicals with several thousand members. They are used in a variety of industrial and consumer applications and products, including: fire-fighting foams; personal care and cleaning products; as well as oil, stain, grease, and water-repellent coatings on carpet, textiles, leather, and paper [1]. Perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), and perfluorohexane sulfonic acid (PFHxS) are the most extensively studied PFAS but there is little toxicity data available for other PFAS.

PFOS is no longer manufactured in the United States. In January 2006, the Environmental Protection Agency (EPA) initiated the 2010/15 PFOA Stewardship Program, in which the eight major companies in the PFAS industry committed to working toward eliminating emissions and product content of PFOA by 2015 [2, 3]. The goals set forth by this program were met, resulting in a significant decrease in the manufacture and use of PFOA in the United States. However, PFOA, PFOS, and other PFAS continue to be found in the environment, wildlife, and blood of the general population [4-7]. Additionally, new PFAS have been developed to replace PFOA and PFOS, many of which have been detected in environmental samples near manufacturing facilities [8-10]. Very little is known about these new PFAS, though they may have the potential to cause adverse health effects.

Due to past environmental contamination, PFAS have been detected in numerous public and private drinking water systems throughout the United States. As a result, public health agencies are concerned about the possible health risks for communities exposed to these drinking water supplies as well as other sources of PFAS contamination. In 2016 the EPA established a lifetime health advisory level of 70 parts per trillion for two PFAS (PFOA and PFOS, either separately or combined) in drinking water [11, 12]. This health advisory level offers a margin of protection for all Americans throughout their life from adverse health effects resulting from exposure to PFOA and PFOS in drinking water. These values may be revised as the science of PFAS progresses or if new values are established for other PFAS. In addition, several states have developed their own standards and guidance.

Human dietary exposure is thought to be a significant exposure route for PFAS [13-19]. Some PFAS have been shown to accumulate in fish. In the general population, fish and shellfish consumption have been associated with PFAS serum levels [20-22]. In communities near PFAS point-sources, a positive relationship between consumption of fish from PFAS-impacted waters and serum PFAS concentrations have been clearly demonstrated [23]. Additionally, several peer reviewed studies have shown a direct correlation between PFAS concentrations in soil and bioaccumulation in plants [13, 14, 24]. PFAS have been detected in potatoes and cereal seeds as well as leafy vegetables and fruits [24]. Thus, consideration of the consumption of locally-grown fruits and vegetables as well as locally-caught fish is important for exposure assessment.

Infant consumption of formula reconstituted with PFAS-contaminated water as well as consumption of breastmilk from mothers who have been exposed to PFAS are significant dietary sources of PFAS exposure for young children. Empirical data have demonstrated that infant PFOA serum concentrations are higher than those of older individuals exposed to the same contaminated drinking water source for breastfed infants and those fed formula reconstituted with PFAS-contaminated water [25, 26]

ATSDR is currently updating its Toxicological Profile for Perfluoroalkyls. The profile will include Minimal Risk Levels (MRLs) for four PFAS (PFOA, PFOS, PFHxS, and PFNA). MRLs are estimates of daily human exposure to a hazardous substance at or below which that substance is not expected to pose a measurable risk of adverse non-cancerous (e.g., neurological, respiratory, or reproductive) effects. MRLs are used to derive screening values used by ATSDR health assessors and others to identify potentially harmful levels of contaminants at hazardous waste sites and determine whether further investigation is needed to protect communities from exposure.

Limited epidemiological studies have assessed the relationship between PFAS exposure and adverse health effects in humans. These studies have been conducted in occupationally exposed populations, residential populations exposed to PFAS through contaminated drinking water, and the general United States population.

PFOS, PFOA, PFHxS, and PFNA have been more widely studied than other PFAS. Some, but not all, studies in humans with PFAS exposure have shown that certain PFAS may:

- affect growth [27, 28], learning [29], and behavior [30-32] of infants and older children
- lower a woman's chance of getting pregnant [33, 34]
- interfere with the body's natural hormones [35, 36]
- increase cholesterol levels [37-40]
- affect the immune system [41-45]
- increase the risk of cancer [46]

Scientists are still learning about the health effects of exposures to mixtures of PFAS. More research will help scientists fully understand how PFAS may affect human health.

Although none of the results are definitive due to limitations in the study designs and relevance of the PFAS exposures in those studies to community settings and relevance of other factors that may influence health effects in affected communities, these studies have generated concerns amongst communities with identified exposures to PFAS. Though the PFAS exposure assessments described in this protocol are not designed to assess the relationship between PFAS exposure and health effects, they will measure body burden of PFAS, may result in recommendations to reduce exposure, and will inform the design and implementation of future health studies.

For instance, epidemiological studies have demonstrated a positive association between serum PFOA and elevated cholesterol levels in occupational and residential populations, though no consistent trend between serum PFOA and low density lipoprotein (LDL) and high density lipoprotein (HDL) is evident [47-50]. PFOA and PFOS have been shown to modulate expression of genes related to cholesterol metabolism and transport in men and women [51].

Evaluation of liver enzymes suggests that there is a positive association between serum PFOA and liver enzymes and an inverse association between serum PFOA and bilirubin levels [48-50, 52, 53]. This association is evident in both occupational and residential populations. A positive relationship between liver enzyme gamma-glutamyl transferase (GGT) and PFOA serum concentration was observed in an occupational cohort [49]. A positive association between serum PFOA and serum PFOS concentrations and serum alanine aminotransferase (ALT) levels (a marker of hepatocellular damage) was observed in a large residential study [52].

There is evidence to suggest a positive association between serum PFOA and chronic kidney disease [54, 55] in the general population, although questions remain. Because of the cross-sectional nature of some studies, it is not clear if high PFOA and PFOS serum concentrations preceded the observed chronic kidney disease or vice versa [4]. Similarly, some cross-sectional studies also indicate an association between serum PFAS concentrations and early menopause, however the design of these studies makes it difficult to determine the direction of causality [4].

PFOA has been associated with kidney and testicular cancer in a survivor cohort living near a chemical plant [54]. A retrospective cohort study showed an association between length of employment at 3M Chemical Division (while PFAS production was ongoing) and prostate cancer [56]. In 2005, EPA's Science Advisory Board suggested that PFOA is "likely to be carcinogenic in humans," based on the evidence available at the time [57]. The International Agency for Research on Cancer has characterized PFOA as "possibly carcinogenic to humans [46, 58]."

Immune system responses have been observed in adults exposed to PFAS. Epidemiological studies suggest a positive association between serum PFOA and serum PFOS concentrations and suppressed antibody responses to vaccines. *In vitro* studies with human cell lines suggest that PFOA inhibits cytokines that help regulate immune responses [59]. In studies of children, evidence suggests that early development of the adaptive immune system may be vulnerable to exposure to PFOA and PFOS [60]. Studies in the Faroe Islands showed that a doubling in PFOA and PFOS exposure at seven years of age was associated with clinically-significant decreases in diphtheria antibody concentrations at 7 and 13 years of age [61]. In 2016, the National Toxicology Program concluded that both PFOA and PFOS are presumed to be an immune hazard to humans [62].

Cross-sectional studies provide some evidence for associations between exposure to PFOA and other PFAS species and asthma-related outcomes in children, though this is not yet well studied [63, 64]. There is no evidence of association between human maternal serum PFOA or PFOS and preterm birth [65], despite observed impacts on pup mortality in rodent studies [66]. A modest inverse association between maternal PFOS serum concentration and birth weight in full term infants has been observed [65].

In animals, adverse health effects have been demonstrated in response to PFOA and PFOS exposure [67, 68]. These studies identify increased liver weight as one of the primary critical effects [67, 69-73]. Other effects include changes in spleen and thymus [70, 74], as well as developmental effects [68, 75]. However, it is important to note that extrapolation from animals to humans is uncertain because of pronounced differences in elimination rates and substantial variability across species [76-78].

There is much uncertainty regarding the toxicokinetics of PFAS, especially in humans [79]. The toxicokinetic behavior of these compounds appears to be very different in humans than in laboratory species. The rate at which PFAS are eliminated from the body is an important driver of toxicity, with longer half-lives indicating greater potential for bioaccumulation [80]. Biological half-life has been estimated in humans for several PFAS in both occupationally [81] and residentially exposed populations [80, 82, 83]. However, differences in the studied populations, including the level of exposure and the treatment of ongoing background exposures, have resulted in discrepancies across estimates [83].

PFAS excretion is an important determinant of human body burden for these compounds. In humans, PFAS are excreted primarily in the urine [78, 80, 84, 85]. Renal excretion of PFAS occurs by both active and passive mechanisms and is determined by the sum of glomerular filtration, renal tubular secretion

and renal tubular absorption [77-79]. Diabetes [86] is associated with a significant lifetime risk or kidney disease [87] and diabetic kidney disease is the leading cause of end-stage renal disease in North America [87]. Diabetic kidney disease is characterized by the development of macroalbunuria which is followed by a decline in glomerular filtration rate [88, 89]. Hepatitis C has been shown to be an important risk factor for the development of renal insufficiency and decline in glomerular filtration rate [90]. Chronic kidney disease is characterized by decreased kidney function [91]. Clinically, decreased kidney function is a diagnostic marker of chronic kidney disease and is defined by a glomerular filtration rate persistently below 60 mL/minute/1.73 m^2 [89, 92, 93]. Anemia is a common complication of chronic kidney disease [94]. An analysis of NHANES data demonstrated that lower estimated glomerular filtration rate was associated with higher prevalence of anemia in non-Hispanic white persons, non-Hispanic black persons, and Mexican Americans [95]. Diabetes, hepatitis C, chronic kidney disease and decreased kidney function, and anemia may have the potential to significantly impact glomerular filtration and PFAS excretion.

Dialysis treatment, often prescribed for individuals with kidney disease, may also have the potential to increase the removal of some PFAS from the body and thereby lower some PFAS serum concentrations. The primary treatment for renal failure is hemodialysis, a process by which a patient's blood is drawn out through a tube, pumped through a dialyzer to remove waste products and then returned to the patient's body. The membranes used in dialysis have been shown to provide clearance of PFAS [96]. In particular, concentrations of POFA and PFOS were reduced following dialysis with polysulfone dialysis membranes [96, 97].

Scientific evidence reported in the peer reviewed literature clearly demonstrates that PFAS accumulate in humans in protein-rich compartments including kidney, liver, and blood. This is attributed primarily to the fact that PFAS have a strong affinity for binding to serum proteins, serum albumin in particular [84]. For example, PFOA and PFNA have been reported to be 90% and 99.9% bound to human serum albumin [98]. As such, anything that causes significant blood loss will impact the excretion profile. In particular, menstrual fluid contains high levels of albumin [99]. Epidemiologic studies have shown that higher PFAS serum concentrations are measured in postmenopausal women compared with women who are still menstruating [100, 101]. Further, pharmacokinetic modeling provides additional evidence that menstrual cycles effect PFAS serum concentrations [102, 103].

Relatedly, PFAS have been demonstrated to pass through the placental barrier and into the developing fetus during gestation. PFAS have been measured in maternal serum [104-109], cord blood [27, 29, 104, 108, 110-114], placenta [76, 106, 107, 115], fetal tissue [116], and neonates [117, 118]. These studies clearly establish gestation and birth as a significant excretion pathway for mothers and a significant exposure pathway for infants. Women who have been pregnant have a distinct excretion profile from women who have not.

Further, lactation is also a significant excretion pathway for breastfeeding women, and an exposure route for breastfed infants [119-129]. PFAS have been measured in breastmilk in many populations and the duration of breastfeeding has been demonstrated to be positively associated with serum-PFAS concentrations in children and negatively associated with PFAS-serum concentrations in mothers [130].

Justification for Exposure Assessments

Human exposure to PFAS is a growing environmental health concern. These EAs will fulfill the requirements of the 2018 Consolidated Appropriations Act, which requires CDC/ATSDR to conduct

statistically-based biomonitoring EAs in “no less than eight current or former domestic military installations” that have or have had documented exposures to PFAS in drinking water.

The results of these EAs may help individual participants and their communities better understand the magnitude of their environmental exposures to PFAS. The sampling is designed to yield results that are generalizable to the entire population consuming the drinking water in each community and to allow for estimation of serum PFAS concentrations in community members who were not tested.

Limitations of the Investigation

PFAS concentrations measured in this EA cannot be used to predict the occurrence of disease for an individual and cannot explain an individual’s current health problems.

Serum, urine, and environmental PFAS concentrations may improve the understanding of exposure in this community, but will not provide discrete information about all sources of exposure. Additionally, it is not possible to identify every potential confounding exposure. CDC/ATSDR will take this limitation into account when drawing conclusions. The results of this investigation may generate new hypotheses about which PFAS exposure pathways exist in this community. The results of this investigation will be applicable to all the individuals eligible for inclusion in the investigation (see ‘Biological Sampling Eligibility and Recruitment’ section for eligibility criteria), but cannot be generalized to groups not eligible for inclusion in the investigation.

The results will not be applicable to residents who previously lived in the community but moved away prior to this work or to residents who have moved into the community within one year of this work. While the results are generalizable to the community as a whole, they will not be able to estimate the exact concentrations for individual community members. After analysis of the data, ATSDR will include information on our website and through community meetings to provide individuals with specific information about what the data can and can not say about their exposures. The investigation is designed to estimate the mean concentration of PFOS in the population with a given level of precision. Estimates for other species or in sub-populations may not have the same level of precision in estimating means. The actual precision for other estimated means will be presented with the results.

While CDC/ATSDR will strive to obtain a representative sample at each site, the ultimate outcome of recruitment may introduce limitations in the ability to make generalizations in each community. These limitations may result in uncertainty in conclusions regarding the comparison of a community’s exposure profile to nationally representative data. CDC/ATSDR will track non-response rates in order to evaluate the potential impact of the response on generalizability of conclusions.

At all sites identified for exposure assessments, mitigation actions have been implemented to reduce concentrations of PFOA and PFOS in drinking water to below 70 ppt. While there may be ongoing exposure to lower concentrations of PFAS in drinking water, the elevated exposures to PFOA and PFOS have been stopped (to the best of our knowledge). While remediation targeted PFOA and PFOS (per the EPA lifetime health advisory guidance) it is likely that the concentrations of some of the other PFAS chemicals were also reduced. In most cases, less than one biological half-life of time has passed since exposure was reduced. This means that the exposure assessments will attempt to quantify PFAS concentrations in blood and urine based on past exposure to PFAS above 70 ppt, not current exposure.

Intended/Potential Use of Exposure Assessment Findings

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 for the multi-site PFAS health study 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).

Exposure Assessment Locations

EAs will occur at no less than eight communities associated with current or former military facilities that have or have had documented exposures to PFAS in drinking water.

ATSDR developed a multistep approach to selecting sites for the PFAS exposure assessments. The process reflects the legislative requirements and the scientific needs of the project. At each step of the process, efforts were made to collect as much information as possible.

ATSDR drew on a variety of candidate sources to assemble a list of candidate sites. Sources of information included information from other federal agencies, including DoD and EPA's UCMR3 data. ATSDR applied inclusion criteria to the candidate list to ensure that the communities were near a current or former military installation, had a completed drinking water exposure pathway for PFOA and/or PFOS above the EPA's lifetime health advisory of 70 ppt, a population of potentially exposed persons larger than the sample size calculated in the 'Sampling Strategy' section, no previous CDC/ATSDR sponsored PFAS biomonitoring at the site, and how recently PFAS exposure mitigation had been implemented.

ATSDR categorized the eligible sites based on the predominant source of drinking water to ensure the exposure assessments included communities served by both public and/or private water systems and private wells. ATSDR used information from the local water utilities to estimate the exposed population for each site. ATSDR evaluated the maximum measured concentrations of PFOA and PFOS combined in drinking water to assess the magnitude of exposure. ATSDR estimated the duration of exposure using information about initial use of AFFF at nearby military installations, service dates for drinking water wells, and information about documented releases of AFFF to surface water. Based on the information available, ATSDR chose sites that included both private well and water system sites and a geographical diversity of sites.

Listed in alphabetical order by county, the sites selected for PFAS exposure assessments are:

- Berkeley County, WV near Shepherd Field Air National Guard Base (Berkeley County)
- El Paso County, CO near Peterson Air Force Base (El Paso County)
- Fairbanks North Star Borough, AK near Eielson Air Force Base (Fairbanks North Star Borough)
- Hampden County, MA near Barnes Air National Guard Base (Hampden County)
- Lubbock County, TX near Reese Technology Center (Lubbock County)
- New Castle County, DE near New Castle Air National Guard Base (New Castle County)
- Orange County, NY near Stewart Air National Guard Base (Orange County
- Spokane County, WA near Fairchild Air Force Base (Spokane County)

To our knowledge, all municipal systems serving the communities identified as exposure assessment sites took steps to reduce concentrations of PFOA and PFOS below 70 ppt between 2014 and 2017. Additionally, the information available for private wells within these communities indicates that either treatment systems were installed, or alternate sources of water provided between 2015 and 2018 in cases where PFOA and PFOS concentrations in private wells exceeded 70 ppt. Exposure to lower levels of a wide range of PFAS may be ongoing. When available, concentrations of PFAS over time will be used to understand the exposure history at these sites, including after mitigation, but PFAS data are not generally available prior to 2013.

Six of the selected communities (Berkeley County, El Paso County, Hampden County, New Castle County, Orange County, and Spokane County) have water systems that had PFOA + PFOS above 70 ppt. In order to draw generalizable conclusions, the sample frame in these communities will include only public water customers. The other two communities (Fairbanks North Star Borough and Lubbock County) had a large number of private wells with PFOA + PFOS above 70 ppt but no affected municipal systems. The sample frame in these communities will include only households with private wells.

Site-specific Community Engagement

ATSDR/NCEH will hold a community-wide public information meeting during the recruitment phase in all EA locations. The intended audience is prospective EA participants. A Community Event Evaluation Survey ("the Survey") (Appendix A) will be used as a way for the EA team to receive feedback from prospective EA participants about ATSDR's PFAS public health messaging, the ATSDR PFAS EA enrollment processes, and to gauge local feelings toward the ATSDR PFAS EA project. The survey data will help EA team members adjust and enhance public health messaging and EA project information in real time.

The goals of the Survey are:

1. To learn whether our messages and materials were understood by the audience;
2. To understand community feelings towards the project; and
3. To document whether potential participants understand how individuals are selected for potential participation in the Exposure Assessment.

The Survey questions have been adapted from the ATSDR Communications Toolkit available here: https://www.atsdr.cdc.gov/communications-toolkit/documents/16_event-evaluation-form-final-101315_508.pdf.

Objectives

The overall objective of the PFAS Exposure Assessments (all sites) is to characterize exposures and biomonitoring levels in communities exposed to PFAS in drinking water, and to identify patterns in exposure amongst these communities. Each EA will attempt to answer the following questions:

- What are serum PFAS concentrations in the community? How do these concentrations compare to United States reference populations (e.g. NHANES)?
- Can PFAS be detected in urine samples from members of the community? If so, how do these concentrations compare to reference populations across the United States?
- What are environmental contributors to PFAS concentrations in blood and urine? What does environmental sampling data suggest about exposure in the community?
- What can we learn about PFAS exposures to inform future PFAS studies?

Procedures and Methods

Sampling Strategy

A one-stage cluster sample – where each household in the area receiving impacted water is a cluster and all individuals in a selected household are included in the sample – will be used to identify participants for each EA. Clusters (households) will be randomly selected from the sampling frame. This sampling design is representative of the impacted population, allowing for inferences to be made on the entire sampling frame. A step-by-step approach for the one-stage cluster sampling is described below.

1. **ESTABLISH THE SAMPLING FRAME**

   A geographic area where PFAS exposure is known or expected will be defined and a complete list of all exposed/affected households in this area will be identified. This list comprises the sampling frame. Depending on the operations of the water system, the geographic area may be defined by the service boundaries of specific municipal water systems. The geographic area may also be defined as the area with impacted private drinking water wells.

   For simple water systems expected to deliver drinking water with consistent PFAS concentrations to all end users (e.g. municipal drinking water systems with one ground water supply well, or municipal drinking water systems with a surface water source), the sampling frame will consist of all households served by the impacted water system.

   The list of households served by municipal water systems can be obtained from the water company or from local municipal water supply billing information.

   Sequential numbers will be assigned to each household (1, 2, 3,…N) in the sampling frame.

2. **CALCULATE SAMPLE SIZE**

   The required sample size of independent individuals in each community for blood sampling is given by:

$$m = \left[\frac{z_{\alpha/2} \cdot \sigma}{E}\right]^2$$

Where,

m = sample size (individuals)
z = Z value (e.g. 1.96 for 95% confidence level)
α = level of significance
E = maximum error
σ = standard deviation of the logarithm of measured PFAS levels.

If local biomonitoring data are available to determine the standard deviation of the natural logarithm of measured PFAS levels, this data can be used. If these data are not available, national data from NHANES will be used to calculate the necessary sample size, as described below.

The geometric mean for serum PFOS was 4.72 µg/L for the US population in 2015–2016 NHANES. The corresponding 95% confidence interval (4.40, 5.07) and the NHANES sample size of 1,993 are used to estimate the standard deviation of the ln (values). Using the upper limit of the confidence interval:

$$\hat{\sigma} = \frac{\sqrt{1993} \cdot [\ln(5.07) - \ln(4.72)]}{1.96} = 1.63$$

Then, the sample size of independent individuals to estimate the mean with precision 15% of the ln (geometric mean), and 5% level of significance is:

$$m = \left[\frac{1.96 \cdot 1.63}{0.15 \cdot \ln(4.72)}\right]^2 = 188$$

Since data are collected using a cluster design, individuals within a household are not independent. The lack of independence must be accounted for by incorporating the design effect (DE) into calculation of the required sample size. The required sample size for a cluster sample is the sample size for an independent sample multiplied by DE.

$$DE = 1 + ICC * (k - 1)$$

Where,

DE = design effect
ICC = intra-cluster correlation coefficient
k = cluster size

A pilot of representative biomonitoring for PFAS conducted by the New York State Department of Health and the Pennsylvania Department of Health resulted in retrospective calculations of the intra-cluster correlation coefficient (ICC) for PFAS in serum ranging from 0.39 to 0.54 (unpublished data from New York State Department of Health and Pennsylvania Department of Health, 2019). To be conservative, we assume an ICC of 0.54 for our calculation of the design effect.

The average household (cluster) size for the communities selected as exposure assessment sites ranges from 2.4 to 3.0 individuals per household. To be conservative, we assume a household (cluster) size of 3 for our calculation of the design effect.

Using these values, the design effect is:

$$1 + 0.54 * (3 - 1) = 2.1$$

As a conservative assumption, we use a design effect of 2.1 to calculate our required sample size.

$$sample\ size = m \cdot DE$$

This results in a sample size of 2.1*188=395 individuals accounting for intracluster correlation. To be conservative, we will use this design effect for all communities, even when a smaller average household size would result in a lower design effect.

Assuming all individuals from each selected household are included in the sample, the required number of households that should be contacted for recruitment is given by

$$n = sample\ size \cdot ({}^{N}/_{M})$$

Where,

n = required number of households
N = the total number of households in the sampling frame
M = the total number of individuals in the sampling frame

In the Hampden County community (the first exposure assessment site) m = 395, N = 2,882, M = 7,665 so a sample of n = 149 households is needed. Values for N and M taken from 2010 census data for census tract 8125 in Hampden County, MA. At the pilot sites, a within household response rate of 85% was achieved for households in which at least one person participated. Assuming this response rate applies at all sites, the total number of households that need to be contacted in order to get 395 individuals to participate is 269 households. This value is based on an 85% household participation rate (149/0.85 = 175) and a general response rate of 65% (175/0.65 = 269).

