

# Human Health Effects of Drinking Water Exposures to Per- and Polyfluoroalkyl Substances (PFAS) at Pease International Tradeport, Portsmouth, NH

(The Pease Study)

New Information Collection Request

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

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## Part B. Collections of Information Employing Statistical Methods

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### B.1. Respondent Universe and Sampling Methods

The **Pease Study Protocol** covers two separate studies by age group: the Adult Study and the Child Study. The main goals of the research studies are to: 1) evaluate the study procedures and methods to identify any issues that need to be addressed before embarking on a multi-site study; and 2) examine associations between health outcomes and measured and historically reconstructed serum levels of per- and polyfluoroalkyl substances (PFAS). ATSDR will not employ statistical methods to recruit participants; nevertheless, it is providing details about its data collection procedures in **Part B**.

#### Background

ATSDR will be largely recruiting from the existing cohort from the New Hampshire Department of Health and Human Services (NH DHHS) 2015 Pease Perfluorochemical (PFC)<sup>1</sup> Blood Testing Program.<sup>2</sup> The purpose of the NH DHHS PFC serum testing was to provide concerned community members with more information about their level of exposure to the PFCs. As a community service, the NH DHHS enrolled participants in several waves for laboratory testing. The cohort was a convenience sample and no statistical sampling methods were applied.

Individuals requested PFC testing if they had, at any time, consumed contaminated drinking water while working on, living on, or attending childcare on Pease, or if they consumed water from a contaminated private drinking well in proximity to Pease that was tested as part of the Pease Superfund Assessment and found to have levels of PFCs above the EPA's Provisional Health Advisory levels.<sup>3</sup> Infants or children who were exposed in utero through their mother's consumption of contaminated drinking water at Pease were also included in the testing at the parent's discretion.<sup>1</sup>

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<sup>1</sup> *Perfluorinated chemicals* is a term that some scientists use to refer to the group of toxic chemicals that includes PFOA and PFOS and other per- and polyfluoroalkyl substances (PFASs). See <https://www.epa.gov/pfas/what-are-pfas-and-how-do-they-relate-and-polyfluoroalkyl-substances-pfass>.

<sup>2</sup> See Final Report for the Pease PFC Blood Testing Program: April 2015 – October 2015 available at <https://www.dhhs.nh.gov/dphs/documents/pease-pfc-blood-testing.pdf>.

<sup>3</sup> These new EPA drinking water Health Advisories for PFOA and PFOS recommend, if a person's drinking water contains levels of PFOA or PFOS or both combined above 70 ppt, that they do not consume the water or use it in preparing food. The EPA reports that these recommended drinking water levels should be safe for all individuals, including babies exposed during pregnancy, nursing infants, and children, even if these water levels are consumed over a person's lifetime.

A total of 1,578 individuals submitted blood samples for testing from April to October 2015; 366 (23.2%) were children aged 11 years or younger, 31 (2.0%) were aged 12–19 years, and 1,181 (74.8%) were aged 20 years or older. The majority of individuals tested (n=856, 54.3%) were female. Other exposure characteristics are outlined in **Table B.1.1** and are discussed further below.

Table B.1.1. Characteristics of Pease PFC Blood Testing Program Participants, 2015 (n=1,578)

Characteristics	N (%)
Age Group (years)	(median=40)
0-2	75 (4.8%)
3-5	164 (10.4%)
6-8	91 (5.8%)
9-11	36 (2.3%)
12-19	31 (2.0%)
20-39	369 (23.4%)
40-59	611 (38.7%)
60+	201 (12.7%)
Sex	
Male	639 (40.1%)
Female	856 (54.3%)
Unknown	83 (5.3%)
Water Consumption (cups/day)	(median=4)
<4	572 (36.3%)
4-7	539 (34.2%)
8+	227 (14.4%)
Unknown	240 (15.2%)
Time Spent on Pease (years)	(median=6.5)
<1	75 (4.8%)
1-4	429 (27.2%)
5-9	378 (24.0%)
10-19	318 (20.2%)
20+	88 (5.6%)
Unknown	290 (18.4%)
Time Since Last on Pease (years)	(median=0.0)
<1	948 (60.1%)
1-4	144 (9.1%)
5-9	88 (5.6%)
10-19	74 (4.7%)
20+	34 (2.2%)
Unknown	290 (18.4%)
Firefighter (yes)	98 (6.2%)
Abnormal Kidney Function (yes)	22 (1.4%)

Out of all participants, 1,171 (74%) reported at least one place of business where they worked or attended childcare on Pease. There were approximately 218 different places of business represented in the testing population, and out of all participants, 404 (26%) identified as working at one of five companies. Out of the 218 companies reported on the questionnaire, 193 (88%) had fewer than 10 persons who participated in the testing program.