Sample size estimate will be adjusted to ensure adequate precision despite non-participating households, using an estimated household response rate of 65%. In Hampden County, n = 75/0.65 = 269 households will be contacted. The number of households contacted in each community will be based on the total number of households and total number of individuals in the sampling frame but will use the same sample size of individuals for all sites. The sample size of 188 independent individuals (based on the original NHANES calculation) will be used for all sites and will be modified by response rate, design effect and required household sample size.

Sampling weights for both households and children are needed to calculate prevalence estimates and make inferences about the entire population of children three years of age or older. Sampling weights can be adjusted to account for unequal probabilities of selection that may have occurred due to non-response from potential participants. Complex survey procedures in SAS/SUDAAN software or EpiInfo software will be used to account for unequal weighting, stratification and clustering in the sample (SAS Institute, Inc., Cary, NC; RTI International, Research Triangle Park, NC).

3. **SELECT HOUSEHOLDS**

   Each household in the sampling frame will be assigned a number (1, 2, 3,…N). A random number generator will be used to create a list of random numbers equal in size to the number of households in the sampling frame. Households will be contacted for recruitment into the EA based on estimated household size in the community and using an estimated response rate. If the response rate is lower than estimated, a reserve sample of households will be contacted for recruitment into the EA to reach the target sample size. If the reserve sample is used, households within the reserve sample will be given equal opportunity to participate as households initially invited to participate.

Biological Sampling Eligibility Criteria and Recruitment

Households identified in the sampling strategy will be contacted by mail and phone. The recruitment letter and script for recruitment phone calls can be found in Appendix A. Based on response rates from national surveys (e.g., National Health and Nutrition Examination Survey, Behavior Risk Factor Surveillance System) EA staff will make up to eight attempts to reach each randomly selected household by phone. For randomly selected households we are unable to reach by phone, we will attempt one in-person visit to recruit EA participants.

In order to ensure that a sufficient number of participants are included in each EA to allow for generalizable conclusions about the exposure of the impacted community, a target for the number of participants in each EA will be set, as described in the 'Sampling Strategy' section of the protocol.

To increase the likelihood that the target sample size will be reached at each EA site, a reserve sample will be contacted for recruitment if the response rate is lower than estimated. Site-specific response rate estimates will be used to calculate the number of households to be approached for recruitment to meet the target sample size. Each randomly-selected household in this block of households will have an equal opportunity to participate, meaning that study staff will carry out the planned outreach to all households within the block, regardless of whether the target sample size was met before all households were contacted for recruitment. If, on the other hand, sample size requirements are not met after attempting recruitment from the initial sample, a reserve sample will be identified and approached using the same outreach described above. The size of the reserve sample required will vary from site to site.

To decrease the chance of participation bias – in which those that do not choose to participate are substantively different from those that do – households that choose not to participate will not be replaced. Information on recruitment, contact attempts, eligibility, enrollment, and batch number will be collected and used to assess for bias and also to weight data accordingly during the analysis phase.

EA staff will schedule biological sampling appointments for all recruited participants during the initial phone call. Recruited participants will receive a letter that confirms their participation, provides information about the assessment and includes a toll-free number for participants to call with any questions.

For sampled households that agree to participate, each individual will be screened in to the study using a series of eligibility questions when they are contacted for recruitment into the EA (Appendix A).

Individuals within each selected household must meet the following inclusion criteria to participate in this investigation:

- Is three years of age or older
- Has lived in the community for at least one year
- Does not have a bleeding disorder and is not anemic

Children younger than 3 years old are excluded from the assessments because the reference values to be used for comparison for serum concentrations in this investigation are only available for children ages three and older [5, 131]. Children under three years old may still be sampled at the request of parents or guardians; however, the child's general state of health, age, and size will be taken into consideration and EA personnel may elect not to collect a blood sample from any child identified as potentially at risk from doing so. While individual results from children under age three will be reported to parents or guardians, data from these participants will not be included in the analysis. Individuals with bleeding disorders or anemia will be excluded in order to reduce burden and risk of blood sampling.

To assess for the potential impact on PFAS excretion and resulting concentrations in blood and urine, participants with diagnosed conditions that impact kidney function (e.g., kidney disease, diabetes, hepatitis C) will be asked to self-identify via the questionnaire, but will not be excluded from the assessment. Similarly, because pregnancy can impact PFAS excretion, pregnant women will neither be targeted nor excluded, but will also be asked to self-identify via the questionnaire.

Participants will not be reimbursed or incentivized to take part in the EA and, similarly, there will be no costs to participants.

Environmental Sampling Eligibility and Recruitment

An arbitrary target of ten percent of households recruited into the EA will also be invited to participate in exploratory environmental (indoor dust and tap water) sampling. These households will be randomly selected from the list of households that have been recruited into the EA. Each household must meet the following eligibility criteria to take part in environmental sampling:

- At least one member of the household is participating in biological sampling
- Head of household reports that people who live in the home primarily drink tap water.

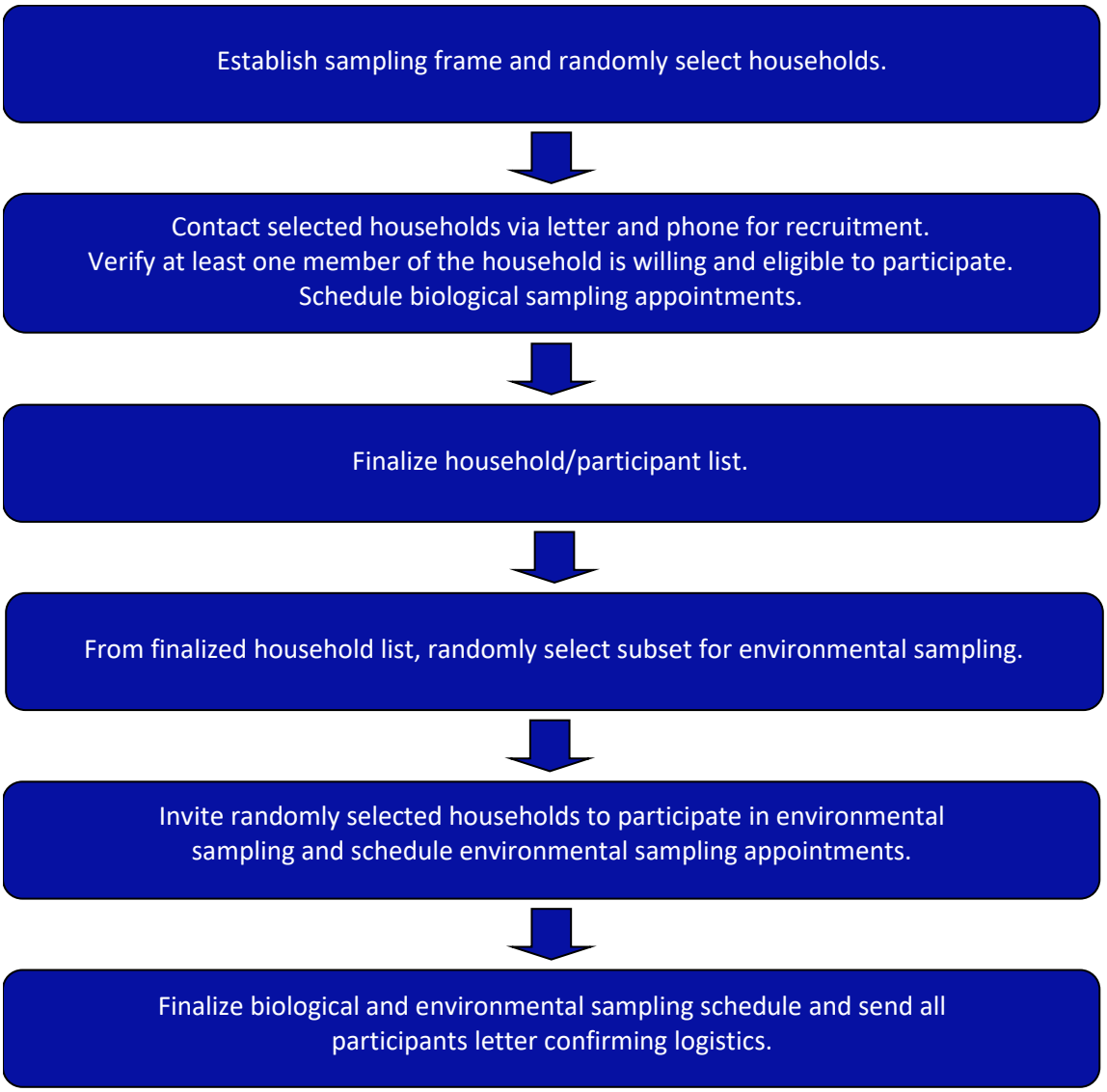
In order to ensure an adequate number of households are identified for environmental sampling, an estimated response rate of 65% will be used to determine how many households will be invited to participate in environmental sampling. For example, if a target of 15 households are needed for environmental sampling, then n = 15/0.65 = 23 will be the number of households randomly selected to receive environmental sampling invitations.

Similar to the multi-stage recruitment approach described above, if sample size goals are not met after attempting to recruit from the first batch of randomly-selected households, subsequent batches will be identified and approached. The head of household from households randomly selected for environmental sampling will be invited to participate in environmental sampling during a follow up phone call. A home visit will be scheduled for environmental sampling during the same two-week period of biological sampling.

All participating households will receive a follow-up letter confirming their participation and sampling appointments.

Figure 1 visually depicts the recruitment process.

Figure 1: PFAS Exposure Assessment Recruitment Process



Sample Collection Procedures

Informed Consent/Assent

Upon arrival at the centralized sample collection location, a Privacy Act Statement, PRA statement, consent, assent, and parental permission forms (Appendix B) will be provided for participants to read and sign prior to any sample collection activities. Participants will also be provided a Biological Testing Tracking Form that they will carry with them throughout the EA testing process to ensure that all appropriate forms are completed and biological samples are provided (Appendix B). Consent forms will

be provided for all adults aged ≥ 18 years (Appendix B). Assent forms (Appendix B) will be provided for children aged 12–17. Parental permission forms (Appendix B) will be provided for the parents or guardians of all children participating in the investigation. Consent/assent forms include: the purpose of the assessment; procedures for sample collection; benefits and risks of participation; and contact information should participants have additional questions. All forms are written at the appropriate reading level for each group. All signed consent/assent/parental permission forms will be mailed to and securely archived at ATSDR.

Blood Sampling

A licensed/qualified phlebotomist will collect approximately 6 mL of blood in a red top tube by venipuncture from all EA participants (adults and children). Each blood tube will be labeled with a preprinted bar-coded label associated with the participant. A collection log will also be maintained (Appendix C). Each sample tube will be placed upright in a rack; the blood will be allowed to clot for 30 minutes to 1 hour to create maximum serum yield. Following clotting, the red top tube will be centrifuged for 15 minutes at 1000 – 1300 g force.

After the contents in the tube have clotted and been centrifuged, two serum aliquots will be obtained. In the first, a minimum of 1.0 mL serum will be pipetted into a cryovial (designated as serum sample #1). The remaining serum (max 1.8 mL) will be pipetted into a second cryovial (designated as serum sample #2). Following serum aliquoting, the red top tube and its contents will be safely discarded into a biohazard multipurpose container.

To protect anonymity, the samples will be labeled with a coded identification number. The identification number on the serum sample will match the identification number on the blood sample in order to pair each individual's blood and urine samples.

All serum sample #1 cryovials will be placed inside storage boxes provided by the laboratory. Each box will be placed inside a plastic Saf-T-Pak™ biohazard bag along with an absorbent pad and sealed. This plastic bag will be placed inside a larger Tyvek® bag and sealed. The bagged specimen boxes will be placed inside a Styrofoam shipping container. Dry ice will be added to the shipper and serum specimens will be maintained in their frozen state. EA personnel will perform twice daily checks to ensure that samples remain frozen and add dry ice as needed. The blood samples will be shipped overnight on dry ice to the NCEH Laboratory in Atlanta, Georgia preferably on Wednesdays and Mondays during the sample collection period. Field and laboratory staff will maintain and manage proper chain of custody (Appendix D) for all serum samples.

All serum sample #2 cryovials will be packed in storage boxes and shipping containers and maintained in a frozen state on dry ice as described above. These samples will be shipped overnight on dry ice to a centralized bio-specimen repository where they will be stored. Consent forms will allow participants to choose whether or not they consent to the storage of their serum sample for future use (Appendix B).

Serum sample #1 cryovials will be received by the NCEH laboratory and analyzed for the suite of PFAS measured in the most recent NHANES cycle with publicly available data. Additional analytes may be added should methods become available. Test results will be reported as nanograms of the analyte per milliliter of serum (ng/mL). All laboratory analysis will be conducted with established procedures for quality assurance and control according to NCEH methodology.

Table 1 provides the list of the PFAS currently measured in NHANES in serum and the associated limits of detection. For PFOA and PFOS, samples will be analyzed for individual PFOA and PFOS isomers, but both isomer-specific and aggregated values will be reported to allow for comparison to past NHANES that only reported aggregate measurements (up to NHANES 2011-12).

Table 1: List of PFAS Proposed to Be Measured in Serum in this Investigation – Abbreviation, Associated Chemical Name, and Current Limit Of Detection (LOD)

Abbreviation	Chemical Name	LOD (ng/mL)
MeFOSAA	N-methyl perfluorooctanesulfonamidoacetic acid	0.1
PFHxS	perfluorohexane sulfonic acid	0.1
Total PFOS	perfluorooctane sulfonic acid	--
n-PFOS	sodium perfluoro-1-octanesulfonate	0.1
Sm-PFOS	mixture of sodium perfluoro-5-methylheptane sulfonate isomers	0.1
Total PFOA	perfluorooctanoic acid	--
n-PFOA	ammonium perfluorooctanoate	0.1
Sb-PFOA	mixture of perfluoro-5-methylheptanoic acid isomers	0.1
PFNA	perfluorononanoic acid	0.1
PFDA	perfluorodecanoic acid	0.1
PFUnA	perfluoroundecanoic acid	0.1
PFDoA	perfluorododecanoic acid	0.1

ng/mL – nanograms per milliliter

Urine Sampling

All participants will be mailed a labeled urine collection cup, urine collection instructions (Appendix E), insulated cooler, and ice pack, which they'll be instructed to store in their freezer. The morning of their blood sampling appointment, participants will collect a first-morning urine sample (filling at least one quarter of the cup, if possible), cap the container, seal the container in a plastic bag, and place in a refrigerator until they travel to the blood sampling location. Participants will transport their sample to EA staff in an insulated cooler with the frozen ice pack.

Urine samples will be placed inside storage boxes provided by the laboratory. Each box will be placed inside a plastic Saf-T-Pak™ biohazard bag along with an absorbent pad and sealed. This plastic bag will be placed inside a larger Tyvek® bag and sealed. The bagged specimen boxes will be placed inside a Styrofoam shipping container. Dry ice will be added to the shipper and urine specimens will maintained in their frozen state. EA personnel will perform twice daily checks to ensure that samples remain frozen and will add dry ice as needed. All urine samples will be shipped overnight on dry ice to a centralized bio-specimen repository on Wednesdays and Mondays during the sample collection period. Field and bio-specimen repository staff will maintain and manage proper chain of custody (Appendix D) for all urine samples.

In order to evaluate whether the available method for measuring PFAS in urine is able to detect PFAS in urine samples, an initial subset of ten percent of urine samples will be analyzed for PFAS. If possible, the initial subset of urine samples will be selected randomly from participants with the highest drinking

water exposures. If it is not possible to stratify participants based on drinking water exposure, ten percent will be randomly selected from the entire sampling frame. For each sample selected for laboratory analysis, biorepository personnel will pipette 1.8 mL of urine into a cryovial and ship samples overnight on dry ice from the bio-specimen repository to the NCEH laboratory in Atlanta, Georgia. Biorepository staff and NCEH/ATSDR personnel will maintain and manage proper chain of custody (Appendix D) for all urine samples.

If the geometric mean PFAS urine concentrations in a community are higher than the NHANES 95th percentile, all urine samples for the community will be shipped from the repository to the NCEH laboratory and analyzed. The geometric mean will be used in this instance because it minimizes the effect of very high or very low values.

To protect anonymity, the samples will be labeled with a coded identification number. The identification number on the urine sample will match the identification number on the serum sample in order to pair each individual's blood and urine samples.

Urine samples selected for laboratory analysis will be analyzed for PFAS and creatinine. Additional analytes may be added should methods become available. If the geometric mean PFAS concentrations in this initial subset are elevated compared to the U.S. national reference population, as defined by the 2013-2014 NHANES 95th percentile, all other urine samples from the site will be analyzed.

PFAS test results will be reported as nanograms per milliliter of urine (ng/mL). Creatinine results will be reported as milligrams per deciliter of urine (mg/dL). Laboratory processing, analysis methods, quality assurance and quality control measures will be conducted in accordance with NCEH laboratory methods.

Table 2 provides the list of PFAS to be measured in urine in this investigation and associated limits of detection. For PFOA and PFOS, samples will be analyzed for individual PFOA and PFOS isomers, but both isomer-specific and aggregated values will be reported.

Table 2: List of Proposed PFAS to Be Measured in Urine in this Investigation – Abbreviation, Associated Chemical Name, and Current Limit of Detection (LOD)

Abbreviation	Chemical Name	LOD (ng/mL)
PFBS	perfluorobutane sulfonic acid	0.1
PFHpS	perfluoroheptane sulfonic acid	0.1
PFHxS	perfluorohexane sulfonic acid	0.1
Total PFOS	perfluorooctane sulfonic acid	--
n-PFOS	sodium perfluoro-1-octanesulfonate	0.1
Sm-PFOS	mixture of sodium perfluoro-5-methylheptane sulfonate isomers	0.1
PFBA	perfluorobutanoic acid	0.1
PFPeA	perfluoropentanoic acid	0.1
PFHxA	perfluorohexanoic acid	0.1
PFHpA	perfluoroheptanoic acid	0.1
Total PFOA	perfluorooctanoic acid	--
n-PFOA	ammonium perfluorooctanoate	0.1
Sb-PFOA	mixture of perfluoro-5-methylheptanoic acid isomers	0.1

Abbreviation	Chemical Name	LOD (ng/mL)
PFNA	perfluorononanoic acid	0.1
PFDA	perfluorodecanoic acid	0.1
PFUnA	perfluoroundecanoic acid	0.1
HFPO-DA (GenX)	hexafluoropropylene oxide dimer acid	0.1
DONA	4,8-dioxa-3H-perfluorononanoic acid	0.1
9Cl-PF3ONS	9-chlorohexadecafluoro-3-oxanone-1-sulfonic acid	0.1

ng/mL – nanograms per milliliter

Questionnaire

An EA team member will administer a questionnaire (Appendix F) to each participant to gather information on risk factors for exposure to PFAS through food pathways, contact with contaminated soil, and water consumption. This information will be used to interpret biomonitoring data and to help understand any unexpected or unusual results. An EA team member will administer the questionnaire and record each participant's responses using the Epi Info suite of software tools. An ATSDR staff person will train EA teams on how to ask each question, which questions should be asked of which participants, and how to accurately and consistently record responses. All questionnaire records will be provided to ATSDR.

Participants will be asked their current address, how long they have lived there, and to identify their primary source of drinking water. Participants will be asked to characterize how much water they drink on a daily basis, and to identify where their drinking water comes from (bottled water, tap water, filtered water, etc.). Participants will also be asked for information about their residential history prior to living in their current home. This information will help characterize the extent and duration of their potential exposure to PFAS-contaminated drinking water in the community.

PFAS are excreted primarily in the urine and are highly bound in the blood. Participants will be asked about the frequency with which they donate blood (participants over the age of 17 only) and if they have been told they have kidney disease in order to characterize excretion. PFAS are also excreted during pregnancy and lactation. Adult women will be asked about their history of pregnancy and breastfeeding. This information will be used to help interpret unusual or unexpected biomonitoring data.

In the event that unexpected serum PFAS concentrations are measured in an individual, ATSDR may use this information to provide context to the result. For example, if an individual reports that they have kidney disease and has PFAS serum concentrations that are significantly higher than others in the household, ATSDR may inform the individual that kidney disease may reduce the rate at which PFAS are cleared from the body, which could have contributed to the observed PFAS serum concentration. Similarly, if a woman who reports multiple pregnancies and significant breastfeeding duration and has lower PFAS serum concentrations that others in her household, ATSDR may inform the individual that pregnancy and breastfeeding are excretion pathways that may have resulted in lower PFAS serum concentrations in her body. In all cases, ATSDR will explain that an individual's PFAS body burden is the product of many complex factors, including but not limited to drinking water exposure, non-drinking water exposure, as well as active and passive excretion.

ATSDR will not use this information to assess impact at the aggregate level or to inform comparisons to the NHANES cohort.

Children (ages 12 – 17) participating in the study will not be asked questions that are inappropriate for their age (pregnancy, blood donation) and will be allowed to obtain parental assistance in answering questions they have difficulty answering.

In order to characterize the potential for additional exposures, participants will also be asked about their occupational history; use of certain consumer products; and the frequency with which they work with the soil, consume locally grown vegetables, and eat locally caught fish. In an effort to understand recent behavioral changes that may impact PFAS exposure, participants will be asked to identify any recent changes related to drinking water, consumption of locally caught fish and locally grown vegetables, or other changes that may impact their exposure to PFAS.

Answers to questions on the questionnaire will not be used to disqualify participants from the study.

Environmental Sample Collection Teams

Sample collection teams comprised of at least two EA staff people, at least one of whom is an ATSDR staff person, will travel together to each household selected to participate in environmental sampling.

Drinking Water Sampling

A subset of 10% of participating households will be selected for environmental sampling, including drinking water sampling. Identification and recruitment of these households is described in more detail in the 'Environmental Sampling Eligibility and Recruitment' section of this protocol.

A drinking water sample will be collected from the primary drinking water location (e.g. kitchen tap) at each household. If point of use filtration is in place, every attempt will be made to collect a sample prior to filtration and after filtration. Samples will be collected in accordance with EPA Method 537.1. Each sample will be collected in a 250 mL polypropylene bottle with a polypropylene screw cap. A preservation reagent (Trizma) will be added as a solid to each sample bottle prior to shipment to the field (or prior to sample collection).

Sample handlers will wash their hands before sampling and wear nitrile gloves while filling and sealing the sample bottles. The tap will be opened and allowed to flush until the water temperature has stabilized (approximately 3 to 5 min). Samples will be collected from the flowing system, taking care not to flush out the sample preservation reagent. Bottles should be filled to near capacity, but samples do not need to be collected headspace free. After collecting the sample, the sample handler will cap the bottle and agitate by hand until preservative is dissolved. The sample will be kept sealed from time of collection until extraction at the laboratory.

A field reagent blank (FRB) will be prepared along with each household tap water sample, and field duplicates collected when indicated per EPA Method 537.1. Prior to the investigation, laboratory staff will prepare two bottles for each household, one empty (preservative free) bottle, and another filled with reagent water and preservatives, which will be sealed. These bottles will be shipped to the sampling site along with the sample bottles. At the sampling site, the sampler will open the bottle containing the preserved reagent water and pour it into the empty sample bottle, after which the sampler will seal and label this bottle as the FRB. The FRB will be shipped back to the laboratory along

with the tap water sample and analyzed to ensure that PFAS were not introduced into the sample during sample collection/handling.

Samples placed in insulated shipping containers with ice packs and cooled to less than 10 degrees Celsius (but not frozen). Tap water samples will be maintained in their cooled state with EA personnel performing twice daily checks of cooler temperature and adding ice packs as needed. Water samples will be shipped overnight to a laboratory accredited to perform EPA Method 537.1. Staff will maintain and manage proper chain of custody (Appendix D) for all water samples.

Samples will be analyzed for PFAS according to EPA method 537.1 by an EPA-approved laboratory. Test results will be reported as ng/L. All laboratory analysis will be conducted with established procedures for quality assurance and control. Table 3 provides the list of PFAS that will be measured in drinking water in this EA.

Table 3. List of PFAS to Be Measured in Drinking Water in this Investigation – Abbreviation, Chemical Name, and Lowest Concentration Minimum Reporting Level (LCMRL)

Abbreviation	Chemical Name	LCMRL (ng/L)
HFPO-DA	hexafluoropropylene oxide dimer acid	4.3
EtFOSAA	N-ethyl perfluorooctanesulfonamidoacetic acid	4.8
MeFOSAA	N-methyl perfluorooctanesulfonamidoacetic acid	4.3
PFBS	perfluorobutane sulfonic acid	6.3
PFDA	perfluorodecanoic acid	3.3
PFDoA	perfluorododecanoic acid	1.3
PFHpA	perfluoroheptanoic acid	0.63
PFHxS	perfluorohexane sulfonic acid	2.4
PFHxA	perfluorohexanoic acid	1.7
PFNA	perfluorononanoic acid	0.83
PFOS	perfluorooctan esulfonic acid	2.7
PFOA	perfluorooctanoic acid	0.82
PFTA	perfluorotetradecanoic acid	1.2
PFTrA	perfluorotridecanoic acid	0.53
PFUnA	perfluoroundecanoic acid	5.2
11Cl-PF3OUdS	11-chloroeicosafluoro-3-oxaundecane-1-sulfonic acid	1.5
9Cl-PF3ONS	9-chlorohexadecafluoro-3-oxanone-1-sulfonic acid	1.8
DONA	4,8-dioxa-3H-perfluorononanoic acid	0.55

ng/L – nanograms per liter

Indoor Dust Sampling

Measurements of household dust may act (to some extent) as a proxy for the presence of the analytes in products used in the household and as a descriptor of direct exposures (dust ingestion). Dust collection is intended to generate additional information about the contribution of non-drinking water exposures to overall PFAS exposure. Dust collection is exploratory and will yield information about how levels of PFAS in indoor dust samples correlated with PFAS serum concentrations. A subset of 10% of

participating households will be selected for environmental sampling, including indoor dust sampling. Identification and recruitment of these households is described in more detail in the 'Recruitment' section of this protocol.

A composite dust sample will be collected from the floor of three locations inside each selected home – the primary living space as identified by the home owner (e.g., living room, family room, television room), the kitchen, and the bedroom in which EA participants spend the most time, as identified by the homeowner. Vacuum sampling will be used to collect dust samples. Unless otherwise indicated, the method described in the EPA technical standard operating procedure for High Volume Indoor Dust Sampling at Residences for Risk-Based Exposure to Metals (available here: https://www.epa.gov/sites/production/files/documents/r8-src_src-dust-01.pdf), will be used to collect samples. This protocol is suitable for the collection of interior dust samples from either hard or smooth and highly textured surfaces, including brickwork and rough concrete as well as carpeting.

Dust will be removed from the designated surface area by means of a flowing air stream passing through a sampling nozzle at a specific velocity and flow rate. Dust will be separated from the air mechanically by a cyclone and collected in a catch bottle attached to the bottom of the cyclone. After collection, the bottle will be tightly capped, labeled, and placed upright in a storage container. All sampling equipment will be decontaminated and inspected for cleanliness prior to collection of each sample. Quality control samples will be collected to identify any potential cross-contamination between samples. Samples will be kept at an ambient temperature and shipped to an EPA approved and DOD accredited laboratory for analysis.

Indoor dust samples will be analyzed for 24 PFAS and PFAS precursors by an EPA-approved laboratory. An EPA-validated isotope dilution method (such as SWA 846) will be used to measure PFAS in indoor dust samples when it is available and approved for use. Samples will be held at the identified laboratory until the analytical method is available for analysis.

Table 4 identifies the species to be measured in indoor dust samples.

Table 4. List of PFAS and PFAS Precursors to Be Measured in Indoor Dust Samples in this Investigation – Abbreviation and Chemical Name

Abbreviation	Chemical Name
PFTA	perfluorotetradecanoic acid
PFTrA	perfluorotridecanoic acid
PFDoA	perfluorododecanoic acid
PFUnA	perfluoroundecanoic acid
PFDA	perfluorodecanoic acid
PFNA	perfluorononanoic acid
PFOA	perfluorooctanoic acid
PFHpA	perfluoroheptanoic acid
PFHxA	perfluorohexanoic acid
PFPeA	perfluoropentanoic acid
PFBA	perfluorobutanoic acid
PFDS	perfluorodecane sulfonic acid

Abbreviation	Chemical Name
PFNS	perfluorononane sulfonic acid
PFOS	perfluorooctane sulfonic acid
PFHpS	perfluoroheptane sulfonic acid
PFHxS	perfluorohexane sulfonic acid
PFPeS	perfluoropentanes ulfonic acid
PFBS	perfluorobutane sulfonic acid
PFOSA	perfluorooctanesulfonamide
FtS 8:2	fluorotelomer sulfonic acid 8:2
FtS 6:2	fluorotelomer sulfonic acid 6:2
FtS 4:2	fluorotelomer sulfonic acid 4:2
EtFOSAA	N-ethyl perfluorooctanesulfonamidoacetic acid
MeFOSAA	N-methyl perfluorooctanesulfonamidoacetic acid

Anticipated Risks and Benefits

Participants may experience some discomfort and bruising in the area where the blood sample was collected. Blood samples will be collected by licensed and trained phlebotomists. Risk of harm from participation in this investigation is considered minimal.

All participants in this EA will be informed of the concentration of PFAS in their serum and how their serum concentrations compare to national reference populations. The subset of participants whose urine was randomly selected for analysis will be informed of the concentration of PFAS in their urine; as detailed in the methods above, if the geometric mean for a subset exceeds the NHANES 95th percentile, all urine samples from that site will be analyzed and results shared with participants. The subset of participants whose households were randomly selected for dust and tap water PFAS analysis will receive these results.

Participants will be informed that their participation in this EA will help advance the understanding of PFAS exposure and will inform future PFAS health studies. Upon completion of the EA, participants will be provided an interpretation of their results by a public health professional.

The total time it will take participants to read through and sign consent/assent/parental permission forms, respond to the questionnaire, and provide a blood and urine specimen is estimated to be less than one hour. The total time it will take participants to have environmental samples collected is estimated to be about 20 minutes.

All sample collection and analysis is provided at no cost to participants.

Privacy Protections

Personal privacy will be protected to the fullest extent possible by applicable federal and state laws and regulations. For the data sets collected at each site, the HIPAA Safe Harbor de-identification method will be applied to extract specific personally identifiable information (PII) and store them separately from other information. When the data sets from all sites are reconciled at CDC/ATSDR, statistical re-identification risk assessment principles and methods will be used to fully de-identify the data set. All

documents with personally identifiable information (i.e., consent forms, assent forms, collection logs, etc.) will be kept in locked cabinets and all electronic data will be stored on a password-protected network servers behind firewalls, accessible only to those staff working directly with raw data. Coded biospecimens and environmental samples will be sent to the laboratories – no personally identifiable information will be included. Any reports produced from this information will not identify specific individuals.

Records will be retained and disposed of in accordance with the ATSDR Records Control Schedule. Physical copies of assessment materials and reports will be maintained at ATSDR until no longer needed by program officials and will be kept in accordance with the corresponding retention schedules. Computer documents will be disposed of when no longer needed by program officials. Personal identifiers will be deleted from records when no longer needed and will be retained no longer than five years. Disposal methods will include erasing computer files, shredding paper materials, or transferring records to the Federal Records Center when no longer needed for evaluation and analysis. Records are retained for 20 years.

In compliance with federal and state privacy protection laws and regulations, the limited data set may be shared with other federal, state and/or local public health and environmental agencies via data use agreements for research purposes to advance the scientific understanding of human exposures to PFAS. These agencies must also protect this private information. Each state health department will act in compliance with their respective Sunshine Laws, which may impact the potential for information sharing.

Data Handling and Analysis

Data Handling

A detailed data management plan for all data collected in the exposure assessment can be found in Appendix I.

For all serum and urine samples, sample analysis, data quality assurance and quality control will be performed by the NCEH laboratory according to CDC/ATSDR protocols. Data that meets the required quality assurance and quality control specifications will be used for analysis.

For tap water data, data quality assurance and quality control will be performed by the identified laboratory as described in EPA Method 537.1 and only valid data will be used for analysis.

For indoor dust data, data quality assurance and data quality control will be performed by the identified laboratory according to the EPA-approved method (when available) or in accordance with another identified method capable of quantifying PFAS in a solid matrix should no EPA method be available in time to satisfy the needs of this project.

Questionnaire data will be collected using the Epi Info software tool and will be kept in a secure and encrypted electronic database.

All data will be transmitted via secure connections and methods to ATSDR or ATSDR contractor for incorporation into a centralized data management repository protected by CDC/ATSDR network firewall and additional security access controls. All results will be electronically transmitted in spreadsheet format using a secured and password-protected network.

Statistical Analysis of Serum and Urine Data from Individual Participants

National values for 12 PFAS in serum are available from the 2013–2014 NHANES and are considered to be national measures of exposure for the general US population. The NHANES geometric mean and 95th percentile for each PFAS serum concentration will be used as a comparison value for each EA participant.

National values for 18 PFAS in urine are being developed from the 2013–2014 NHANES. These will be considered national measures of exposure in the US population. The NHANES geometric mean and 95th percentile for each PFAS urine concentration will be used as a comparison values for each EA participant, when available. Only 10% of collected urine samples will be analyzed initially. If the geometric mean PFAS urine concentrations in a community are higher than the NHANES 95th percentile, all urine samples for the community will be shipped from the repository to the NCEH laboratory and analyzed as described above.

Questionnaire data will be used to aid in the interpretation of anomalous biomonitoring results.

Statistical Analysis of Aggregate Data

Individual participant data will be analyzed in aggregate to estimate community-level PFAS exposure. Aggregate urine data analysis will only be performed if all samples are analyzed at a site. Based on prior studies showing a log-normal distribution of PFAS concentrations in humans, and to allow for direct comparison to NHANES data, the geometric mean with associated 95th percentile confidence interval, 90th percentile, and 95th percentile will be calculated for total PFAS and for each species, provided the proportion of censored data (data below the limit of detection [132]) does not equal or exceed 40%. For datasets in which the rate of censoring is below 40%, the limit of detection divided by square root of 2 (LOD/√2) will be substituted for non-detect values [133]. For datasets in which censoring is equal to or greater than 40%, only high sample percentiles will be reported (e.g., 90th percentile, 95th percentile) [132].Given the limitations in using substitution when calculating summary statistics for censored data, a sensitivity analysis of aggregated PFAS data will be performed using other statistical methods to account for censoring. For datasets in which <50% data are censored, Kaplan-Meier method [132] will be used to estimate the geometric mean with associated 95th percent confidence interval, 90th percentile, and 95th percentile. For datasets in which 50–80% of data are censored, maximum likelihood estimation will be used, and for datasets with >80% censoring, only high sample percentiles will be reported. Given that no nationally representative comparison values using these methods are available, results of this sensitivity analysis will be used only as a comparison to results obtained using simple substitution of censored values.

Where possible, summary statistics will be stratified based on participants characteristics (male/female, age categories, drinking water source, etc…) as reported in the questionnaires.

Environmental Data

Concentrations of PFAS in tap water samples will be compared to federal and/or state drinking water guidelines/advisories for PFAS as they are available.

Prior to any statistical evaluation, one participant will be identified from each household that is expected to be most exposed to the conditions in that household. For example, an adult who does not

work outside of the home and who reports drinking primarily unfiltered tap water would be preferable over an adult who works outside of the home or who frequently drinks bottled water.

Following an exploratory analysis to confirm the distribution of the environmental data we will apply statistical tests as appropriate. If appropriate, Pearson's correlation test will be applied to evaluate the strength of the association between PFAS concentrations in drinking water and indoor dust, and the serum and urine concentrations measured in the sentinel participant. Data distributions will be assessed and transformed as necessary to meet statistical assumptions such as normality. Statistical significance of correlation will be evaluated using a two-sided Student's t-test based on a 95% confidence level. Correlation coefficients and statistical significance will only be determined when the rate of detection is greater than 60%.

Other statistical analyses (e.g., regression modeling) may be performed as appropriate and will be described in detail in the final reports.

Anticipated Products

Individual test results with a written explanation of meaning will be provided by mail to the participants (Appendix G). Biological sampling results for individuals will be provided separately from environmental sampling results. Following dissemination of individual results, an EA team member will be available to discuss individual questions by phone or email.

At the conclusion of each exposure assessment, a report will summarize the overall aggregate findings and conclusions of the assessment, but will not reveal personal identifiers. If warranted, recommendations for additional actions such as continued monitoring, educational activities, or interventions to reduce exposure will be made. Aggregate findings from all exposure assessments will be summarized in a final report and in manuscript(s) submitted for publication in the peer-reviewed scientific literature.

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Appendix A: Community Event Evaluation Survey, Recruitment Letter, and Phone Script

Appendix A1: Community Event Evaluation Survey

Form Approved
OMB No. 0923-0059
Exp. Date 6/30/2022

PFAS Exposure Assessment Community Event Evaluation Survey

Thank you for attending this event. We would appreciate your feedback.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Information Provided					
1. The information presented today was clear and easy to understand.					
2. The materials were helpful and contained useful information used (for example, presentation slides, brochures, videos, etc.).					
3. I understand what is happening in my community regarding the PFAS Exposure Assessment.					
4. I understand who to get in touch with if I have a question about the Exposure Assessment project.					
5. I understand what ATSDR will do next in my community for the Exposure Assessment.					
Presenter					
6. The presenter spoke in a way that was clear and easy to understand.					
7. The presenter interacted well with the audience.					
8. The presenter seemed well-informed about my community.					
Logistics					
9. This event was held at a time that was convenient for me.					
10. This event was held at a location that was convenient for me.					

Please continue on the back.

HHS/ATSDR Lockup Graphic

11. How did you hear about this event? Please check all that apply:

    □ Letter □ Email □ Flier □ Facebook/Twitter □ Friend or family member
    □ ATSDR website □ TV □ Other _____

12. Was there any information you expected to receive at this event but did not get? Y / N Please explain _____

13. Do you understand how individuals are selected for potential participation in the Exposure Assessment? Y / N

14. Anything else you want to share? _____
    _____
    _____
    _____
    _____
    _____
    _____
    _____

Appendix A2: Household Recruitment Letter

Form Approved
OMB No. 0923-0059
Exp. Date 6/30/2022

PFAS Exposure Assessment, biological sampling
Household Recruitment Letter
Reading Level: 9.9

Dear [Insert Name],

Your household is invited to be a part of an assessment that will measure the levels of per- and polyfluoroalkyl substances (PFAS) in people living in your community. PFAS are a large group of man-made chemicals that have been used in industry and consumer products worldwide since the 1950s. The Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry (CDC/ATSDR) is trying to determine the level of PFAS in the bodies of people who may have consumed contaminated drinking water while living near the [Insert name of city/town/place here]. This exposure assessment is required by Congress to better understand potential exposures to PFAS near current or former military bases.

CDC/ATSDR will conduct this exposure assessment from [*insert dates here*]. **This letter explains the procedures, risks, and benefits of our exposure assessment to help you decide if you would like to participate.**

Please be assured that ATSDR will take all necessary steps to protect members of your community from COVID-19. The exposure assessment will be conducted following all state, local, and CDC guidelines in place at the time the exposure assessment is conducted. ATSDR team members will be monitored twice daily for fever and any COVID-19-related symptoms and will wear surgical masks and gloves to ensure the protection of participants. Similarly, participants will be monitored for fever and COVID-19-related symptoms prior to their entry into the testing facility. Participants will be asked to always wear a face covering or mask when interacting with exposure assessment personnel. If you do not have a mask, one will be provided to you before you enter the facility. If you are unable to wear a mask for medical reasons, please let us know.

Within the next week, an ATSDR representative will call you to discuss the exposure assessment, answer any questions you have, and sign you up if you decide to take part. The call will take about 5 minutes of your time. Only households receiving letters are being asked to participate. You can also contact us at [insert contact information].

Here is what you can expect if you choose to participate in the exposure assessment project:

First, when you arrive for your appointment, we will greet you and check you in and will ask you to sign a form agreeing to participate in the testing. At your appointment, we will schedule a convenient time for you and your family to complete a questionnaire by telephone. The questionnaire will ask you to answer a few questions about yourself, your health, and possible exposure to PFAS through water, food, and your environment. The; the questionnaire should take less than 30 minutes to complete.

We will also ask you to give us a blood sample and urine sample. A phlebotomist will draw a small amount of your blood for testing. On the morning of your blood sampling appointment, you will collect a sample of your first morning urine in a collection cup we will provide. Your samples will be labeled with

a unique code. Only the project coordinator will be able to identify whose blood and urine the sample is from.

Your blood and urine will not be tested for HIV, or for the presence of alcohol or drugs. There will be no charge to you for the sample collection or the laboratory analysis. Your blood sample will be sent to the National Center for Environmental Health (NCEH) laboratory in Atlanta, GA. It will be analyzed for twelve PFAS. Some of the urine samples we collect will be analyzed for PFAS – the rest will be saved and stored for analysis in the future, if you give us permission. We will give you the results if we analyze your urine sample in the future.

As soon as test results are available, we will mail them to you at the address you provided on the consent form. If you would like to talk with a healthcare provider about your results, one working on the exposure assessment will be available to you free of charge.

Your PFAS level results (not including any information that would identify you personally) will also be used by ATSDR to improve the understanding of PFAS exposure.

Research to better understand the health effects associated with PFAS exposure is ongoing, but scientists are not currently certain of how PFAS levels in the blood can affect a person's health. More research is needed to clarify the risks posed by PFAS exposure. It is possible that new tests will be developed in the future that will increase our understanding of how PFAS impact human health. We would like to keep your blood and urine samples so that scientists can test for more things if new tests are developed. To do this, we will need your permission when you give us your samples. We will provide you with the results of future testing.

The Benefits of Participating in Our Exposure Assessment

Your participation in this assessment will give you information about levels of PFAS in your body and potentially help you reduce your exposure. Your participation will provide a better understanding of the extent of exposure to PFAS within your community and will also help scientists understand the range of PFAS exposure and possible exposure sources in your community. Work to better understand the health effects associated with PFAS exposure is ongoing, but scientists are not currently certain of how PFAS levels in the body can affect a person's health. More work is needed to clarify the risks posed by PFAS exposure. Your participation in this assessment will help advance this research.

We will **not** be able to tell you if the PFAS levels in your blood or urine will make you sick now or later in life. You will be able to call project staff during and after the exposure assessment if you have any questions about your results. If your doctor has questions about PFAS, he or she may also call project staff or the physician working on the exposure assessment. The names and phone numbers of people to call are listed below.

The Risks of Participating in Our Exposure Assessment

ATSDR will be taking precautions to minimize the risk associated with COVID-19 transmission for both participants and ATSDR/CDC EA team members.

This exposure assessment requires 6 milliliters of blood (which is about 1 teaspoon). You may feel a sharp sting from the needle used to draw your blood. Sometimes a bruise or small blood clot appears at the site. These bruises or clots usually go away on their own. Putting heat on the site can also help the

bruise or clot to go away. Although it is not common, the needle could irritate a nerve. This irritation can cause temporary numbness in part of the arm.

Risk of injury from the blood draw is higher for people with bleeding disorders and for anyone on blood thinning medications (such as Coumadin) and other therapies. If you have a bleeding disorder or are taking blood thinning medication, we recommend that you talk to your doctor before participating in this exposure assessment. Another possible risk from the blood draw is infection, which can develop as a result of the puncture through the skin. Much like they do in other healthcare settings such as doctor's offices and hospitals, our certified phlebotomists will follow standard precautions to minimize this risk. You or your health insurance company would be responsible for any follow-up care if you are injured as a result of the blood draw.

Additional Information and Privacy Act Statement:

- **Results**: We will send you a letter with your PFAS test results along with how they compare to levels in other people in the United States. We do not yet know enough to say whether there are levels in the blood or urine that are safe or unsafe. This assessment will only tell you how much PFAS are currently in your body. It will not tell you when or for how long you were exposed.
- **Privacy:** All personally identifiable information (such as name, address, date of birth) gathered for the exposure assessment is private. This information is protected to the extent possible by (*insert name of state here*) and federal laws related to privacy protection. Only trained and authorized project staff will have access to information that can identify you, and we will keep all of the information in a secure, locked database or file at all times. Aside from the exposure assessment team, you are the only one who will receive your individual results. In accordance with CDC/ATSDR's policy regarding data access, sampling results that do not include PII may be used by public health researchers for approved research purposes.
- **Voluntary Participation:** Participation in this exposure assessment is completely voluntary. Your choice will not affect your current or future relationships with groups that are part of the exposure assessment. Even if you decide to participate, you are free to quit the exposure assessment at any time. If project staff decide it is in your best interest, or if you fail to meet the exposure assessment criteria, you may be removed from the exposure assessment without your consent.

The enclosed fact sheets provide more information about PFAS.

You can expect a call within the next week from [INSERT CALL DETAILS] inviting you to participate in the exposure assessment.

If you would like to indicate your willingness to be a part of this exposure assessment now, please contact us [INSERT PHONE NUMBER and HOURS OF OPERATION]. Remember, only households receiving an invitation letter are eligible to participate.

If you have any additional questions, please feel free to contact [*insert contact information*].

Thank you,

Enclosures:

- PFAS Frequently Asked Questions Fact Sheet
- PFAS Family Tree Fact Sheet
- PFAS Exposure Assessment Fact Sheet

From: https://www.atsdr.cdc.gov/pfas/additional_resources.html

8/22/17

Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)

Frequently Asked Questions

What are PFAS?

Perfluoroalkyl and polyfluoroalkyl substances (PFAS) are a large group of man-made chemicals that have been used in industry and consumer products worldwide since the 1950s.

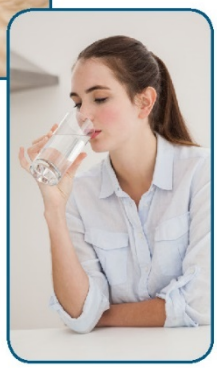
- PFAS do not occur naturally, but are widespread in the environment.
- PFAS are found in people, wildlife and fish all over the world.
- Some PFAS can stay in people's bodies a long time.
- Some PFAS do not break down easily in the environment.

How can I be exposed to PFAS?

PFAS contamination may be in drinking water, food, indoor dust, some consumer products, and workplaces. Most non worker exposures occur through drinking contaminated water or eating food that contains PFAS.

Although some types of PFAS are no longer used, some products may still contain PFAS:

- Food packaging materials
- Nonstick cookware
- Stain resistant carpet treatments
- Water resistant clothing
- Cleaning products
- Paints, varnishes and sealants
- Firefighting foam
- Some cosmetics



How can I reduce my exposure to PFAS?

PFAS are present at low levels in some food products and in the environment (air, water, soil etc.), so you probably cannot prevent PFAS exposure altogether. However, if you live near known sources of PFAS contamination, you can take steps to reduce your risk of exposure.

- If your drinking water contains PFAS above the EPA Lifetime Health Advisory, consider using an alternative or treated water source for any activity in which you might swallow water:
  - drinking
  - food preparation
  - cooking
  - brushing teeth, and
  - preparing infant formula
- Check for fish advisories for water bodies where you fish.
  - Follow fish advisories that tell people to stop or limit eating fish from waters contaminated with PFAS or other compounds.
  - Research has shown the benefits of eating fish, so continue to eat fish from safe sources as part of your healthy diet.
- Read consumer product labels and avoid using those with PFAS.

Agency for Toxic Substances and Disease Registry
Division of Community Health Investigations

ATSDR

CS278160-E

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From: https://www.atsdr.cdc.gov/pfas/additional_resources.html

The family tree of perfluoroalkyl and polyfluoroalkyl substances (PFAS)

Names and abbreviations

6/9/17

This fact sheet tells you about chemical names within the family of perfluoroalkyl and polyfluoroalkyl substances (PFAS) and their basic chemical structure. It also spells out abbreviations for common PFAS.

PFAS are a family of man-made chemicals that contain carbon, fluorine, and other elements.

The family tree image below, Figure 1, shows some of the different families of PFAS. For simplicity, it does not include all PFAS subfamilies. Follow along – starting at the "fallen apple" of PFC and then continuing up the tree trunk into the branches.

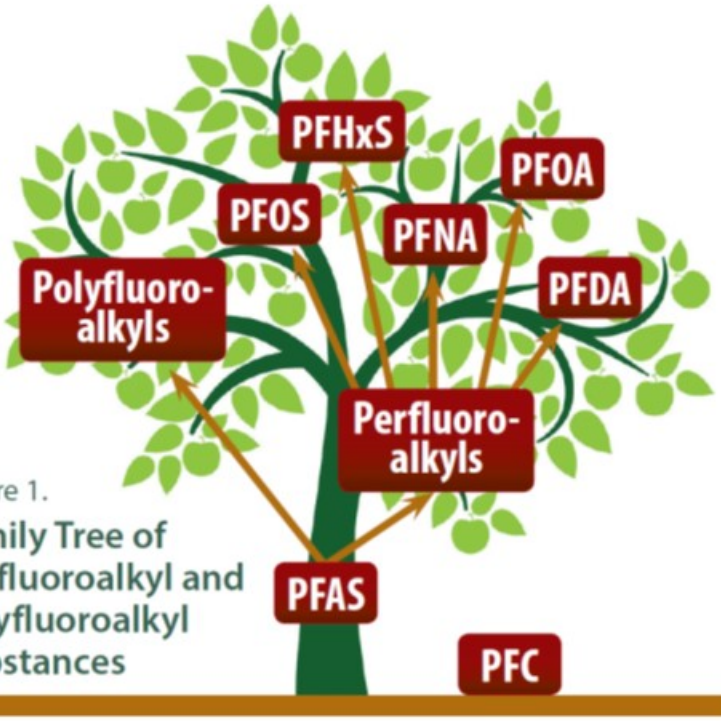


Figure 1.
Family Tree of perfluoroalkyl and polyfluoroalkyl Substances

Agency for Toxic Substances and Disease Registry
Division of Community Health Investigations

ATSDR

CS278160-A

Page 1

PFC

In the past, scientists used the abbreviation PFC to stand for perfluorinated chemicals.

However, using the abbreviation PFC can be confusing because it is also an abbreviation for perfluorocarbons. Perfluorocarbons are an entirely different family of chemicals, also known as greenhouse gases.

The term PFC has fallen off the family tree, but it remains in the diagram as a reminder of past use. You may still see informational materials using the term "PFC" instead of PFAS.

PFAS

Perfluoroalkyl substances and polyfluoroalkyl substances are called PFAS for short. The PFAS family includes hundreds of chemicals. The different structures of the PFAS molecules are the basis for different chemical properties and different chemical names. See Table 1 for abbreviations and chemical names.

Table 1. **Common PFAS: Abbreviations and Names**

Abbreviation	Chemical name
PFOS	Perfluorooctane sulfonic acid
PFOA (aka C8)	Perfluorooctanoic acid
PFNA	Perfluorononanoic acid
PFDA	Perfluorodecanoic acid
PFOSA (aka FOSA)	Perfluorooctane sulfonaminde
MeFOSAA (aka Me-PFOSA-AcOH)	2-(N-Methyl-perfluorooctane sulfonamido) acetic acid
Et-FOSAA (aka Et-PFOSA-AcOH)	2-(N-Ethyl-perfluorooctane sulfonamido acetic acid
PFHxS	Perfluorohexane sulfonic acid

Appendix A3: Household Eligibility Screener

Form Approved
OMB No. 0923-0059
Exp. Date 6/30/2022

PFAS Exposure Assessment, biological sampling
Household Eligibility Screener
Reading Level: 8.5

Hello, I am _____ from [*Insert affiliation*], calling on behalf of the Agency for Toxic Substances and Disease Registry, or ATSDR for short. May I please speak with the head of the household?

I would like to take about 5 minutes of your time today to invite you and the members of your household to be part of an exposure assessment. The assessment will measure chemicals called per- and polyfluoroalkyl substances, or PFAS, in the bodies of people living in your area. PFAS are a large group of man-made chemicals that have been used in industry and consumer products worldwide since the 1950s.

ATSDR is a federal public health agency that is part of the Centers for Disease Control and Prevention). It is working to understand how people living in your area have been exposed to PFAS. This will help us determine if exposure to these chemicals is a problem in your community and it will help us to design future studies to understand how these chemicals affect people's health. To do this, we need people in this community to participate in blood and urine testing.

We are calling today because ATSDR is interested in recruiting everyone in your household who is eligible to take part in this assessment. Taking part in the exposure assessment will include signing a form agreeing to be tested, giving a blood sample, giving a urine sample, and completing a short questionnaire. ATSDR will ask questions to better understand the lab test results. The time required to participate is about 30 minutes.

ATSDR will take COVID-19 prevention measures at every step of our work in your community. Would you like me to tell you about those?

If the resident says "no", move on with the script.

If the resident says "yes", tell them the following:

The exposure assessment will be conducted following all state, local, and CDC guidelines in place at the time the EA is conducted. ATSDR team members will be monitored twice daily for fever and any COVID-19-related symptoms and will wear surgical masks and gloves to ensure the protection of participants. Similarly, participants will be monitored for fever and COVID-19-related symptoms prior to their entry into the testing facility. Participants will be asked to always wear a face covering or mask when interacting with exposure assessment personnel. If you do not have a mask, one will be provided to you before you enter the facility. If you are unable to wear a mask for medical reasons, please let us know.

According to the Privacy Act, we will protect the private information that you provide for yourself and your family. If you enroll in the assessment, we will give you a copy of our Privacy Act Statement before we get your consent to participate.

Is it okay if I ask you a few questions to see if you and other members of your household qualify to take part in the exposure assessment?

Yes No

OK, thanks a lot. You are free to answer or not answer these questions. You can also ask me any questions you have.

If 'Yes', Screening Questions:

1. Have you or someone in your household lived in the community full time for at least one year?

   Yes No Don't Know Refused to Answer

   a. Of these people how many are 3 years old and older? _____

   b. Do any of these people have a bleeding disorder that prevents them from giving a blood sample?

      Yes No Don't Know Refused to Answer

      i. **If 'yes'**, how many? _____

   ****If there are people who have lived in the community for more than one year, are older than 3, and don't have a bleeding disorder, proceed to question 2.**

2. Are you and others from your household willing to participate in the exposure assessment? This will include a blood test, urine test, and answering questions from a questionnaire.

   Yes No Refused to Answer

If No: Okay, thank you for your time. Goodbye.

If Yes: Thank you very much.

All members of your household who have lived in the home for at least one year, who are older than the age of 3, and who do not have a bleeding disorder will be eligible to participate. Each individual will be given the opportunity to decide for him or herself whether or not they want to participate. We will attempt to schedule your sample collection appointment now. You will receive a letter in the mail with confirmation of your appointment time and location. At your appointment, we will schedule a convenient time for you and your family to complete a questionnaire by telephone.

We have two additional questions.

- While at home, do you and your family members primarily drink tap water?

  Yes No Refused to Answer.

- Can you please confirm the best contact information to reach you?

Name: _____

Address: _____

Phone Number: _____

Appendix A4: Household Recruitment Script for Environmental Sampling

Form Approved
OMB No. 0923-0059
Exp. Date 6/30/2022

PFAS Exposure Assessment, environmental sampling
Household Recruitment Script for Environmental Sampling
Reading Level: 10.1

Note: Ten percent of household recruited into the exposure assessment that report drinking tap water in the home will be randomly selected for environmental sampling. This script will be used to contact and invite these selected households to participate in environmental sampling.

Hello, I am _____ from [*insert affiliation*], calling on behalf of the Agency for Toxic Substances and Disease Registry. May I please speak to someone who can make decisions about participating in our study?

As I'm sure you remember, your household recently agreed to participate in an exposure assessment to measure chemicals called per- and polyfluoroalkyl substances, or PFAS, in the bodies of people living in your area. A small subset of households participating in the exposure assessment has been selected for additional environmental sampling of PFAS in the home.

We would like to collect tap water and indoor dust samples from some homes to understand if people living in your area are exposed to PFAS while at home. To do this, we need households in this community to participate in environmental sampling as well as blood and urine testing.

For this part of the exposure assessment, we will collect a drinking water sample from the source in your home you and your family most often drink water (e.g. kitchen tap). Then, we will collect indoor dust samples from up to three locations inside your home. The time required for us to collect these samples is estimated to be about 20 minutes. The environmental sampling will be in addition to collection of blood and urine from you and others in your household.

ATSDR will take COVID-19 prevention measures at every step of our work in your community. Would you like me to tell you about those?

If the resident says "no", move on with the script.

If the resident says "yes", tell them the following:

The exposure assessment will be conducted following all state, local, and CDC guidelines in place at the time the EA is conducted. ATSDR team members will be monitored twice daily for fever and any COVID-19-related symptoms and will wear surgical masks and gloves to ensure the protection of participants. ATSDR team members who will enter your home will wear personal protective equipment, or PPE, that includes a full body coverall, an N95 respirator and gloves. Participants will be monitored for fever and COVID-19-related symptoms prior to exposure assessment staff entering the home. Participants will be

asked to always wear a face covering or mask when interacting with exposure assessment personnel. If you do not have a mask, one will be provided to you before we enter your home. If you are unable to wear a mask for medical reasons, please let us know.

Are you willing to participate in the environmental sampling part of the exposure assessment?

Yes No Refused to Answer

If No: Okay, thank you for your time. Goodbye.

If Yes: Thank you very much. We will be in your community to collect samples [insert dates]. Your blood and urine sampling appointment is at [insert date and time]. When would be a good time for us to schedule a home visit to collect your environmental samples?

Appendix B: Privacy Act Statement, Consent, Parental Permission and Assent Forms, and Biological Testing Tracking Form

Appendix B1: Privacy Act Statement

PRIVACY ACT STATEMENT
FOR
PFAS EXPOSURE ASSESSMENT – BIOLOGICAL AND ENVIRONMENTAL SAMPLING

This statement provides the notice required by the Privacy Act of 1974 (5 USC § 552a(e)(3)).

- **Authority:** The Agency for Toxic Substances and Disease Registry (ATSDR) has the authority to collect this information under ***Section 8006 of the Consolidated Appropriations Act*** of 2018. ATSDR also conducts exposure assessments under the ''Comprehensive Environmental Response, Compensation, and Liability Act of 1980'' (CERCLA) as amended by ''Superfund Amendments and Reauthorization Act of 1986'' (SARA) (42 U.S.C. 9601, 9604).

- **Purpose:** ATSDR is conducting this assessment to study your exposure to per- and polyfluoroalkyl substances (PFAS) from drinking water. ATSDR is collecting this information on you or your child for:
  - Adult consent, parental permission, and child assent to participate in questionnaires, and blood and urine collections.
  - Collection of drinking water and dust samples in a subset of households.
  - Sending your, your child's, or your household results back to you.

- **Routine Uses:**
  - ATSDR will share these records with the National Center for Environmental Health (NCEH). NCEH may provide investigation or support staff, laboratory and statistical analysis, etc.
  - ATSDR may disclose these records to its contractors to locate individuals exposed or potentially exposed to PFAS, and to conduct interviews and other assessment activities. The contractor must comply with the requirements of the Privacy Act to protect your or your child's records.
  - Other routine uses as described in System of Records Notice (SORN) No. 09-19-0001 - ''Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances." See https://www.gpo.gov/fdsys/pkg/FR-2011-01-25/pdf/2010-33004.pdf.

- **Disclosure:** Providing this information is voluntary. ATSDR needs this information for you or your child to take part in the study. ATSDR may not include incomplete records in the data analysis. ATSDR needs up-to-date contact information to send your or your child's study results.

Appendix B2: Adult Consent Form

Respondent ID No:

Form Approved
OMB No. 0923-0059
Exp. Date 6/30/2022

PFAS Exposure Assessment, Biological Sampling
Adult Consent Form (≥ 18 years of age)
Reading Level: 8.7

We are doing an exposure assessment (EA) on chemicals called PFAS. PFAS stands for Per- and Polyfluoroalkyl Substances. We want to give you some information so you can decide whether you want to take part.

PFAS have been found in the drinking water supply in (*insert name of city/town/place here*). Scientists and doctors don't yet know how PFAS may affect people's health. A first step in figuring that out is measuring the amount of PFAS in the bodies of people who may have come into contact with this contaminated water.

PFAS are chemicals that were used in a wide range of ways in the United States, such as in personal care and cleaning products; oil, stain and grease-repelling coatings on carpet, textiles, leather and paper; and in fire-fighting foams. PFAS are found in the environment (in the air, soil, and water). And they can stay in the human body for years.

The main goal for this assessment is to find out how much PFAS are in the blood and urine of people in (*Insert name of city/town/place here*) who may have been exposed to contaminated drinking water. We will conduct this assessment from (*insert dates here*).

We hope you will agree to be part of this exposure assessment. If you have any questions about this form while filling it out, please don't hesitate to ask. Thank you for considering being in this assessment.

Follow these instructions: This form tells you about the assessment. It also says what will happen if you decide to take part. If you agree to take part in this assessment, please sign at the end of the form.

Procedures for the Exposure Assessment

First, we will ask you to answer a few questions.

A few weeks ago, we mailed you a container for a urine collection and instructions on how to collect the sample. After you sign this consent form, we will ask for the urine sample you collected first thing this morning. We will also ask you to give us a blood sample today. A phlebotomist will draw a small amount of your blood for testing. We will label your blood and urine samples with a code only. Only the project coordinator will be able to identify who gave the blood and urine samples. The questionnaire should take about 30 minutes to complete.

We will send your blood to the National Center for Environmental Health (NCEH) laboratory in Atlanta, GA, for analysis. Your urine sample will be sent to [*insert name and location of bio-specimen repository*]. Only recently have scientists been able to measure PFAS in urine. Because the method for measuring PFAS in urine is developing, not all urine samples collected will be analyzed for PFAS. Instead, ATSDR will randomly chose a percentage of urine samples for PFAS analysis. All of the blood and urine samples will be stored and may be analyzed in the future. If your urine or blood samples are analyzed in the future, we will give you the results.

Your blood and urine will not be tested for HIV, or for the presence of alcohol or drugs and your DNA will not be used for any purpose. There will be no charge to you for the sample collection or the laboratory analysis.

At the end of the exposure assessment, we will mail your test results to you at the address you provide today. If you would like to talk with a doctor about your results, you can talk to one working on the exposure assessment free of charge.

ATSDR will also use your PFAS level results (but not any information that would identify you personally) to better understand PFAS exposure in your community.

Scientists are not sure how PFAS levels in the blood can affect a person's health. However, our main purpose for this assessment is to see if people in your community are exposed to unusual levels of PFAS. It is possible that new tests will be developed in the future that will increase our understanding about PFAS. We would like to keep your blood and urine samples so that scientists can test for more things if new tests are developed. To do this, we need your permission.

The Benefits of Taking Part in Our Exposure Assessment

Your participation in this assessment will help us understand the range of PFAS exposure and possible exposure sources in your community. Scientists are not sure how PFAS levels in the body can affect a person's health. More work is needed to clarify the risks posed by PFAS exposure. Your participation in this assessment will help advance this knowledge.

We will **not** be able to tell you if the PFAS levels in your blood or urine will make you sick now or later in life. You will be able to call project staff during and after the exposure assessment if you have any questions about your results. If your doctor has questions about PFAS, he or she may also call project staff or the physician working on the exposure assessment. The names and phone numbers of people to call are listed below.

The Risks of Taking Part in Our Exposure Assessment

This exposure assessment requires approximately 6 milliliters of blood (which is about 1 teaspoon). You may feel a sharp sting from the needle used to draw your blood. Sometimes a bruise or small blood clot appears at the site. These bruises or clots usually go away on their own. Putting heat on the site can also help the bruise or clot to go away. Although it is not common, the needle could irritate a nerve. This irritation may cause temporary numbness in part of the arm.

Risk of injury from the blood draw is higher for people with bleeding disorders, such as aplastic anemia, and for anyone on blood thinning medications (such as Coumadin) and other therapies. If you have such a bleeding disorder or are taking blood thinning medication, we recommend that you talk to your doctor

before joining this exposure assessment. Also, infection could also develop as a result of the puncture through the skin. You or your health insurance company would be responsible for any follow-up care if you are injured as a result of the blood draw.

Additional Information:

- **Results**: We will send you a letter with your PFAS test results along with how they compare to levels in other people in the United States. All participants will receive blood testing results and a percentage of participants will receive urine testing results. We do not yet know enough to say whether there are levels in the blood or urine that are safe or unsafe. This assessment will only tell you how much PFAS are currently in your body. It will not tell you when or for how long you were exposed.
- **Privacy:** All personally identifiable information (PII) (such as name, address, date of birth) gathered during the exposure assessment is private and will not be publicly released. This information is protected to the extent possible by (*insert name of state here*) and federal laws and regulations related to privacy protection. Only trained and authorized project staff will have access to information that can identify you, and we will keep all of the information in a secure, locked database or file at all times. Aside from the exposure assessment team, you are the only one who will receive your individual results. In accordance with CDC/ATSDR's policy regarding data access, sampling results that do not include PII may be used by public health researchers for approved research purposes.
- **Voluntary Participation:** Participation in this exposure assessment is completely voluntary. Your choice will not affect your current or future relationships with groups that are part of the exposure assessment. Even if you decide to participate, you are free to quit the exposure assessment at any time. If project staff decide it is in your best interest, or if you fail to meet the exposure assessment qualifications, you may be removed from the exposure assessment without your consent. If at any time in the future, you would like to have your blood or urine sample destroyed or removed from the assessment, please call (*insert name and phone number of Study coordinator*).

Adult Consent

By marking the check boxes below and signing this form, you are confirming that you understand the goals of the exposure assessment, and that you agree, of your own free will, to participate. You are also confirming you will allow the project staff to collect, store, and share the information gathered for the exposure assessment as described above. You will receive a copy of this form for your records.

I agree to participate in this Exposure Assessment and provide a blood and urine sample.
☐ **Yes** ☐ **No**

I understand that I will receive my PFAS test results by mail. I will be able to compare some of my test results with national levels.
☐ **Yes** ☐ **No**

I understand that project staff will not be able to determine if the PFAS levels in my body will impact my health.
☐ **Yes** ☐ **No**

I agree that my PFAS test results may be shared with other federal, state, and local environmental and health agencies. Your identifying information will be protected to the extent possible by law should you choose to allow ATSDR to share your results with other federal, state or local agencies.

☐ **Yes** ☐ **No**

I understand that my PFAS test results and questionnaire data may be used for additional analysis in the future.

☐ **Yes** ☐ **No**

I agree to allow my blood and urine samples to be saved and used for other PFAS-related tests. If your blood and urine are analyzed in the future, we will send you the results.

☐ **Yes** ☐ **No**

I agree to let ATSDR/NCEH keep my contact information and contact me in the future for possible follow-up studies (may be research or non-research studies).

☐ **Yes** ☐ **No**

Participant's Name:_____
(Printed)

Participant's Signature:_____

Date Signed:_____

Street Address:_____

City: _____ State:_____ Zip:_____

Phone number (area code):_____

Project Representative's Name:_____
(Printed)

Project Representative's Signature:_____

Appendix B3: Parental Permission Form

Form Approved
OMB No. 0923-0059
Exp. Date 6/30/2022

PFAS Exposure Assessment, Biological Sampling
Parental Permission Form (<18 years of age)
Flesch-Kincaid Reading Level: 9.2

We are doing a study on chemicals called PFAS. PFAS stands for Per- and Polyfluoroalkyl Substances. We want to give you some information about it so you can decide whether you want your child/ward to participate.

PFAS have been found in the drinking water supply in (*insert name of city/town/place here*). PFAS are chemicals that were used in a wide range of ways in the United States. PFAS are found in the environment (in the air, soil, and water). And they can stay in the human body for years.

Scientists and doctors don't yet know how PFAS may affect people's health. The first step in figuring that out is measuring the amount of PFAS in the bodies of people who may have come into contact with this contaminated water.

The main goal for this assessment is to find out how much PFAS are in the blood and urine of people in (*Insert name of city/town/place here*) who may have been exposed to contaminated drinking water. We will conduct this study from (*insert dates here*).

We hope you will agree to let your child be part of this exposure assessment. If you have any questions about this form at any time while filling it out, please don't hesitate to ask. Thank you for considering allowing your child/ward to be in this assessment.

Follow these instructions: This form contains information about the assessment and what will happen if you and your child decide to participate. If you and your child agree for the child to take part in this assessment, please sign at the end of the form.

Procedures for the Exposure Assessment

First, we will ask you to answer a few questions.

We will also ask your child to give us a blood and urine sample. A phlebotomist will draw a small amount of his or her blood for testing. We will ask for the urine sample your child collected this morning. Your child's samples will be labeled with a code only. Only the project coordinator will be able to identify who gave the blood and urine samples. The questionnaire should take about 15 minutes to complete.

We will send your child's blood to the National Center for Environmental Health (NCEH) laboratory in Atlanta, GA, for analysis. Your child's urine sample will be sent to [*insert name and location of bio-specimen repository*].

Only recently have scientists been able to measure PFAS in urine. Because the method for measuring PFAS in urine is developing, not all urine samples collected will be analyzed for PFAS. Instead, ATSDR will randomly chose a percentage of urine samples for PFAS analysis. All of the blood and urine samples will be stored and may be analyzed in the future. If your child's urine or blood samples are analyzed in the future, we will give you the results.

Your child's blood and urine will not be tested for HIV, or for the presence of alcohol or drugs and your DNA will not be used for any purpose. There will be no charge for the sample collection or the laboratory analysis.

At the completion of the exposure assessment, we will mail your child's test results to you at the address you provide today. If you would like to talk with a doctor about your results, you can talk to one working on the exposure assessment free of charge.

ATSDR will also use your child's PFAS level results (not including any information that would identify him or her personally) to better understand PFAS exposure in your community.

Research to better understand the health effects associated with PFAS exposure is ongoing, but scientists are not currently certain of how PFAS levels in the blood can affect a person's health. More research is needed to clarify the risks posed by PFAS exposure. It is possible that new tests will be developed in the future that will increase our understanding of how PFAS impact human health. We would like to keep your child's blood and urine samples so that scientists can test for more things if new tests are developed. To do this, we need your permission. If your child's samples are tested again in the future, you will be contacted again to give permission for the tests.

The Benefits of Taking Part in Our Exposure Assessment

Your child's participation in this assessment will help us understand the range of PFAS exposure and possible exposure sources in your community. Work to better understand the health effects associated with PFAS exposure is ongoing, but scientists are not currently certain of how PFAS levels in the body can affect a person's health. More work is needed to clarify the risks posed by PFAS exposure. Your child's participation in this assessment will help advance this knowledge.

We will **not** be able to tell you if the PFAS levels in your child's blood or urine will make your child sick now or later in life. You will be able to call project staff during and after the exposure assessment if you have any questions about your child's results. If your child's doctor has questions about PFAS, he or she may also call project staff or the physician working on the exposure assessment. The names and phone numbers of people to call are listed below.

The Risks of Taking Part in Our Exposure Assessment

This exposure assessment requires approximately 6 milliliters of blood (which is about 1 teaspoon). Your child may feel a sharp sting from the needle used to draw your blood. Sometimes a bruise or small blood clot appears at the site. These bruises or clots usually go away on their own. Putting heat on the site can also help the bruise or clot to go away. Although it is not common, the needle could irritate a nerve. This irritation may cause temporary numbness in part of the arm.

Risk of injury from the blood draw is higher for people with bleeding disorders, such as aplastic anemia, and for anyone on blood thinning medications (such as Coumadin) and other therapies. If your child has

such a bleeding disorder or are taking blood thinning medication, we recommend that you talk to your doctor before joining this exposure assessment. Infection could also develop as a result of the puncture through the skin. You or your health insurance company would be responsible for any follow-up care if your child is injured as a result of the blood draw.

Additional Information:

- **Results**: We will send you a letter with your child's PFAS test results along with how they compare to levels in other children in the United States. All participants will receive blood testing results and a percentage of participants will receive urine testing results. We do not yet know enough to say whether there are levels in the blood or urine that are safe or unsafe. This assessment will only tell you how much PFAS are currently in your child's body. It will not tell you when or for how long your child was exposed.
- **Privacy:** All personally identifiable information (PII) (such as name, address, date of birth) gathered during the exposure assessment is private and will not be publicly released. This information is protected to the extent possible by (*insert name of state here*) and federal laws and regulations related to privacy protection. Only trained and authorized project staff will have access to information that can identify your child, and we will keep all of the information in a secure, locked database or file at all times. Aside from the exposure assessment team, you are the only one who will receive your child's individual results. In accordance with CDC/ATSDR's policy regarding data access, sampling results that do not include PII may be used by public health researchers for approved research purposes.
- **Voluntary Participation:** Participation in this exposure assessment is completely voluntary. Your choice will not affect your current or future relationships with groups that are part of the exposure assessment. Even if you decide to let your child participate, you are free to quit the exposure assessment at any time. If project staff decide it is in your child's best interest, or if your child fails to meet the exposure assessment qualifications, he or she may be removed from the exposure assessment without your consent. If at any time in the future, you would like to have your child's blood or urine sample destroyed or removed from the assessment, please call (*insert name and phone number of Study coordinator*).

Consent Form

By marking the check boxes below and signing this form, you are confirming that you understand the goals of the exposure assessment, and that you agree, of your own free will, to let your child participate. You are also confirming you will allow the project staff to collect, store, and share the information gathered for the exposure assessment as described above. You will receive a copy of this form for your records.

I agree to allow my child/ward to participate in this Exposure Assessment and that a blood and urine sample will be collected.
☐ **Yes** ☐ **No**

I understand that I will receive my child/ward's PFAS test results by mail. I will be able to compare some of my child/ward's test results with national averages.
☐ **Yes** ☐ **No**

I understand that project staff will not be able to determine if the PFAS levels in my child/ward's body will impact my health.

☐ **Yes** ☐ **No**

I agree that my child/ward's PFAS test results may be shared with other federal, state, and local environmental and health agencies. Your identifying information will be protected to the extent possible by law should you choose to share your results with other federal, state or local agencies.

☐ **Yes** ☐ **No**

I understand that my child/ward's PFAS test results and questionnaire data may be used for additional analysis in the future.

☐ **Yes** ☐ **No**

I agree to allow my child/ward's blood and urine samples to be saved and used for other PFAS-related tests. If your child/ward's blood and urine are analyzed in the future, we will send you the results.

☐ **Yes** ☐ **No**

I agree to let ATSDR/NCEH keep my child/ward's contact information and contact me in the future for possible follow-up studies (may be research or non-research studies).

☐ **Yes** ☐ **No**

Parent/Guardian's Name:_____
(Printed)

Parent/Guardian's Signature:_____

Respondent ID No:

Child/Ward Name and Age: _____

Date Signed:_____

Street Address:_____

City: _____ State:_____ Zip:_____

Phone number (area code):_____

Project Representative's Name:_____
(Printed)

Project Representative's Signature:_____

Appendix B4: Assent Form

Respondent ID No:

Form Approved
OMB No. 0923-0059
Exp. Date 6/30/2022

PFAS Exposure Assessment, Biological Sampling
Assent Form (12-17 years of age)
Reading Level: 7.0

We are doing a study on chemicals called PFAS. PFAS stands for Per- and Polyfluoroalkyl Substances. Your parents have said that you could take part in the study. We want to give you some information about it so you can decide whether you want to participate.

PFAS have been found in the drinking water supply in (*insert name of city/town/place here*). PFAS are chemicals that were used in a wide range of ways in the United States. PFAS are found in the environment (in the air, soil, and water). And they can stay in the human body for years.

Scientists and doctors don't yet know how PFAS may affect people's health. The first step in figuring that out is measuring the amount of PFAS in the bodies of people who may have come into contact with this contaminated water.

The main goal for this assessment is to find out how much PFAS are in the blood and urine of people in (*Insert name of city/town/place here*) who were exposed to contaminated drinking water. We will conduct this study from (*insert dates here*).

We hope you will agree to be part of this exposure assessment. If you have any questions about this form at any time while filling it out, please don't hesitate to ask. Thank you for considering being in this assessment.

The questionnaire should take about 15 minutes to complete.

Follow these instructions: This form contains information about the assessment and what will happen if you decide to participate. If you agree to take part in this assessment, please sign at the end of the form.

What will happen?

If you choose to be in this assessment, we will draw a small amount of blood from a vein in your arm. First we will clean the skin on your arm by gently rubbing it with alcohol. The needle stick may hurt a little for a few seconds. The person taking the blood will be very careful. You will also be asked to give us the urine sample you collected this morning. Your blood and urine samples will not have your name or other personal information on them. **Your blood and urine will not be tested for HIV, or for the presence of alcohol or drugs and your DNA will not be used for any purpose.**

You have the right to refuse or withdraw.

It is your choice whether to be in this assessment. You can expect the same medical care from your doctor whether you are in the assessment or not in the assessment. There is no penalty if you choose not to be in this assessment. You may stop being in this assessment at any time. If at any time in the future, you would like to have your blood or urine sample destroyed or removed from the assessment, please call (*insert name and phone number of Study coordinator*).

Project Name:_____

Project Coordinator's Name:_____
(Printed)

Project Coordinator's Signature:_____

As described above, you are being asked to participate in an exposure assessment. You may participate by indicating your assent to the items below. You may assent to all, some, or none of the items.

To be in this assessment, please sign your initials in the box next to each item you agree to.

☐ I agree to have a sample of my blood drawn from my arm with a needle.

☐ I agree to give a urine sample.

☐ I agree to allow my blood and urine samples to be saved and used for other PFAS-related tests in the future.

☐ I agree to let ATSDR/NCEH keep my contact information and contact me or my parents in the future for possible follow-up studies (may be research or non-research studies).

I have read the assent form (or someone has read it to me), and I agree to be in this assessment. My initials above show which parts of the assessment I agree to participate in.

Participant's Name:_____
(Printed)

Participant's Signature:_____

Date Signed:_____

Street Address:_____

City: _____ State:_____ Zip:_____

Phone number (area code):_____

Appendix B5: Environmental Sampling Consent Form

Form Approved
OMB No. 0923-0059
Exp. Date 06/30/2022

PFAS Exposure Assessment, Environmental Sampling
Head of Household Consent Form
Flesch-Kincaid Reading Level: 9.7

You are invited to take part in an assessment that will measure the levels of per- and polyfluoroalkyl substances (PFAS) in your drinking water and indoor dust. We are trying to determine the levels of PFAS in the homes of people who may have consumed contaminated drinking water while living near (*Insert name of city/town/place here*).

This letter will explain the procedures, risks, and benefits of our exposure assessment to help you decide if you will take part.

Procedures for the Exposure Assessment

First, we will collect a drinking water sample from the source in your home you and your family most often drink water (e.g. kitchen tap). Then, we will collect indoor dust from up to three locations inside your home.

We will label your water and dust samples with a code only. Only the project coordinator will be able to identify whose house the samples are from.

We will send your water and dust samples to [*insert names of laboratory]* to measure the levels of PFAS. There will be no charge for the sample collection or the laboratory analysis. At the end of the exposure assessment, we will mail your test results to you at the address you provided today. If you would like to talk with an exposure assessment staff person about your results, you can free of charge.

Methods to measure PFAS in water and dust samples are still being developed and improved. It is possible that new tests will be developed in the future that will increase our ability to measure PFAS in water and dust. We would like to keep your water and dust samples so that scientists can test for more things if new tests are developed. To do this, we need your permission.

The Risks of Taking Part in Our Exposure Assessment

You might be inconvenienced. It will take about 15 minutes for us to collect samples from your home. We may need to run water from your well which might lower the volume of water in your well for a brief recharge period.

The Benefits of Taking Part in Our Exposure Assessment

Your participation in this assessment will help us understand the range of PFAS exposure and possible exposure sources in your community. You will find out the levels of PFAS in your home. If we find PFAS levels that may be of concern for your health, we will recommend things you can do to reduce your exposure.

Additional Information:

- **Results**: We will send you a letter with your PFAS level results along with how they compare to any available health based guidelines.
- **Privacy:** All personally identifiable information (PII) (such as name, address, date of birth) gathered for the exposure assessment is private and will not be publicly released. This information is protected to the extent possible by (*insert name of state here*) and federal laws and regulations related to privacy protection. Only trained and authorized project staff will have access to information that can identify you. We will keep all of the information in a secure, locked database or file at all times. Aside from the exposure assessment team, you are the only one who will receive your individual results. In accordance with CDC/ATSDR's policy regarding data access, sampling results that do not include PII may be used by public health researchers for approved research purposes.
- **Voluntary Participation:** Participation in this exposure assessment is completely voluntary. Your choice will not affect your current or future relationships with groups that are part of the exposure assessment. Even if you decide to take part, you are free to quit the exposure assessment at any time. If at any time in the future, you would like to have your samples destroyed or removed from the assessment, please call (*insert name and phone number of Study coordinator*).

Consent Form

By marking the check boxes below and signing this form, you are confirming that you understand the goals of the exposure assessment, and that you agree, of your own free will, to participate. You are also confirming you will allow the project staff to collect, store, and share the information gathered for the exposure assessment as described above. You will receive a copy of this form for your records.

I agree to allow drinking water and indoor dust samples to be collected from my home and analyzed for PFAS.
☐ **Yes** ☐ **No**

I understand that I will receive my environmental sampling results by mail. I will be able to compare some of my results with health advisory levels.
☐ **Yes** ☐ **No**

I agree that my environmental sampling results may be shared with other federal, state, and local environmental and health agencies and local water utilities. Your identifying information will be protected to the extent possible by law should you choose to share your results with other federal, state or local agencies.
☐ **Yes** ☐ **No**

I agree that my indoor dust and water samples may be saved for additional PFAS-related analysis in the future.

☐ **Yes** ☐ **No**

I agree to let ATSDR/NCEH keep my contact information and contact me in the future for possible follow-up studies (may be research or non-research studies).

☐ **Yes** ☐ **No**

Participant's Name:_____
(Printed)

Participant's Signature:_____

Date Signed:_____

Street Address:_____

City: _____ State:_____ Zip:_____

Phone number (area code):_____

Project Representative's Name:_____
(Printed)

Project Representative's Signature:_____

Appendix B6: Biological Testing Tracking Form

Form Approved
OMB No. 0923-0059
Exp. Date 6/30/2022

PFAS EA Biological Testing Tracking Form

ATSDR estimates the average public reporting burden for this collection of information as 20 minutes per response, including the time for moving from station to station at the data collection site and providing a blood and urine sample to the PFAS EA team. An agency may not conduct or sponsor, and a person is not required to respond to collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0923-0059).

PFAS EA Biological Testing Tracking Form:

Participant ID Number_____ Sample Collection Date_____

Adult and Child Participants

- **Please indicate when you have completed the activity at each station**
- **Make sure to bring your sheet of labels with you to each station**
- **Return this form to the check-in area before you leave**
- **Thank you for participating!**

Station	Completion		Comments
Temperature below 100.4°F/ no self-reported symptoms	Yes	No	
Sign In	Yes	No	
Consent/Parental Permission/ Assent Form	Yes	No	
Appointment Made for Questionnaire	Yes	No	
Blood Draw	Yes	No	
Urine Sample Collection	Yes	No	

Appendix C: Sample Collection Logs

Appendix C1: Sample Collection Log Sheet

PFAS Exposure Investigation, blood and urine sampling

DLS Study number **DLS study Name** **SAMPLE COLLECTION LOG SHEET**	
DATE:____________________________	COLLECTION DATE:________________________
VISIT NUMBER:____________________	RECEIVED BY:______________________________

UC= Urine Cup, BLD= Red top (blood tube for serum yield)

Place a label in the label section of the specimen log sheet.

☒ = SPECIMEN COLLECTED ☐ = SPECIMEN NOT COLLECTED **(Please leave blank if specimen is not collected**)

			Comments:				Comments:
	UC				UC		
	BLD				BLD		
LABEL				LABEL			
			Comments:				Comments:
	UC				UC		
	BLD				BLD		
LABEL				LABEL			
			Comments:				Comments:
	UC				UC		
	BLD				BLD		
LABEL				LABEL			

LABEL			Comments:	LABEL			Comments:
	UC				UC		
	BLD				BLD		
LABEL			Comments:	LABEL			Comments:
	UC				UC		
	BLD				BLD		

Appendix C2: Environmental Sample Collection Form

Form Approved
OMB No. 0923-0059
Exp. Date 06/30/2022

Environmental Sample Collection Form

ATSDR estimates the average public reporting burden for this collection of information as 15 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0923-0059).

EA ID:_____

Date and time of Sample Collection:_____

Address of Sample Collection:_____

Notes:

Samples Collected:

☐ Tap Water – Sample ID _____

Tap Water Sample Location Description _____

☐ Tap Water 2 – Sample ID _____

Tap Water 2 Sample Location Description _____

☐ Tap Water Blank – Sample ID _____

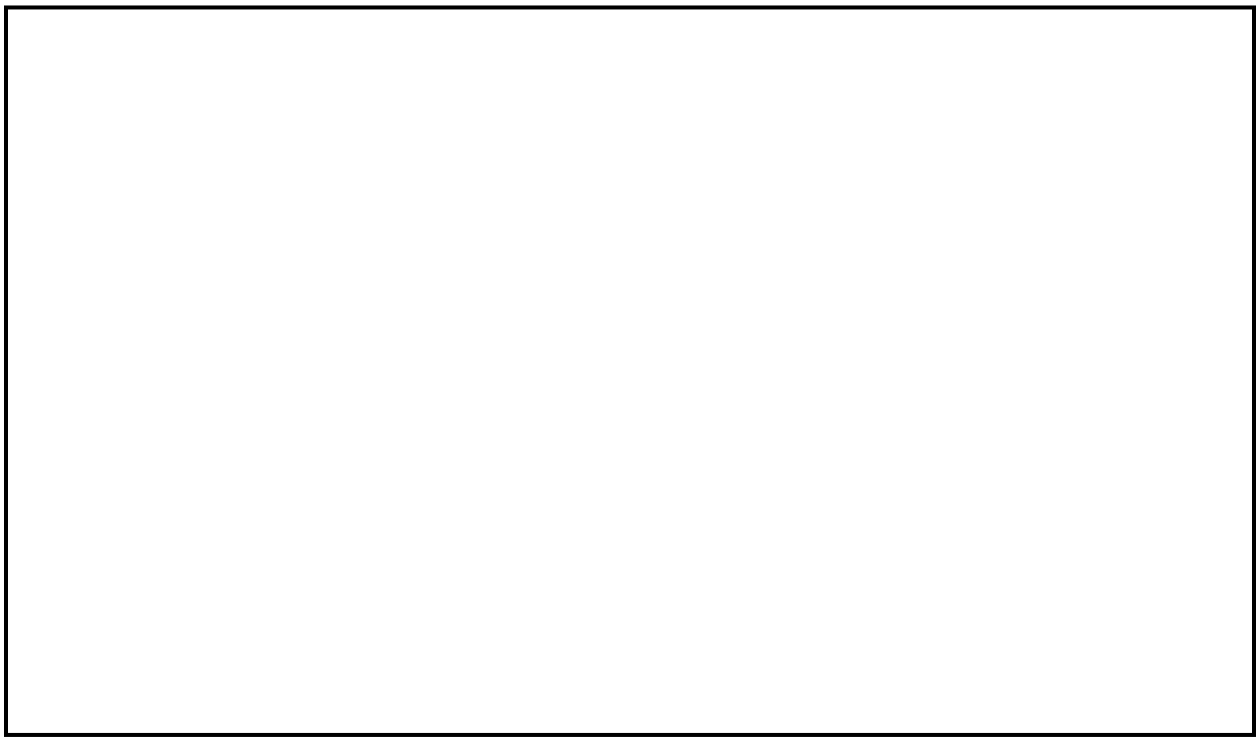
☐ Indoor Dust – Sample ID _____

Indoor Dust Sample Location Description _____

☐ Indoor Dust Blank – Sample ID _____

Data Collection Technician:_____ _____
Printed Name Signature

Location of Samples Inside the Home:



Appendix D: Chain of Custody Forms

Chain of Custody Forms

NCEH/Chamblee Sample Logistics Chain of Custody
Sample Shipping/Receiving Form

1. Project:_____ **Project #:**_____

2. Sender	3. Carrier	4. Receiver
Signature_____ Date_____ Sent from_____	Company_____ Date_____ Pkg Tracking No._____	Date_____ Lab Custodian Signature_____ Date_____ Condition upon Receipt _____ _____

5. Shipment Description

Number of packages_____
Sealed (yes or no)_____
Types of containers_____

Condition prior to shipment_____
_____
_____

6. Contents

Sample I.D. Number	Type of Sample	Legal Seal Intact? (yes or no)	Legal Seal No. (if any)	Condition (damaged, loss of liquid, etc.)

Please sign and Fax or email to Sample Logistics 770-488-4301 (fax) NCEHSampleLogistics@cdc.gov

Appendix E: Urine Collection Instructions

Urine Collection Instructions

PFAS Exposure Assessment
Urine Collection Instructions
Flesch-Kincaid Reading Level (without agency or chemical names): 8.5

When you receive the urine collection kit, please put the freezer pack in the freezer so you can use it to transport your sample to the collection location. Please collect a sample of your first morning urine void on the day of your scheduled blood collection appointment. Write down the date and time of the collection. Please use the following instructions:

Step 1: When you get up in the morning, collect a sample of your urine in the provided cup the first time you use the bathroom. Please try to fill at least one quarter of the cup.

- Make sure to wash your hands with **water only** before collecting your sample. Do not use any soap, lotion, or other personal care products.
- Put on the provided gloves before collecting your sample.

Step 2: Cap the urine collection cup and seal in the provided plastic bag.

Step 3: Record the date and time of your collected urinary sample on your urine collection log.

- If some of the sample spills, or you forget to record the time of collection your sample will still be able to be used for the investigations. Please write down any comments you want us to know about on your collection log.

Step 4: Place your sample in your refrigerator until it is time to go to your blood collection appointment.

Step 5: Bring your urine sample, inside the provided cooler box packed with the frozen ice pack, and your urine collection log to your blood collection appointment.

Appendix F: Questionnaire

Appendix F1: Adult Questionnaire

Respondent ID No:

Form Approved
OMB No. 0923-0059
Exp. Date 06/30/2022

PFAS Exposure Assessment,
ADULT (≥ 18 years of age) Questionnaire

Note: Questionnaire will be administered by Exposure Assessment staff.

Script: Hello. As a part of the PFAS Exposure Assessment, I'm going to ask you some questions to learn about things that might impact your exposure to PFAS. Before I do so, I want to tell you about why we are collecting this information, and how we will protect your privacy. The statement I'm about to read you is required by the Privacy Act of 1974.

Note: The Privacy Act Statement below will be read to the participants and they will be provided a hard copy (see Appendix B of protocol).

"PRIVACY ACT STATEMENT:
ATSDR has the authority under Section 8006 of the Consolidated Appropriations Act of 2018 and the "Comprehensive Environmental Response, Compensation, and Liability Act of 1980" (CERCLA) as amended by "Superfund Amendments and Reauthorization Act of 1986" (SARA) to collect this information from you. We are conducting this assessment to evaluate your exposure to per- and polyfluoroalkyl substances, also called PFAS. ATSDR is collecting information from you to learn more about things that might impact your exposure to PFAS, and so that we can send your results back to you. ATSDR will share these records with the National Center for Environmental Health (NCEH), who may provide research or support staff and laboratory or statistical analysis. ATSDR may also disclose these records to its contractors in order to locate individuals who have been exposed to PFAS and to conduct interviews and other research activities. The contractor must comply with the requirements of the Privacy Act to protect your records. Providing this information is voluntary. ATSDR needs this information for you to take part in the assessment. ATSDR may not include incomplete records in the data analysis. ATSDR needs up-to-date contact information to send you your results."

Now I'm going to ask you some questions. Answering these questions and collecting your blood and urine should take about 30 minutes.

Name (last name, first name):_____

Date of Birth: _____ (Month/Day/Year) **Sex:** Male Female

Address: _____

Height (inches):_____ **Weight (pounds):**_____

1. Do you consider yourself to be Hispanic, Latino, or of Spanish origin?

   ☐ Yes

   ☐ No

2. Which one or more of the following would you say is your race? (select all that apply)

   ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American

   ☐ Native Hawaiian or Other Pacific Islander ☐ White

3. How long have you lived at your current address?

   ☐ _____ (months) _____ (years)

   ☐ Don't Know

   ☐ Refused to Answer

4. Is this your full-time residence?

   ☐ Yes

   ☐ No

   If No, how much time do you reside at this address?

   ___ Days per week ___ Weeks per month ___ Months per year ☐ Not Applicable

   ☐ Don't know

   ☐ Refused to answer

5. Please list the places you have lived for the last 20 years:

Location (City, State)	Dates (MM/YYYY) of Residence

6. Has your doctor ever told you that you have:

   Kidney Disease ☐ Yes ☐ No ☐ Don't Know ☐ Refused to Answer

Questions 7 – 8 are for adult (≥18 years) females only.

7. Do you have any biological children?

   ☐ Yes

   If Yes, how many? ____

   ☐ No

   ☐ Don't Know

   ☐ Refused to Answer

8. Have you ever breastfed?

   ☐ Yes

   If Yes, for how long (total for all children)? _____ (months)

   ☐ No

   ☐ Don't Know

   ☐ Refused to Answer

9. How frequently do you donate blood and/or plasma (select one)?

   ☐ Once every eight weeks ☐ A few times per year ☐ Once per year ☐ Rarely ☐ Never ☐ Don't Know ☐ Refused to Answer

10. What is your current main source of drinking water in your home? (select one)

    ☐ Public water system (City or County) Provide name: _____

    ☐ Private Well

    ☐ Community well

    ☐ Bottled Water

    ☐ Don't Know

    ☐ Refused to answer

11. If you have a private well, has it been tested for PFAS?

    ☐ Yes

    ☐ No

    ☐ Don't Know

    ☐ Refused to Answer

If yes, do you know the date it was tested, who did the testing, and the results of the PFAS testing?

Date (month/year)	Company/Government	PFAS Results

12. During the time you lived in a home served by the water source identified above, on average how many 8-oz cups of water or beverages prepared with tap water did you drink while at home per day?

    ____ (8-oz cups)

    ☐ Didn't drink tap water

    ☐ Don't know

    ☐ Refused to answer

    Note: 1 cup = 8-oz; 2 cups = 1 pint (16-oz); 4 cups = 1 quart (32-oz); 16 cups = 1 Gallon (128-oz)

13. Which, if any, water filter or treatment device(s) are you currently using to filter or treat the tap water you drink? (select all that apply)

    ☐ Whole house carbon filter
    ☐ Under the sink carbon filter
    ☐ Faucet filter
    ☐ Pitcher filter
    ☐ Refrigerator filter
    ☐ None, use bottled water only
    ☐ Reverse osmosis (RO) system
    ☐ Other, specify:_____
    ☐ Don't Know
    ☐ Refused to answer
    ☐ Not Applicable
    ☐ None, no filter or treatment device used

14. How often is your home cleaned (e.g. sweep, mop, vacuum)?

    ☐ Every day

    ☐ Once per week

    ☐ Once per month

    ☐ A few times per year

    ☐ Rarely

    ☐ Never

- ☐ Don't know
- ☐ Refused to Answer

15. How frequently do you apply stain resistant products (i.e. Scotchguard – sometimes applied to carpeting or upholstered furniture) in your home?
    - ☐ Every day
    - ☐ Once per week
    - ☐ Once per month
    - ☐ A few times per year
    - ☐ Rarely
    - ☐ Never
    - ☐ Don't know
    - ☐ Refused to Answer
16. What type of flooring do you have in your living room?

    ☐ Hardwood ☐ Tile ☐ Laminate ☐ Carpet ☐ Vinyl ☐ Other
17. What type of flooring do you have in your kitchen?

    ☐ Hardwood ☐ Tile ☐ Laminate ☐ Carpet ☐ Vinyl ☐ Other
18. What type of flooring do you have in your bedrooms?

    ☐ Hardwood ☐ Tile ☐ Laminate ☐ Carpet ☐ Vinyl ☐ Other
19. How frequently do you come into direct contact with the soil (e.g. gardening, digging, farming, building, repairing, etc…) in [*insert affected area/sampling frame/locations*] (select one)?
    - ☐ Every day
    - ☐ Once per week
    - ☐ Once per month
    - ☐ A few times per year
    - ☐ Rarely
    - ☐ Never
    - ☐ Don't know
    - ☐ Refused to Answer

20. If you come into direct contact with soil, at what address or place (e.g. daycare) does this occur (list all locations)? If you come into contact with soil at more than one location, what percentage of your total contact with soil happens at each location (percentages should sum to 100%)?

    _____

    _____

    ☐ Don't know

    ☐ Refused to answer

    ☐ Not Applicable

21. Do you eat vegetables or fruits grown at your home or other locally grown vegetables or fruits from [*insert affected area/sampling frame/locations*]?

    ☐ Yes

    ☐ No

    ☐ Don't Know

    ☐ Refused to Answer

    If yes, how often do you eat locally grown or home grown fruits or vegetables? (select one)

    ☐ Every day

    ☐ Once per week

    ☐ Once per month

    ☐ A few times per year

    ☐ Rarely

    ☐ Never

    ☐ Don't know

    ☐ Refused to Answer

22. Do you eat fish locally caught from ponds, lakes or rivers in [*insert affected area/sampling frame/locations*]?

    ☐ Yes

    ☐ No

    ☐ Don't Know

    ☐ Refused to Answer

If yes, how often do you eat locally-caught fish (select one)?

- ☐ 3 times per week or more
- ☐ A few times per month
- ☐ A few times per year
- ☐ Rarely
- ☐ Never
- ☐ Don't know
- ☐ Refused to Answer

23. How often you consume milk from animals raised on farms within [*insert affected area/sampling frame/locations*]?

- ☐ Every day
- ☐ Once per week
- ☐ Once per month
- ☐ A few times per year
- ☐ Rarely
- ☐ Never
- ☐ Don't know
- ☐ Refused to Answer

24. How often you consume fast food?

- ☐ Every day
- ☐ Once per week
- ☐ Once per month
- ☐ A few times per year
- ☐ Rarely
- ☐ Never
- ☐ Don't know
- ☐ Refused to Answer

25. Please select any changes that have occurred in the last 12 months:

- ☐ My drinking water source changed from private well to public water system.
- ☐ My drinking water source changed from private well to bottled water.
- ☐ My drinking water source changed from public water system to bottled water.
- ☐ I have installed a filtration system on my private well.
- ☐ My drinking water source changed in some other way (please explain):

  _____

- ☐ My consumption of locally caught fish has increased.
- ☐ My consumption of locally caught fish has decreased.
- ☐ My consumption of locally grown vegetables has increased.
- ☐ My consumption of locally grown vegetables has decreased.
- ☐ Other behaviors related to PFAS exposure (please explain):

  _____

- ☐ Refused to Answer

26. Please list your job title and where you have worked for the past 20 years. Please also identify the main source of drinking water used at each workplace (public water, private well, community well, bottled water), if known.

- ☐ Not Applicable
- ☐ Refused to Answer

Company Name	Workplace location	Job Title	Year Started	Year Ended	Drinking Water Source

27. During the time you worked, on average how many 8-oz cups of tap water or beverages prepared with tap water did you drink while at work per day?

    ☐ ____ (8-oz cups)

    ☐ Didn't drink tap water

    ☐ Not applicable

    ☐ Don't know

    ☐ Refused to answer

    Note: 1 cup = 8-oz; 2 cups = 1 pint (16-oz); 4 cups = 1 quart (32-oz); 16 cups = 1 Gallon (128-oz)

28. Did you in the last 20 years work in any of the following industries? (select all that apply)

    ☐ Manufacturing of nonstick cookware such as Teflon® coated pots/pans

    ☐ Manufacturing of stain resistant coatings (e.g. Scotchguard®) used on carpets, upholstery, and other fabrics

    ☐ Manufacturing of water resistant clothing (e.g. Gore-Tex®)

    ☐ Manufacturing of aqueous film forming foam (AFFF)

    ☐ Manufacturing/Processing/Formulating facility of PFAS chemicals (3M, DuPont, Chemours, etc)

    ☐ Military

    ☐ Aviation

    ☐ Firefighting

    ☐ Never worked in the industries listed above

    ☐ Refused to answer

29. If you worked in any of the industries listed in question 28, worked in the production of any of the consumer products listed in Table 1 (below), worked with PFAS-containing substances as described in Table 1 under the header "Industrial Uses," please provide your job title, brief job description, and duration of your work.

Job Title	Job Description	Years Worked

30. Have you ever had your blood tested for any PFAS?

- ☐ Yes
- ☐ No
- ☐ Don't Know

If yes, when, where, and what was the result?

Date of PFAS Test	Who conducted test?	Results

31. Is there anything else you want to tell us about your PFAS exposures?

_____

Table 1. Common Uses of PFAS

Consumer Products	Industrial Uses
Cookware (Teflon®, Nonstick)	Photo-Imaging
Fast Food Containers	Metal Plating
Candy Wrappers	Semiconductor Coatings
Microwave Popcorn Bags	Aviation Hydraulic Fluids
Personal Care Products (Shampoo, Dental Floss)	Medical Devices
Cosmetics (Nail Polish, Eye Makeup)	Fire-Fighting Foam
Paints and Varnishes	Insect Baits
Stain Resistant Carpet	Printer and Copy Machine Parts
Stain Resistant Chemicals (Scotchguard®)	Chemically Driven Oil Production
Water Resistant Apparel (Gore-Tex®)	Textiles, Upholstery, Apparel and Carpets
Cleaning Products	Paper and Packaging
Electronics	Rubber and Plastics

*** THANK YOU ***

Appendix F2: Child Questionnaire

Respondent ID No:

Form Approved
OMB No. 0923-0059
Exp. Date 6/30/2022

PFAS Exposure Assessment,
Child (<18 years or age of majority) Questionnaire

Note: Questionnaire will be administered by Exposure Assessment staff to the child. However, a parent or legal guardian can help answer all questions on behalf of the child. In particular, the parent or legal guardian may be asked to assist in completion of questions related to infant feeding history and places of residence.

Script: Hello. As a part of the PFAS Exposure Assessment, I'm going to ask you some questions to learn about things that might impact your exposure to PFAS. Before I do so, I want to tell you about why we are collecting this information, and how we will protect your privacy. The statement I'm about to read you is required by the Privacy Act of 1974.

Note: The Privacy Act Statement below will be read to the participants and they will be provided a hard copy. Privacy Act Statement is available in Appendix B.

"PRIVACY ACT STATEMENT:
ATSDR has the authority under Section 8006 of the Consolidated Appropriations Act of 2018 and the "Comprehensive Environmental Response, Compensation, and Liability Act of 1980" (CERCLA) as amended by "Superfund Amendments and Reauthorization Act of 1986" (SARA) to collect this information from you. We are conducting this assessment to evaluate your exposure to per- and polyfluoroalkyl substances, also called PFAS. ATSDR is collecting information from you to learn more about things that might impact your exposure to PFAS, and so that we can send your results back to you. ATSDR will share these records with the National Center for Environmental Health (NCEH), who may provide research or support staff and laboratory or statistical analysis. ATSDR may also disclose these records to its contractors in order to locate individuals who have been exposed to PFAS and to conduct interviews and other research activities. The contractor must comply with the requirements of the Privacy Act to protect your records. Providing this information is voluntary. ATSDR needs this information for you to take part in the assessment. ATSDR may not include incomplete records in the data analysis. ATSDR needs up-to-date contact information to send you your results."

Now I'm going to ask you some questions. Answering these questions and collecting your blood and urine should take about 30 minutes.

Child's Name:_____

Date of Birth: _____ (Month/Day/Year) **Sex:** Male Female

Address: _____

Height (inches):_____ **Weight (pounds):**_____

1. What is your birth order (e.g. first, second, or third born etc.)?

   _____

   ☐ Don't know

   ☐ Refused to answer

2. Do you consider yourself to be Hispanic, Latino, or of Spanish origin?

   ☐ Yes

   ☐ No

3. Which one or more of the following would you say is your race? (select all that apply)

   ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American

   ☐ Native Hawaiian or Other Pacific Islander ☐ White

4. How many years have you lived in your current home?

   Note: If parent is assisting in response, please ask how long the child has lived in the home.

   _____ (months) _____ (years)

   ☐ Don't know

   ☐ Refused to answer

5. Is this your full-time residence?

   ☐ Yes

   ☐ No

   If No, how much time do you reside at this address?

   ___ Days per week ___ Weeks per month ___ Months per year ☐ Not Applicable

   ☐ Don't know

   ☐ Refused to answer

6. How many 8-oz cups of tap water or beverages prepared with tap water do you drink per day at home?

   ☐ _____ (8-oz cups)

   ☐

   ☐ Don't drink tap water

☐ Don't know

☐ Refused to answer

Note: 1 cup = 8-oz; 2 cups = 1 pint (16-oz); 4 cups = 1 quart (32-oz); 16 cups = 1 Gallon (128-oz)

7. How frequently do you play in or touch the soil or dirt in [*insert affected area/sampling frame/locations*]? (Select one)

☐ Every day ☐ A few times per week ☐ A few times per month

☐ Rarely ☐ Never ☐ Don't know

☐ Refused to answer

8. If you play in or touch the soil or dirt, at what address or place (e.g. daycare) does this occur (list all locations)? If you play in or touch the soil or dirt at more than one location, what percentage of your total contact with soil happens at each location (percentages should sum to 100%)?

_____

_____

☐ Don't know

☐ Refused to answer

☐ Not Applicable

9. During the growing season, how often do you eat vegetables or fruits grown at your home or other locally grown vegetables or fruits from (*insert affected area/sampling frame/locations*)? (Select one)

☐ Every day

☐ Once per week

☐ Once per month

☐ A few times per year

☐ Rarely

☐ Never

☐ Don't know

☐ Refused to Answer

10. How often do you eat fish locally caught from ponds, lakes or rivers in (*insert affected area/sampling frame/locations*)? (Select one)

    ☐ Every day

    ☐ Once per week

    ☐ Once per month

    ☐ A few times per year

    ☐ Rarely

    ☐ Never

    ☐ Don't know

    ☐ Refused to Answer

11. How often do you consume milk from animals raised on farms within (*insert sampling/affected area/location or list of affected farms*)?

    ☐ Every day

    ☐ Once per week

    ☐ Once per month

    ☐ A few times per year

    ☐ Rarely

    ☐ Never

    ☐ Don't know

    ☐ Refused to Answer

12. Did you drink formula <u>reconstituted with tap water</u> as an infant?

    ☐ Yes

    If Yes, for how long? ____ (months)

    ☐ No

    ☐ Don't know

    ☐ Refused to answer

    ☐ Not Applicable

13. Are you currently, or were you previously breastfed?

    ☐ Yes

    If Yes, for how long? ____ (months)

    ☐ No

    ☐ Don't know

    ☐ Refused to answer

    ☐ Not Applicable

14. Are you currently attending, or have you attended, a school or daycare?

    ☐ Yes

    ☐ No

    ☐ Don't know

    ☐ Refused to answer

    ☐ Not Applicable

15. Please provide the name of your school or daycare and duration you attended each school/daycare, as well as the main drinking water source (public water, private well, community well, bottled water, water from home, don't know), if known.

Name of School/ Daycare	Address	Duration Attended		Located in Affected area?		Main Drinking Water Source
		Start Year	End Year	Yes	No	

16. How many 8-oz cups of water or beverages prepared with tap water do you drink per day at day care/school?

    _____

    ☐ Don't drink tap water

    ☐ Don't know

    ☐ Refused to answer

    Note: 1 cup = 8-oz; 2 cups = 1 pint (16-oz); 4 cups = 1 quart (32-oz); 16 cups = 1 Gallon (128-oz)

17. Have you ever had your blood tested for PFAS?

    ☐ Yes

    ☐ No

    ☐ Don't Know

    If yes, when, where, and what was the result?

Date of PFAS Test	Who conducted test?	Results

18. Is there anything else you want to tell us about your PFAS exposures?

    _____

*** THANK YOU***

Appendix G: Results Letters

Appendix G1: Results Letter Biological Sampling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

[*Insert Date*]

[*Name*
Address
City, State, Zip code]

Dear [*Insert Name*],

Thank you for being a part of the CDC/ATSDR PFAS exposure assessment. We are grateful for the time and effort you gave to this project. We tested your blood and urine for per- and polyfluoroalkyl substances (PFAS). This letter is to give you your test results along with how they compare to measurements from others. You may share these results with your doctor if you would like – it's your choice, however we note that there are no clinical guidelines for interpreting PFAS blood and urine levels. Research to better understand the health effects associated with PFAS exposure is ongoing, but scientists are not currently certain of how PFAS levels in the blood can affect a person's health. More research is needed to clarify the risks posed by PFAS exposure.

The remainder of this letter summarizes the results of your blood and urine sample results. As a reminder, only a small subset of urine samples collected from study participants have been analyzed at this time. If your results are not provided in this letter, they were not randomly selected for the initial analysis of 10% of urine samples. Should ATSDR decide to analyze all urine samples based on the results of the initial 10% analysis, ATSDR will mail you a summary of your results at a later date.

The Results of Your Blood Test

Table 1 provides a list of all the specific PFAS that we measured in your blood. The table also lists the acronyms for the PFAS.

Table 2 shows the concentration of specific PFAS we found in your blood. Your result is in units of micrograms per liter (µg/L). One µg/L equals one part per billion, equivalent to about one drop of ink in a large tanker ship. The table also compares your PFAS levels to people in the United States, namely, the geometric mean and 95th percentile values, when available.

Table 3 shows your results compared to results from other members in your community who also participated in this assessment. These are preliminary results for your community. Our final report will include a more detailed analysis.

The Results of Your Urine Test (Include only if urine sampling was conducted)

Table 4 provides a list of all the specific PFAS that we measured in your urine. The table also lists the acronyms for the PFAS.

Table 5 shows the concentration of specific PFAS we found in your urine. Your result is in units of micrograms per liter (µg/L). One µg/L equals one part per billion, equivalent to about one drop of ink in a large tanker ship. The table also shows range of PFAS levels for people in the United States, namely, the geometric mean and 95th percentile values, when available.

Table 6 shows your results compared to results from other members in your community who also participated in this assessment. These are preliminary results for your community. Our final report will include a more detailed analysis.

Suggestions for Interpreting the Results

The tables in this letter provide a lot of information. To fully understand all this information, it helps to know about a survey called NHANES (the National Health and Nutrition Examination Survey).

Every year, the CDC examines about 5,000 people from across the country. As part of the survey, CDC takes blood and urine samples and tests them for chemicals including PFAS. The NHANES blood and urine tests for PFAS chemicals come from a representative sample of members of the U.S. population.

Having a representative sample of the U.S. population means NHANES helps CDC estimate, for example, the levels of PFAS in the U.S. population. That is how we can compare the results of your blood and urine tests to reference values for people in the United States.

Now, let's talk about interpreting your results presented in Tables 2, 3, 5, and 6. The diagrams below can help you understand the data we are giving you.

This column lists each different PFAS chemical that we measured in your blood or urine.

This column shows the geometric mean ("average") of results from the 2015-–2016 NHANES survey (Table 2 and Table 5) or your community (Table 3 and Table 6).

PFAS	Your Level in µg/L	Geometric Mean in µg/L	95th percentile in µg/L
PFDA			

This column shows the concentration that we found in your blood.

This column shows the 95th percentile of results from the 2015–2016 NHANES survey (e.g., Table 2) or your community (e.g., Table 3).

A couple of important notes:

- If your PFAS result is in **bold**, then it is higher than the 95th percentile. When comparing to the U.S. population, this means that your result is higher than what is measured in most people in the United States. When comparing to your community, this means that your result is higher than that measured in most people living in your community.
- If your result is not in bold, then it is lower than 95th percentile and is lower than what is measured in either most people in the United States or most people in your community.

Table 1: List of PFAS Measured in Blood and Corresponding Acronyms

PFAS	Acronym
perfluorodecanoic acid	PFDA
perfluorohexane sulfonic acid	PFHxS
perfluorononanoic acid	PFNA
total perfluorooctanoic acid	PFOA
ammonium perfluorooctanoate	n-PFOA
mixture of perfluoro-5-methylheptanoic acid isomers	Sb-PFOA
total perfluorooctane sulfonic acid	PFOS
sodium perfluoro-1-octanesulfonate	n-PFOS
mixture of sodium perfluoro-5-methylheptane sulfonate isomers	Sm-PFOS
N-methyl perfluorooctanesulfonamidoacetic acid	MeFOSAA
perfluoroundecanoic acid	PFUnA

Table 2: Your PFAS Blood Levels Compared to What Has Been Measured in the General U.S. Population

PFAS	Your Level in µg/L	U.S. Population (all ages) Geometric Mean in µg/L[a]	U.S. Population (all ages) 95th percentile in µg/L[a]
PFDA	**[insert level]**	**[insert value]**	**[insert value]**
PFHxS			
PFNA			
PFOA[b]			
n-PFOA			
Sb-PFOA			
PFOS[b]			
n-PFOS			
Sm-PFOS			
MeFOSAA			
PFUnA			

Note: U.S. Population results above from NHANES 2015-2016.
ND – Not detected (limit of detection = 0.1 µg/L)
** Geometric mean was not calculated because not enough people had results that were detectable.*
***95th percentile was below the limit of detection, 0.1 µg/L.*
[a]Source: CDC. Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables, January 2019. Available at: https://www.cdc.gov/exposurereport/
[b]PFOA was calculated by adding n-PFOA and Sb-PFOA results. PFOS was calculated by adding n-PFOS and Sm-PFOS results. When one ND and one measured value are reported, a value of 0.07 µg/L is substituted for ND values, which equals 0.1 µg/L (the limit of detection) divided by the square root of two.

Table 3: Your PFAS Blood Levels Compared to Other People Who Participated in This Assessment from [insert community name]

PFAS	Your Level (µg/L)	Geometric Mean in your Community in µg/L[a]	95th Percentile in your Community in µg/L[a]
PFDA	**[insert level]**	**[insert value]**	**[insert value]**
PFHxS			
PFNA			
PFOA[b]			
n-PFOA			
Sb-PFOA			
PFOS[b]			
n-PFOS			
Sm-PFOS			
MeFOSAA			
PFUnA			

ND- Not detected (limit of detection = 0.1 µg/L)

** Geometric mean was not calculated because not enough people had results that were detectable.*

***95th percentile was below the limit of detection, 0.1 µg/L.*

[a] The statistics shown here are based on results from XX participants in your community.

[b]PFOA was calculated by adding n-PFOA and Sb-PFOA results. PFOS was calculated by adding n-PFOS and Sm-PFOS results. When one ND and one measured value are reported, a value of 0.07 µg/L is substituted for ND values, which equals 0.1 µg/L (the limit of detection) divided by the square root of two.

(Only include Tables 4-6 if urine sampling was conducted.)

Table 4: List of PFAS Measured in Urine and Corresponding Acronyms

PFAS	Acronym
perfluorobutane sulfonic acid	PFBS
perfluoroheptane sulfonic acid	PFHpS
perfluorohexane sulfonic acid	PFHxS
total perfluorooctane sulfonic acid	PFOS
sodium perfluoro-1-octanesulfonate	n-PFOS
mixture of sodium perfluoro-5-methylheptane sulfonate isomers	Sm-PFOS
perfluorobutanoic acid	PFBA
perfluoropentanoic acid	PFPeA
perfluorohexanoic acid	PFHxA
perfluoroheptanoic acid	PFHpA
total perfluorooctanoic acid	PFOA
ammonium perfluorooctanoate	n-PFOA
mixture of perfluoro-5-methylheptanoic acid isomers	Sb-PFOA
perfluorononanoic acid	PFNA
perfluorodecanoic acid	PFDA
perfluoroundecanoic acid	PFUnA
hexafluoropropylene oxide dimer acid	HFPO-DA (GenX)
4,8-dioxa-3H-perfluorononanoic acid	DONA
9-chlorohexadecafluoro-3-oxanone-1-sulfonic acid	9Cl-PF3ONS

Table 5: Your PFAS Urine Levels Compared to What Has Been Measured in the General U.S. Population

PFAS	Your Level in µg/L	U.S. Population (all ages) Geometric Mean in µg/L[a]	U.S. Population (all ages) 95th percentile in µg/L[a]
PFBS	**[insert level]**	**[insert value]**	**[insert value]**
PFHpS			
PFHxS			
PFOS[b]			
n-PFOS			
Sm-PFOS			
PFBA			
PFPeA			
PFHxA			
PFHpA			
PFOA[b]			
n-PFOA			
Sb-PFOA			
PFNA			
PFDA			
PFUnA			
HFPO-DA (GenX)			
DONA			
9Cl-PF3ONS			

Note: Above results from NHANES 2013–2014.

ND – Not detected (limit of detection = 0.1 µg/L)

** Geometric mean was not calculated because not enough people had results that were detectable.*

***95th percentile was below the limit of detection, 0.1 µg/L.*

[a] Source: Calafat, A., Kato, K, Hubbard, K., et al (2019). Legacy and alternative per- and polyfluoroalkyl substances in the U.S. general population: Paired serum-urine data from the 2013–2014 National Health and Nutrition Examination Survey. Environment International, 131.

[b] PFOA was calculated by adding n-PFOA and Sb-PFOA results. PFOS was calculated by adding n-PFOS and Sm-PFOS results. When one ND and one measured value are reported, a value of 0.07 µg/L is substituted for ND values, which equals 0.1 µg/L (the limit of detection) divided by the square root of two.

Table 6: Your PFAS Urine Levels and the Range of PFAS Urine Levels Found in Other People in your Community Who Were Tested

PFAS	Your Level in µg/L	Range of levels in your community (10% of study participants) in µg/L
PFBS	**[insert level]**	**[insert minimum result or ND and maximum detected concentration]**
PFHpS		
PFHxS		
PFOS[a]		
n-PFOS		
Sm-PFOS		
PFBA		
PFPeA		
PFHxA		
PFHpA		
PFOA[a]		
n-PFOA		
Sb-PFOA		
PFNA		
PFDA		
PFUnA		
HFPO-DA (GenX)		
DONA		
9Cl-PF3ONS		

ND – Not detected (limit of detection = 0.1 µg/L)

[a]PFOA was calculated by adding n-PFOA and Sb-PFOA results. PFOS was calculated by adding n-PFOS and Sm-PFOS results. When one ND and one measured value are reported, a value of 0.07 µg/L is substituted for ND values, which equals 0.1 µg/L (the limit of detection) divided by the square root of two.

What about Your Exposure? [Include only one category below]

Results from your blood sample:

[Use for letters when all results are <u>below</u> applicable NHANES and community reference values [i.e., 95th percentiles)]

- Your sample showed that your PFAS levels are within the values of what has been reported for people living in US and in the [insert community name] community.
- Please see the included handouts for more information about PFAS and how to reduce your exposure.

[Use for results when at least one PFAS was measured above applicable NHANES and community-specific reference values [i.e., 95th percentiles]

- While your results were above the 95th percentile for people living in the United States for [insert list of PFAS chemical names for which the participant's results were above the NHANES 95th percentile] and above the 95th percentile in the [insert community name] for [insert list of PFAS chemical names for which the participant's results were above the community 95th percentile], it is important to remember that scientists do not know what these levels mean for your health.
- Please see the included handouts for more information about PFAS and how to reduce your exposure.

[Use for results when all PFAS are below applicable NHANES reference values, but at least one PFAS is above community reference values]

- Your results were below the 95th percentile for people living in the United States but above the 95th percentile in the [insert community name] for [insert list of PFAS chemical names for which the participant's results were above the community 95th percentile]. It is important to remember that scientists do not know what these levels mean for your health.
- Please see the included handouts for more information about PFAS and how to reduce your exposure.

[Use for results when at least one PFAS is above applicable NHANES reference values, but when all PFAS are below community reference values]

- Your results were below the 95th percentile for people living in the [insert community name] but above the 95th percentile for the United States for [insert list of PFAS chemical names for which the participant's results were above the NHANES 95th percentile]. It is important to remember that scientists do not know what these levels mean for your health.
- Please see the included handouts for more information about PFAS and how to reduce your exposure.

Results from your urine sample (only included if urine samples were analyzed):

[Use for letters when all urine results are below available NHANES reference values [i.e., 95th percentiles)]

- Your sample showed that your PFAS levels are within the values of what has been reported for people living in the United States.
- Please see the included handouts for more information about PFAS and how to reduce your exposure.

[Use for letters when at least one PFAS was measured in urine above applicable NHANES reference values [i.e., 95th percentiles)]

- While your results were above the 95th percentile for people living in the United States for [insert list of PFAS chemical names for which the participant's results were above the NHANES 95th percentile], it is important to remember that scientists do not know what these levels mean for your health.
- Please see the included handouts for more information about PFAS and how to reduce your exposure.

What Do These Results Mean to Your Health?

These results tell you how much PFAS is currently present in your body from all sources combined, such as water, food, and other environmental sources. You can compare your results with others from your community and also with people across the United States.

Although a number of scientific studies have been completed, outcomes of these studies have not been consistent and additional factors still need to be considered. More research is needed to fully understand the possible negative health effects related to PFAS exposure. As of today, studies in humans and animals have shown that some PFAS may:

- Interfere with the body's natural hormones;
- Increase cholesterol levels;
- Affect the immune system; and
- Increase the risk of some cancers.

While numerous studies have examined possible relationships between levels of PFAS in blood and harmful health effects in people and animals, most of these studies analyzed only a small number of chemicals in the PFAS family. To date, scientists have learned that not all PFAS have the same health effects.

Some (but not all) PFAS build up in the human body. The levels of many PFAS go down slowly over time once exposure stops. Scientists are studying how different amounts of PFAS in the body over time might affect human health. In addition, investigators are actively studying whether being exposed to multiple PFAS chemicals at the same time have health effects that are additive.

It is important to remember that the likelihood of adverse health effects depends on several factors, such as the concentration of PFAS, as well as the frequency and duration of exposure. More frequent exposure can increase risk. Higher concentration and length of time exposed can lead to increased risk.

PFAS are a complex group of chemicals and there is still a lot to learn about how they may affect health. Your participation in this study, when combined with others, may eventually help us better understand any potential health risks from PFAS exposure in the future.

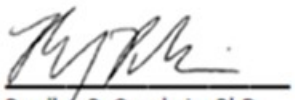
Next Steps

Please call CAPT Tarah Somers at 617-918-1493 to discuss any questions you may have. Your personal test results will be kept private. ATSDR will analyze all the data from your community to determine what they tell us about exposure in the community and will provide a more detailed analysis in our final report. Your results may be combined with other participants in your community and used in the report; however, no one will be able to identify you.

More Information

- If you or your doctor have any medically related questions about these results or wish to further discuss these results, please contact CAPT Tarah Somers RN, MSN/MPH by phone at 617-918-1493 or email at tvs4@cdc.gov. Please also refer to the enclosed clinician guidelines for additional information.
- For additional information about PFAS from the CDC and the Agency for Toxic Substances and Disease Registry, please visit: http://www.atsdr.cdc.gov/pfas/index.html.
- For additional information about PFAS from the U.S. Environmental Protection Agency, please visit: https://www.epa.gov/PFAS.

Thank you again for being part of the PFAS assessment.



Bradley P. Goodwin, PhD
LT, U.S. Public Health Service

Appendix G2: Results Letter Environmental Sampling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

[*Insert Date*]

[*Name*
Address
City, State, Zip code]

Dear [*Insert Name*],

Thank you for being a part of the CDC/ATSDR PFAS exposure assessment. We are grateful to you for allowing us to collect samples from your home for this project. We tested your household drinking water and indoor dust for per- and polyfluoroalkyl substances (PFAS). This letter gives your test results along with what they mean. You may share these results with others if you would like – it's your choice.

The Results of Your Drinking Water Test

Table 1 provides a list of all the specific PFAS that we measured in your drinking water. The table also lists the acronyms for the PFAS.

Table 1 also shows any federal or state drinking water concentration screening values for these PFAS. These values serve as a screening tool to help public health professionals decide where to look more closely at potential health effects from the environment.

Your results are in units of micrograms per liter (µg/L). One µg/L equals one part per billion, equivalent to about one drop of ink in a large tanker ship.

Table 1: Your PFAS Drinking Water Levels Compared to Federal and State Screening Values

PFAS	Abbreviation	Your Tap Water Level in µg/L	USEPA Health Advisory Levels[a]/State Screening Levels[b] in µg/L
perfluorobutane sulfonic acid	PFBS	**[insert level]**	**[insert level] / [insert level]**
perfluorodecanoic acid	PFDA		
perfluorododecanoic acid	PFDoA		
perfluoroheptanoic acid	PFHpA		
perfluorohexane sulfonic acid	PFHxS		
perfluorononanoic acid	PFNA		
perfluorooctanoic acid	PFOA		0.07[c] / [insert state level or NA]
perfluorooctanesulfonic acid	PFOS		0.07 / [insert state level or NA]
N-ethyl perfluorooctanesulfonamidoacetic acid	EtFOSAA		
N-methyl perfluorooctanesulfonamidoacetic acid	MeFOSAA		
perfluoroundecanoic acid	PFUnA		
hexafluoropropylene oxide dimer acid	HFPO-DA		
perfluorohexanoic acid	PFHxA		
perfluorotetradecanoic acid	PFTA		
perfluorotridecanoic acid	PFTrA		
11-chloroeicosafluoro-3-oxaundecane-1-sulfonic acid	11Cl-PF3OUdS		
9-chlorohexadecafluoro-3-oxanone-1-sulfonic acid	9Cl-PF3ONS		
4,8-dioxa-3H-perfluorononanoic acid	DONA		
perfluorooctanoic acid + perfluorooctanesulfonic acid	PFOA + PFOS[d]		0.07 / [insert state level or NA]

ND – Not detected (Reporting limit = 0.005 µg/L for HFPO-DA; 0.002 µg/L for all others))
NA – Not available
[a] *https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos.*
[b] *Will include reference for applicable state screening levels, if available.*
[c] *0.07 µg/L (or parts per billion, ppb) is equal to 70 µg/L (or 70 parts per trillion, ppt)*
[d] *US EPA recommends that the combined levels of PFOA and PFOS also be compared to the health advisory of 0.07 µg/L.*

If any of your PFAS drinking water results are in **bold**, then they exceed the lowest available screening level for that PFAS. This means that your drinking water contains one or more PFAS at levels that are higher than what is recommended by a federal or state environmental or health agency.

[Include text below only if one or more PFAS levels exceed a screening value.]

Since concentrations of [insert list of PFAS that exceed applicable screening criteria] in your drinking water were measured at concentrations above screening levels, we recommend that you consider options to reduce risk, such as seeking an alternative drinking water source or using an appropriate filter, or in the case of parents of formula-fed infants, using formula that does not require adding water. It is not necessary to consider using an alternative water source for bathing, washing dishes, doing laundry, or for other activities that do not cause you to swallow water.

The Results of Your Indoor Dust Test

Table 2 provides a list of all the specific PFAS that we measured in your indoor dust. The table also lists the acronyms for the PFAS. Your results are in units of micrograms per kilogram (µg/kg). One µg/kg equals one part per billion, equivalent to about one grain of sand in a sandbox.

This exposure assessment is one of the first to measure PFAS in indoor dust. Because of this, we cannot tell you what a safe level of PFAS in indoor dust is.

However, your results will help us to understand how people are exposed to PFAS in indoor dust. We will share our findings with you in our final report.

Table 2: Your PFAS Indoor Dust Levels

PFAS	Abbreviation	Your Level in µg/kg
perfluorotetradecanoic acid	PFTA	**[insert level or ND/ [reporting limit]]**
perfluorotridecanoic acid	PFTrA	
perfluorododecanoic acid	PFDoA	
perfluoroundecanoic acid	PFUnA	
perfluorodecanoic acid	PFDA	
perfluorononanoic acid	PFNA	
perfluorooctanoic acid	PFOA	
perfluoroheptanoic acid	PFHpA	
perfluorohexanoic acid	PFHxA	
perfluoropentanoic acid	PFPeA	
perfluorobutanoic acid	PFBA	
perfluorodecane sulfonic acid	PFDS	
perfluorononane sulfonic acid	PFNS	
perfluorooctane sulfonic acid	PFOS	
perfluoroheptane sulfonic acid	PFHpS	
perfluorohexane sulfonic acid	PFHxS	
perfluoropentane sulfonic acid	PFPeS	

PFAS	Abbreviation	Your Level in µg/kg
perfluorobutane sulfonic acid	PFBS	
perfluorooctanesulfonamide	PFOSA	
fluorotelomer sulfonic acid 8:2	FtS 8:2	
fluorotelomer sulfonic acid 6:2	FtS 6:2	
fluorotelomer sulfonic acid 4:2	FtS 4:2	
N-ethyl perfluorooctanesulfonamidoacetic acid	EtFOSAA	
N-methyl perfluorooctanesulfonamidoacetic acid	MeFOSAA	
perfluorododecanesulfonate	PFDoS	
N-methylperfluorooctanesulfonamide	N-MeFOSA	
N-ethylperfluorooctanesulfonamide	N-EtFOSA	
N-methylperfluorooctanesulfonamidoethanol	N-MeFOSE	
N-ethylperfluorooctanesulfonamidoethanol	N-EtFOSE	
Perfluoro-2-propoxypropanoate	HFPO-DA	
4-dioxa-3H-perfluorononanoate	ADONA	
9-chlorohexadecafluoro-3-oxanonane-1-sulfonate	9Cl-PF3ONS	
11-chloroeicosafluoro-3-oxaundecane-1-sulfonate	11Cl-PF3OUdS	

ND – Not detected; reporting limits for PFAS that were not detected are included in brackets

Next Steps

If participant's tap water results are higher than the EPA lifetime health advisory, we will use this text:

Your tap water sample contained PFAS at a level higher than the EPA lifetime health advisory. EPA's health advisory levels were calculated to offer a margin of protection against adverse health effects to the most sensitive populations: fetuses during pregnancy and breastfed infants. EPA's health advisory levels are calculated based on the drinking water intake of lactating women, who drink more water than other people and can pass these chemicals along to nursing infants through breastmilk.

ATSDR recommends that you consider options to reduce risk, such as seeking an alternative water source or using an appropriate filter for any activity in which you might swallow water:

- Drinking,
- Food preparation,
- Cooking,
- Brushing teeth, and
- Preparing infant formula.

If participant's tap water results are higher than the EPA lifetime health advisory and a state guideline, we will use this text:

Your tap water sample contained PFAS at a level higher than the EPA lifetime health advisory and [insert state guideline level]. EPA's health advisory levels were calculated to offer a margin of protection against adverse health effects to the most sensitive populations: fetuses during pregnancy and breastfed infants. EPA's health advisory levels are calculated based on the drinking water intake of lactating women, who drink more water than other people and can pass these chemicals along to nursing infants through breastmilk.

ATSDR recommends that you consider options to reduce risk, such as seeking an alternative water source or using an appropriate filter for any activity in which you might swallow water:

- Drinking,
- Food preparation,
- Cooking,
- Brushing teeth, and
- Preparing infant formula.

If participant's tap water results are higher than a state guideline, we will use this text:

Your tap water sample contained PFAS at a level higher than [insert state guideline level]. [Insert description of state level derivation similar to language for EPA level above.]

ATSDR recommends that you consider options to reduce risk, such as seeking an alternative water source or using an appropriate filter for any activity in which you might swallow water:

- Drinking,
- Food preparation,
- Cooking,
- Brushing teeth, and
- Preparing infant formula.

This information will be included in all letters:

Please call CAPT Tarah Somers at 617-918-1493 to discuss any questions you may have. Your test results will be kept private. Your results may be combined with other participants in your community and used in a summary report; however, no one will be able to identify you.

More Information

- If you or your doctor have any medically related questions about these results or wish to further discuss these results, please contact CAPT Tarah Somers RN, MSN/MPH by phone at 617-918-1493 or email at tvs4@cdc.gov.
- For additional information about PFAS from the CDC and the Agency for Toxic Substances and Disease Registry, please visit: http://www.atsdr.cdc.gov/pfas/index.html.
- For more information about remediation technologies and methods for PFAS, **Treatment Technologies and Methods for Per- and Polyfluoroalkyl Substances (PFAS) (itrcweb.org)**

- For additional information about PFAS from the U.S. Environmental Protection Agency, please visit: https://www.epa.gov/PFAS.
- For more information about the EPA Lifetime Health Advisories for PFOA and PFOS, please visit: https://www.epa.gov/sites/production/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf.

Thank you again for being part of the PFAS exposure assessment.

Bradley P. Goodwin, PhD
LT, U.S. Public Health Service

Appendix H: Health and Safety Plan

Health and Safety Plan

Introduction

This Site Health and Safety Plan (SHSP) defines applicability and responsibility regarding compliance with the Agency for Toxic Substances and Disease Registry (ATSDR) Health and Safety Program for Hazardous Substance Field Activities.

This SHSP defines site requirements and protocol applicable during all activities. It extends to all ATSDR employees, ATSDR contractors, and site visitors invited by ATSDR.

Site emergency response procedures and any potential fire, explosion, health, or safety hazards of the operation must be communicated to all personnel. Noncompliance with site safety procedures will not be tolerated. Personnel not observing safety procedures could be suspended from participation in site activities.

Development of this plan included consideration of current safety standards and recommendations as defined by the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), the American Conference of Governmental Industrial Hygienists (ACGIH), health effects and standards for known contaminants, and procedures designed to account for potential exposure to unknown substances.

Additional PPE requirements and precautions added to prevent the spread of COVID-19 during EA activities are detailed in Appendix J.

Personnel Training Requirements

All site personnel will be trained in accordance with the requirements contained in the CDC/ATSDR Mandatory Training Requirements. At a minimum, all personnel will be trained to recognize on-site hazards, the provisions of this SHSP, and identification of responsible personnel.

All personnel are required to complete the following training courses:

- Blood Borne Pathogen Training
- Safety Survival Skills Part 1 - General Responsibilities
- Personal Protective Equipment Training
- Human Research Protections Training
- First aid/CPR/Automated External Defibrillator (AED) Training

All site personnel and agents (on-site contractors, fellows, and others appointed or retained to work under the auspices of CDC) who intend to collection information from human subjects must have a Scientific Ethics Verification (SEV) number.

Personal Protective Equipment

Anyone entering the site must be fully aware of and protected against potential hazards. The purpose of personal protective equipment (PPE) is to shield or isolate individuals from chemical, physical, and biological hazards that could be encountered at the site.

Personnel working with blood or urine samples are required to wear Level D PPE to include closed toed shoes, long pants, and gloves. Personnel working with centrifuges should wear eye protection. Respirators are not required. Gloves should be changed in between handling each participant's sample. Urine containers, used pipettes, gloves, and blood collection materials should be placed in appropriate biohazard containers.

Emergency Procedures

On-site personnel will use the following standard emergency procedures. Notify the site lead of any on-site emergencies. The site lead is responsible for ensuring that appropriate emergency procedures are followed.

Personal Injury

When an injury occurs the site lead will assess its nature. A qualified first aid provider should initiate appropriate first aid and continue appropriate emergency medical services. If necessary, injured personnel will be transported to a local area hospital.

Fire or Explosion

If a fire or explosion occurs on site, the emergency will be announced and all personnel will leave the area through emergency exits (unless directed otherwise). The fire department shall be contacted (911), and all personnel shall be moved a safe distance from the involved area. If it is safe to do so, site personnel can take the following actions:

- Use on site fire-fighting equipment to control or extinguish the fire; and
- Remove or isolate flammable or other hazardous materials that could contribute to the fire.

Natural Hazards

The site lead has responsibility for safety of ATSDR personnel if natural hazards (e.g., thunderstorms, tornadoes, hurricanes, etc.) occur. The site lead will inform personnel of current and impending weather conditions.

Equipment Failure

If any site worker experiences a protective equipment failure or alteration that affects the protection factor, that person shall immediately wash hands as needed and replace the failed equipment.

If any other on-site equipment fails to operate properly, the site lead shall be notified and will then determine the effect of this failure on continuing operations at the site.

Centrifuge Safety Procedures

Prior to starting any operation that deals with a biological, chemical or radiological hazard, emergency procedures should be established to determine the course of action in the case of an incident. The emergency procedures should be based on the materials being used, the hazards associated with the materials, the type of equipment being used, the operations, and the type of incident that could result. The emergency procedures should be posted near the centrifuge. All centrifuge operators should be familiar with the emergency procedures.

1. Put on appropriate personal protective equipment (gloves) when responding to ALL centrifuge incidents and BEFORE opening the centrifuge to retrieve materials.

2. If a tube breaks or a spill occurs, and an aerosol containing an infectious agent is generated, turn off the centrifuge, and immediately evacuate the area. Be sure to notify others in the laboratory to evacuate. Secure the area and notify the Office of Health and Safety.

    - If tubes containing hazardous materials break or leak, the entire rotor load and centrifuge should be considered contaminated. The tubes, rotor, adapters, buckets and centrifuge chamber should be decontaminated using appropriate decontamination procedures and then washed.
    - There is no single cleaning, disinfecting, or decontaminating process that is suitable for all tubes, rotors, and other centrifuge components. The selection of a disinfectant should be based on the agent involved and the rotor material. If the wrong method or type of cleaner is used, it could result in damaged equipment. It is important to follow the manufacturer's recommendations.
    - If a leak should occur, call DLS Logistics for further assistance (Cynthia Weekfall - 770-488-7227)

3. If a liquid spill (with no aerosol) has occurred, contain the liquid and decontaminate as appropriate.

4. If a tube is identified as being broken while removing it from the rotor/carrier, or if there is a suction sound when removing the tube, do not continue to pull the tube from the rotor/carrier. Leave the tube in the rotor/carrier and contain the liquid by sealing the rotor/carrier. Remove the rotor/carrier from the centrifuge, place it in a biological safety cabinet or chemical fume hood, depending upon the hazard, and continue operations to remedy the spill.

Appendix I: Data Management Plan Form

Data Management Plan Form

Table 1: Core DMP Elements *(should be filled out when project approval is sought)*

MRID *(NCEH/ATSDR metadata repository identifier - for NCEH/ATSDR OD use only.)* *P1805-0008*
***Title** Biological and Environmental Sampling of Per- and Polyfluoroalkyl Substances (PFAS)
***Description** A statistically based, community sampling design will be used to determine • PFAS serum concentrations from participants living in communities with exposures to PFAS in drinking water. • PFAS urine concentrations from a subset of participants living in communities with exposures to PFAS in drinking water. – An initial 10% of urine samples will be analyzed for 18 PFAS and creatinine. Additional analytes may be added should methods become available. If the geometric mean PFAS concentrations in this initial subset are elevated compared to the U.S. national reference population, as defined by the 2013-2014 NHANES 95th percentile, all other urine samples from the site will be analyzed. • PFAS concentrations in indoor dust and tap water samples from a subset (10%) of homes of participants in biological sampling. A questionnaire will be administered to all participants to gather information that can be used to characterize each individual's exposure. The collected data will be analyzed to determine PFAS blood levels for individual participants as well as the community as a whole. Serum and urine concentrations will be compared to reference ranges from nationally representative data, and correlations between environmental and biological PFAS concentrations will be evaluated.
***Last DMP Update** May 2, 2018
***Contact Name and Email** CDC PI or POC Name (last, first): Worley, Rachel CDC PI or POC e-mail address: idz7@cdc.gov CDC PI or POC phone number: 770-488-1549
Organization ATSDR/DCHI/SSB
***Unique Identifier and catalog/database name** TBD

***Data Access Level(s) – CHECK ALL APPLY**

(The degree to which the data collected as part of this project could be made publicly available, regardless of whether it has been made available. Projects can have multiple datasets or different data elements within a single dataset that are approved for different levels of public access.)

PUBLIC Release

☐ Public release – Full dataset

*(Dataset can be made available without restrictions; data steward no longer controls data. T**his should be the default selection for all datasets unless justified otherwise.**)*

☒ Public release – Aggregate data

(Underlying dataset cannot be released or shared, but aggregate/summary data can.be made available to public access without restriction)

Justification (required if selected): Underlying dataset cannot be released in order to protect personally identifiable information, only aggregate summary data will be made available to public access without restriction.

☐ Public release - Release by ad-hoc request

(Metadata will be released and the dataset is available by ad-hoc request; data requests CANNOT be denied; no data use agreement or restrictions; data steward no longer controls data.)

Justification (required if selected):

RESTRICTED Release

☒ Restricted use data sharing

(Dataset is available to particular parties under certain use restrictions or use agreement; data not always under CDC custody. The use restriction/agreement (or template) needs to be attached.

Justification (required if selected): Limited data set (including no direct PII) may be shared with approved data requestors for approved scientific purposes via data use agreement.

☐ Restricted access data sharing

(Dataset is only available in an RDC; data need to remain under CDC custody.)

Justification (required if selected):

No Data Release/Sharing

☐ No release or data sharing

Justification (required if selected):

Access Rights/Restrictions

(Include information regarding access or restrictions based on privacy, security, or other policies of the owner of the data. Include an explanation for the selected "Public Access Level" above.)

In compliance with federal and state privacy protection laws and regulations, the limited data set may be shared with other federal, state and/or local public health and environmental agencies via data use agreements for research purposes to advance the scientific understanding of human exposures to PFAS.

License/Other Agreements *(The license or non-license [i.e., public domain] status with which the dataset will be published. See Open Licenses for more information. May include DTA, MTA, IAA, MOU or other agreements concerning data use and access.)*
***Publisher/Owner** *(The publishing entity and optionally their parent organization(s). This could be the "owner" of the data.)* CDC/ATSDR
Access URL(s), If Known *(URL providing indirect access to the DMP, dataset, data dictionary [variable names and valid values], data collection instrument and other relevant information, including the research protocol if possible.)* TBD
Download URL(s), If Known *(URL providing direct access to a downloadable file of the dataset, summary data, or data tables.)* TBD
***Spatial** *(The range of spatial applicability of a dataset. Could include a geographic region or a named place [city, county, state, region, country].)* Data will be collected from no less than eight communities across the United States and U.S. Territories.
***Temporal** *(The range of temporal applicability of project)* Start date of data collection (month/year): April 2019 End date of data collection (month/year): December 2020

Table 2: Additional DMP Elements *(should be filled out where possible when project approval is sought; however, many fields can only be filled out later when publication/report is cleared)*

***Tags/Keywords** *(Keywords to help users discover the dataset.)* PFAS, PFOA, PFOS, PFNA, PFHxS
***Intramural or Extramural Project** ☐ Intramural ☒ Extramural (grant, cooperative agreement, contract, IAA, CDC Foundation, other) Specify mechanism: Project will be conducted using the ATSDR/DCHI Mission Support contract mechanism.
Project Type – CHECK ALL APPLY *(Multiple selections may apply.)* ☐ Research ☐ Emergency ☒ Non-research ☒ Exposure investigation ☐ Surveillance ☐ Ongoing collection ☐ Evaluation ☐ Other
Dates Estimated date of data release/sharing (month/year): December 2020 Preservation expiration date (year that the dataset will be available until): TBD
Data Category *(For explanation of D1 to D10 codes, see Table on page 1)* ☐ D1 ☒ D2 ☐ D3 ☐ D4 ☐ D5 ☐ D6 ☐ D7 ☐ D8 ☐ D9 ☐ D10 Justification: (provide detailed information about the data category selected above. If *D6* is selected, provide quantitative estimates of costs in releasing data and expected volume of use. If *D7* is selected, specify the reason that prevents the owner from releasing/sharing the data.) Data will be collected by a contractor or cooperative agreement partner funded by CDC/ATSDR.
Population Represented *(e.g., "residents of x," "inpatients at x," "users of product x")* TBD – Residents of no fewer than eight communities with PFAS contaminated drinking water. Exact locations to be determined.

Data Collection Protocol

(Brief description with reference to document or website that provides detailed information.)

Participants in each exposure assessment will complete consent/assent/parental permission forms, provide blood and urine samples and respond to a questionnaire. Participants will be responsible for collecting first morning urine samples in their homes and transporting them to the centralized blood collection location. A subset of participant households will be randomly selected for environmental (i.e., indoor dust and tap water) sampling. Administration of consent forms for environmental sampling and indoor dust and tap water sample collection will take place during a home visit.

All blood samples will be shipped to the NCEH laboratory for analysis of PFAS concentrations and then shipped to a bio-specimen repository for storage. A subset of urine samples will be shipped to the NCEH laboratory for analysis of PFAS concentrations. The remaining urine samples will be shipped to a bio-specimen repository for storage. Drinking water and indoor dust samples will be shipped to an EPA-accredited laboratory for analysis of PFAS concentrations and then stored.

Detailed data collection procedures are available in the protocol for the assessments.

Data Management Protocol

(Brief description with reference to physical location(s) or system(s) where data will be housed (e.g., CDC shared network drive, data host system name, SQL database, etc.) and to data formats. Include the locations of dataset both before data release and after data release.)

All data will be transmitted to ATSDR or ATSDR contractor for incorporation into a centralized data management system. All results will be electronically transmitted in spreadsheet format using a secured and password-protected network.

All documents with personal identifying information (i.e., consent forms, assent forms, collection logs, etc.) will be kept in locked cabinets and all electronic data will be stored on a password-protected network servers behind firewalls, accessible only to those staff working directly with raw data.

De-identified samples will be sent to the laboratories—no individual identifiers will be included. Any reports produced from this information will not identify specific individuals.

Process for Omitting Identifying Information

(Description of what identifiers are in the database, how they will be removed, and by whom.)

All samples and data will be identified with a unique code. Only the project coordinator will have access to the link between the sample identification code and personal identifying information in order to facilitate communication of individual results with participants.

Data Quality Protocol (to address issues of privacy protection and statistical stability)

(Brief description with reference to document or website that provides detailed information. Describe methods for data validation and error resolution, removal or shielding of any proprietary information, removal or shielding of sensitive information [i.e., data with dual use applicability], removal or shielding of any individually identifying information including indirect identification.)

All laboratory analyses will be conducted with established procedures for quality assurance and control according to NCEH and EPA protocols. These methods are identified in the protocol for the exposure assessments and are available from NCEH and EPA.

Data Retention/Disposal Plan *(State when and how the dataset will be archived or destroyed [in accordance with CDC/ATSDR Records Control Schedule:* Records will be retained and disposed of in accordance with the CDC Records Control Schedule. Physical copies of assessment materials and reports will be maintained at ATSDR until no longer needed by program officials and will be kept no longer than five years following completion of the exposure assessment in accordance with retention schedules. Computer documents will be disposed of when no longer needed by program officials and will be kept no longer than five years following the study. Personal identifiers will be deleted from records when no longer needed. Disposal methods will include erasing computer files, shredding paper materials, or transferring records to the Federal Records Center when no longer needed for evaluation and analysis. Records are retained for 20 years.
Data Analysis Plan *(Brief description of planned use of the data. Can include reference to document [e.g., information collection request, research protocol, or other] that provides more detailed information.)* Data will be analyzed for each individual participant and in aggregate. Detailed information is provided in the protocol.
Publication Plan *(Brief description of planned CDC-authored and CDC-coauthored publications, including topic, type of publication, and estimated timeline.)* Aggregate findings from the exposure assessments are expected to be published as ATSDR reports and in the peer reviewed literature. The topic of publications will be human exposure to per- and polyfluoroalkyl substances. Reports and publications are estimated to be released in 2020 and 2021.
Data Release Documentation *(List documents provided to users, e.g., variable definitions, codebook, metadata file, guidance on data use.)* TBD
Data Release Format *(Recommend to use non-proprietary format when possible, such as CSV, JSON, etc. Also specify data dictionary file format.)* CSV
Data Release Notification *(State how potential users will be informed of dataset availability.)* TBD

Date Form Completed: _April 14, 2018_____

By: _Rachel Worley, PhD, Environmental Health Scientist_____
Name, Title

Date Form Last Revised: _May 2, 2018_____

By: _Rachel Worley, PhD, Environmental Health Scientist_____
Name, Title

Appendix J: PFAS Exposure Assessment (EA) Restart Plan

PFAS Exposure Assessment (EA) Restart Plan

Last updated 6/11/2020

Introduction

The Per- and Polyfluoroalkyl Substances (PFAS) Exposure Assessments (EAs), and associated activities, including introductory meetings, recruitment, biological sample collection, and environmental sample collection are critical public health activities that should continue in the remaining EA communities if there is evidence of minimal community transmission of SARS-CoV-2, the virus that causes COVID-19, capacity to investigate cases, and open capacity at hospitals and urgent care centers. Data collection activities (introductory meetings, recruitment, and sample collection) have been completed at five sites with activities remaining in Fairbanks North Star Borough, Alaska; El Paso County, Colorado; and Orange County, New York. When possible, we propose alternative strategies for completing essential EA activities to minimize face-to-face interaction and potential for transmission of SARS-CoV-2.

Restarting PFAS EA field work will require that precautions be put in place to ensure that staff, contractors, and members of the public are protected from COVID-19. This plan is based on interim CDC guidance for non-COVID-19 public health activities that require face-to-face interaction during the COVID-19 pandemic and will be used to outline practices for conducting PFAS EA activities.

Changes in the initial EA procedures are proposed to reduce or eliminate close contact (within 6 feet) between CDC/ATSDR staff, CDC/ATSDR contractors, and the public when possible to prevent the spread of SARS-CoV-2 during PFAS EA activities. The precautions and personal protective equipment (PPE) recommended in this plan will be reevaluated at least monthly and more often as needed to ensure they are still in line with CDC and state COVID-19 guidance and may be revised to add or remove precautions as needed. Precautions may vary from site to site based on conditions on the ground and the timing of when activities are conducted.

Plan Objectives

- Minimize risk of exposure, illness, and spread of disease among staff conducting PFAS EAs
- Minimize risk of exposure, illness, and spread of disease among members of the public as a result of PFAS EA activities
- Preserve essential functions of PFAS EAs

Schedule

Schedules for resumption of field work activities will be determined on a site-by-site basis. Work at some sites may resume earlier than others. Decisions about when to restart activities will be made in consultation with regional ATSDR staff as well as state and local public health officials. Scheduling activities will take into account

- the level of local COVID-19 transmission (number of new cases, emergency department visits, and percent positive for testing in each community as available)
- state and local guidance/mandates
- other site-specific factors as described later in this document

Modifications to EA Procedures

Staffing:
Staff travel for PFAS EA activities will be voluntary. Staff will be briefed on their potential role as well as risks prior to travel and will be given the opportunity to opt out of any travel. Staff will be provided with clear information about new procedures and PPE requirements (as shown in the table at the end of this document). All PPE will be provided to staff prior to initiation of activities. Staff will have an opportunity to ask questions about the precautions and PPE requirements prior to travel. Staff at higher risk for severe illness from COVID-19, including age (older adults) and underlying medical conditions, will be encouraged to discuss any concerns with their supervisors and supervisors will stress that any travel for this field work is voluntary.

Cloth face coverings are required for the protection of others and are not PPE for the wearer. Cloth face coverings should not be placed on anyone who has trouble breathing, or is unconscious, incapacitated or otherwise unable to remove the mask without assistance. The cloth face cover is meant to protect other people in case you are infected. In situations where PPE is required for respiratory protection, staff will be provided with appropriate PPE (surgical masks or N95 respirators). In cases where participants arrive to an appointment without a cloth face covering, they will be provided with a surgical mask due to disposability. If participants are unable to wear a cloth face covering or surgical mask due to medical conditions, staff will maintain at least six feet of distance at all times and will wear a surgical mask if closer interaction is required.

Community Meetings:
In April 2020, CDC/ATSDR transitioned to a virtual format for all PFAS EA introductory public meetings. These meetings will provide the same content as has been provided in previous introductory meetings but will be delivered using video-conferencing technology with opportunities for question and answer sessions from participants. This modification is in compliance with an administrative order from New York restricting large social gatherings of more than 50 people and CDC guidance on community gatherings.

While all essential information about the EAs will be presented at the virtual introductory meetings, we recognize that there may still be a need for limited in-person interaction to answer questions and build trust with community members who may not be able to attend virtual meetings. To serve the needs of these community members, we propose holding in-person small group question and answer sessions. Community members will be able to sign up for a small group session in advance. CDC/ATSDR staff will communicate guidance for social distancing, wearing a cloth face covering, and symptom screening with participants when they schedule an appointment. Each session will include two CDC/ATSDR staff and a maximum of seven community members. All attendees will be screened by CDC/ATSDR staff for COVID-19 symptoms with a symptom questionnaire, visual assessment, and temperature check prior to entry and sessions will be setup to promote social distancing of CDC/ATSDR staff from community members and among community members. CDC/ATSDR staff will deny entry to participants if they report symptoms of COVID-19, have a temperature over 100.4° F, or if CDC/ATSDR staff observe signs associated with COVID-19 (e.g. coughing, feeling feverish). If a participant is denied physical entry, we will offer to have a phone conversation to answer any questions they might have. Cloth face coverings for CDC/ATSDR staff and community members will be used in accordance with CDC guidance and hand washing facilities with soap and water will be provided. Hand sanitizer (minimum 60% ethanol or 70% isopropanol) will also be available near the door, and surgical masks will be provided for participants who do not bring their own cloth face covering. Cloth face coverings are not PPE and will be worn by

staff and community members to protect others. If a participant exhibits symptoms after entering the facility they will be asked to leave and the facility will be cleaned and disinfected with a disinfectant listed on EPA List N, following CDC guidance, before reopening.

Door to Door Recruitment:
Staff engaged in door to door recruitment will follow current guidance for personal protective measures and PPE as directed by the Office of Safety, Security, and Asset Management (OSSAM) and specified in the table at the end of this document. Short additional content will be added to door to door recruiter training on briefly and sensitively acknowledging COVID-19 infection control measures taken to protect participants (e.g., "We are wearing surgical masks and standing back here to keep some social distance so we are all safer from COVID-19."). The procedure for door to door recruitment will be that staff will approach a home and knock or ring the doorbell and then step back to a minimum of six feet from the door. If a resident answers the door, staff will remain at least six feet away while sharing information about the EA. If a resident exhibits symptoms, staff will encourage them to seek medical advice. Staff will leave printed educational materials with residents or at the door if there is no answer. Under no circumstances will staff enter homes during door to door recruitment.

Biological Sample Collection (Blood and Urine):
All staff will be screened daily for COVID-19 symptoms prior to entry to the sample collection location using a symptom questionnaire and temperature check. Staff will follow current guidance for PPE as outlined in the table at the end of this document. Staff will also be instructed to stay home (or at their hotel) if they are experiencing any COVID-19 symptoms and will be screened twice daily and enrolled in Text Illness Monitoring (TIM). If symptoms develop, staff will be instructed to contact the Occupational Health Clinic (404 639 3385) for guidance in appropriate actions to take.

EA participants will be instructed not to come for their appointment if they are experiencing COVID-19 symptoms (as defined in the list below). All EA participants will be informed of screening procedures and asked to wear a cloth face covering to their appointment when appointments are scheduled. Participants will be asked about symptoms in a reminder call the day before their scheduled appointment. If community members are found to have symptoms during screening, they will be denied entry to the sample collection venue and will be encouraged to consult with their primary care provider. If a participant exhibits symptoms after entering the facility they will be asked to leave and the facility will be cleaned and disinfected, with a disinfectant listed on EPA List N, following CDC guidance, before reopening. If there is a potential exposure, CDC/ATSDR staff will contact the Occupational Health Clinic for guidance on appropriate actions. Staff will share information about the interaction that led to a suspected exposure and will follow guidance from the clinic on appropriate actions. All staff in the field will be monitored for symptoms during their travel and for 14 days after returning regardless of any potential exposure.

Additional actions that will be used to reduce the potential for SARS-CoV-2 transmission include:

- Selecting facilities for use (e.g. conference suites) that are large enough to physically distance stations by at least 6 feet for intake, waiting, consenting, sampling, etc.
- Scheduling appointments such that never more than 9 individuals (staff and participants, based on the size and configuration of the space) are in the facility at the same time
- Increase physical space between employees and participants (e.g., physical barriers such as partitions)

- Use signs, tape marks, or other visual cues such as decals or colored tape on the floor, placed 6 feet apart, to indicate where to stand when physical barriers are not possible
- Requiring use of surgical masks for staff and cloth face coverings or surgical masks for participants
- Limiting sampling area access to a maximum of 9 people (based on area size and configuration) at a time, with a door monitor allowing one person inside for each person that exits
- Providing proper hand washing facilities
- Providing hand sanitizer and surgical masks for participants who do not bring their own cloth face covering upon entry into the facility for a physical appointment
- Providing signage showing reasons for precautions and proper wear of cloth face coverings

Questionnaires will be transitioned from in-person to telephone administration. At the testing location, each EA participant will complete informed consent and provide blood (collected by a contract phlebotomist) and urine samples and will be scheduled for a telephone appointment to complete the questionnaire. This change will reduce contact time between participants and EA staff and result in a need for fewer staff to travel to the field locations.

We will install physical barriers within the biological sample collection location where feasible. Administrative controls, including staff education on COVID-19, instruction on appropriate PPE for given tasks and how to don and doff PPE, hand hygiene instruction, how to briefly and sensitively acknowledge precautions with participants and note COVID-19 infection control measures taken to protect participants, and instructions for staff to remain home if experiencing any symptoms will be instituted.

There will be a separate area for eating/drinking for staff. These areas will be set up with limited seating to promote social distancing. Breaks areas will be cleaned and disinfected a minimum of two times per day. Juice or other supplies for phlebotomy recovery will be provided only if participants experience symptoms associated with giving blood (feeling faint etc.), will be kept in a separate area, and will be consumed only in a separate unused area near the phlebotomy area. Participants will not enter the staff food area.

Environmental Sample Collection:
Participants will be informed of screening and protective procedures at the time home appointments are scheduled. Staff will confirm that there are no individuals with COVID-19 symptoms in the house before entering. Staff will briefly and sensitively confirm that no individuals on the staff team have symptoms, staff entering the home will wear PPE (N95, coveralls, and gloves) to protect themselves and the household residents, and any other COVID-19 infection control measures they are taking to ensure protection of the household residents. Participants will be asked to wear a cloth face covering while staff are inside their home. If they do not have a cloth face covering, a disposable surgical mask will be provided to them. If a resident exhibits symptoms, staff will recommend they consult with their primary care provider and then leave the home. Informed consent will be obtained outside the home without entering. Staff will wear appropriate PPE as directed by OSSAM for entering participant homes. The number of staff entering the home and duration spent inside will be minimized. All equipment preparation and disassembly will be conducted prior to entry or after leaving the home. After leaving the home staff will discard all disposable PPE (respirator, gloves, and gown) and engage in proper hand hygiene. Staff will use alcohol based hand sanitizer immediately and wash hands with soap and water as soon as convenient after leaving the home.

Travel

During travel, staff will be directed to the considerations for travel in the United States. Staff will also be provided with the guidance below.

Protect yourself and others during your trip:

- Clean your hands often.
  - Wash your hands often with soap and water for at least 20 seconds especially after you have been in a public place, or after blowing your nose, coughing, or sneezing.
  - If soap and water are not readily available, use a hand sanitizer that contains at least 60% alcohol**.** Cover all surfaces of your hands and rub your hands together until they feel dry.
- Avoid touching your eyes, nose, and mouth with unwashed hands.
- Avoid close contact with others.
  - Keep at least 6 feet of social distance from others.
  - Avoiding close contact is especially important if you are at higher risk of getting very sick from COVID-19**.**
- Wear a cloth face covering in public to protect others.
- Cover coughs and sneezes.
- Considerations for visiting a restaurant while traveling**.**

When staying in a hotel:

- Take the same steps you would in other public places—for example, avoid close contact with others, wash your hands often, and wear a cloth face covering.
- When you get to your room, clean and disinfect all high-touch surfaces. This includes tables, doorknobs, light switches, countertops, handles, desks, phones, remote controls, toilets, and sink faucets.
  - Bring an EPA-registered disinfectant and other personal cleaning supplies, including cloths and disposable gloves.
- Considerations for visiting a restaurant while traveling.

Screening of Personnel

All personnel (CDC/ATSDR staff and contractors) will be screened for symptoms prior to travel and twice daily while in the field. CDC/ATSDR staff will be enrolled in CDC's Text Illness Monitoring (TIM) and contractors will report any symptoms to their management daily. Screening will include a temperature check as well as questions about the presence of any signs or symptoms associated with COVID-19. Questions on symptoms will include presence of any of the following:

- Fever or chills
- Cough
- Shortness of breath
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose

- Nausea or vomiting
- Diarrhea

If any employee develops symptoms they will be instructed not to come to work, to inform the site lead, and to contact the Occupational Health Clinic (OHC) 404-639-3385 and the ATSDR site lead. (Contractor staff should inform their supervisor). Site-specific health and safety plans will be developed to include instructions for seeking medical care should any staff develop symptoms while working in the field. If a staff member develops symptoms consistent with COVID-19, we will pause all activities. If the staff member subsequently tests negative, we will consult with CDC and local/state public health before resuming activities. If the staff member tests positive we will notify all staff and participants who have been in contact with the positive individual and consult with OSSAM and local/state public health to determine additional actions.

CDC/ATSDR employees will continue to self-report symptoms in TIM for 14 days after returning from the field and will follow instructions from the OHC should any symptoms develop.

Protective Measures

Specific EA activities are shown in the table below with recommended PPE, and additional precautions. All PPE for CDC/ATSDR staff will be provided by CDC/ATSDR. Contractor will provide PPE originally required for EAs, CDC/ATSDR will provide additional PPE as needed from the table below.

Activity	Description	PPE	Additional Precautions
Travel	Time spent in ride share/ public transportation, in airport, on airplane, time spent in public venues while traveling	None	• Frequent handwashing • Cloth face coverings • General travel precautions • Ride sharing and public transportation
Small Group Question and Answer Session	Small group conversations (2 ATSDR staff and maximum of 7 community members) in an indoor setting	None	• Symptom screening prior to allowing entry to facility • Providing access to soap, water, and proper hand hygiene facilities • Hand sanitizer station at the door • Cloth face coverings • Providing disposable surgical masks for community members if they do not have their own cloth face covering • Layout room to promote social distancing (at least 6 feet of space between chairs, visual cues for social distancing) • Restrict occupancy to maximum of 9 people (including staff) at a time • Cleaning and disinfection of surfaces between groups

Activity	Description	PPE	Additional Precautions
Door to door recruitment	Knocking on doors in the community, having conversations outside, distributing printed materials	Disposable surgical mask, disposable gloves	• Frequent handwashing • Maintain at least six foot distance from community members • No entry of homes (already part of door to door protocol)
Biological sample collection screener	Greet participants outside the sample collection venue, take temperature, ask symptom screening questions	Disposable surgical mask, disposable gloves	• Confirm participants are symptom and fever free before allowing entry to sample collection venue • Ensure occupancy limit allows entry
Biological sample collection paperwork	Check in participants, perform verbal informed consent, schedule telephone questionnaire, check out	Disposable surgical mask, disposable gloves	• Frequent handwashing • Layout of room to promote social distancing • Cleaning and disinfection of surfaces between participants/groups • Physical barriers between participants and staff • Transition questionnaire administration to telephone format
Urine sample processing	Take urine samples from participants, process samples and place in storage	Disposable surgical mask, disposable gloves (already included in protocol)	• Frequent handwashing • Cleaning and disinfection of surfaces between participants/groups • Physical barriers between participants and staff
Blood sample collection	Collect blood sample in one red top tube (approximately 6 mL)	Phlebotomists: Disposable surgical mask, disposable gloves (already included in protocol), disposable gown (already included in protocol), face shield or goggles	• Frequent handwashing • Cleaning and disinfection of surfaces between participants • Blood and plasma collection precautions

Activity	Description	PPE	Additional Precautions
Blood sample processing	Moving collected blood samples to processing area, centrifuging of blood samples, aliquoting of serum into cryovials, packaging of serum for shipment	Disposable surgical mask, disposable gloves (already included in protocol)	• Frequent handwashing • Cleaning and disinfection of surfaces between participants
Environmental sample collection	Entering participant homes, collection of water sample from household tap, collection of dust samples from floors, verbal consent (outside)	N95 mask (to enter home), surgical mask for staff that remain outside, disposable gloves (already included in protocol), coveralls	• Minimize staff entering home to only necessary personnel • Confirmation that no members of the household have symptoms prior to entering • Hand washing after each home • Disinfection of sample collection materials after each home

Site Specific Scheduling Considerations:

Alaska – There is an order requiring travelers entering Alaska to have a negative COVID-19 test within 72 hours of boarding a plane for Alaska. If paperwork is not in order, travelers can be tested on arrival or be subjected to a 14-day self-isolation. If this requirement remains in effect, all staff will be tested for COVID-19 prior to traveling to Alaska.

There is also an order requiring that any business conducting operations in Alaska file a written plan outlining steps that will be taken to ensure that the communities where work is taking place are protected. Businesses are currently reopening state-wide. There have been local concerns that migrant workers may increase the spread of COVID-19 in the coming months. We will continue to monitor the situation and consult with local partners to identify requirements for restarting field work in Alaska.

Colorado – Colorado is currently reopening with no expected impediments to scheduling or conducting field work. We are having conversations with state and local health officials to determine any impediments to field work.

New York – New York started a 4 Phase reopening by region on May 15. Orange County is in the Mid-Hudson Region. This region entered Phase 1 of the reopening on May 26. This phase will last a minimum of two weeks and will be followed by Phase 2, Phase 3, and finally Phase 4 (fully reopened) for a minimum of two weeks in each phase. The Mid-Hudson Region entered Phase 2 of reopening on June 9.

Campus Access Considerations for NCEH/ATSDR Leadership

1. We need a few staff (including contractor staff) to have access to Chamblee Building 102 in order to pack and ship urine collection kits. All materials for these kits are stored in the call center and staff will need to be physically present on campus to get these sent out to participants. Staff will also need to access campus to store and access PPE. Staff will maintain at least 6 feet distance from each another during packing and shipping of urine collection kits. Staff will wear cloth face coverings when in CDC/ATSDR buildings and will have access to facilities for proper hand hygiene.
2. Biorepository and NCEH laboratory staff will need to provide on-campus services for shipping and receiving of samples and supplies as well as sample analysis. We have confirmation that shipping and receiving can begin now and that sample analysis will restart when staff resources permit.