Out of all participants, 1,540 (98%) reported their town or city of residence. There were 150 towns/cities represented in the testing population, and out of all participants, 691 (44%) reported living in one of five towns/cities. Out of the 150 different towns/cities reported on the questionnaire, 122 (81%) had fewer than 10 individuals per town/city participate in the testing program. There were also 12 different states represented; 98.4% of participants reported residing in three of those states: 1,328 (84.2%) reported residing in New Hampshire, 184 (11.7%) reported residing in Maine, and 42 (2.7%) reported residing in Massachusetts.

The NH DHHS noted that three different laboratories carried out the analytical assays at different phases of the 2015-7 Pease PFC Blood Testing Program. During the first round, 471 people had their blood tested by the CDC laboratory. During the second round, 1,107 people had their blood tested: CDC performed the first 300 serum analyses, AXYS performed 700 serum analyses, and the CA State Laboratory performed 107 serum analyses. In total, 771 samples (49%) were tested at the CDC laboratory, 700 (44%) were tested at AXYS, and 107 (7%) were tested at the CA State laboratory. Each laboratory has its own established levels of detection (LOD).

Most serum specimens had detectable levels of PFOS (99.8%), PFOA (99.2%), and PFHxS (94.2%). A majority of participants also had detectable levels of PFNA (85.2%). The remaining PFCs were found in much smaller amounts.

#### Respondent Universe for the Pease Study

The respondent universe will continue to build upon the existing convenience sample established by the 2015-7 Pease PFC Blood Testing Program (n=1,836).<sup>4</sup> For purposes of estimation of time and cost burden (**Section A.12**), ATSDR assumes a 95% eligibility and 70% response for those who participated in the previous Pease PFC Blood Testing Program. For recruiting those who did not participate in that prior study, we assume an eligibility rate of 95%

<sup>4</sup> The initial Pease PFC Blood Testing Program in 2015 enrolled 1,578 participants for which ATSDR is using as a baseline for this research because much more information about this cohort is available in the final report at <https://www.dhhs.nh.gov/dphs/documents/pease-pfc-blood-testing.pdf>.

NH DHHS expanded PFC blood testing in 2016-2017 for a number of southern New Hampshire communities, including testing for an additional 258 Pease Tradeport residents. Their results were consistent with the 2015 Pease PFC Blood Testing Program. ATSDR will also invite these additional 258 participants in Wave One; the age information is not readily available so we assumed the age distribution for the initial 1,578 participants to allow us to estimate the number of adults and children for the estimates in Table B.1.2. See [https://www.bedfordnh.org/DocumentCenter/View/2472/PFC-Blood-Testing-Aggregate-Results-Overview\\_FINAL\\_100517](https://www.bedfordnh.org/DocumentCenter/View/2472/PFC-Blood-Testing-Aggregate-Results-Overview_FINAL_100517).

and a response rate of 80%. ATSDR will enroll 1,625 participants for the two separate age group studies (1,100 adults and 525 children and their parents).

Table B.1.2. Estimated Number of Respondents for Pease Study over Three Years\*

	Estimated Respondent Counts (Wave One 95% eligibility and 70% response rate) (Wave Two and Wave Three 95% eligibility and 80% response rate)						Total		
	Exposure Group Wave One‡		Exposure Group Wave Two		Total Exposure Group	Referent Group Wave Three		Total Referent Group	
	Adult	Child	Adult	Child		Adult			Child
No. Screened for Eligibility	<b>Total=1,836</b>		<i>Total=170</i>		2,006 (1,491 adults; 515 children)	<i>Total=362</i>		362 (132 adults; 230 children)	2,428 (1,623 adults; 745 children)
	1,403	433	88	82		132	230		
No. Eligible and Enrolled	<i>Total=1,221</i>		<i>Total=129</i>		<b>1,350</b> (1,000 adults; 350 children)	<b>Total=275</b>		<b>275</b> (100 adults; 175 children)	<b>1,625</b> (1,100 adults; 525 children)
	933	288	67	62		100	175		

**Bold** numbers indicate fixed number of cohort members (n=1,836=1,578 in 2015 and 258 in 2017) or target sample sizes to be achieved (n = 1,625 = 1,350 exposed + 275 referent). Based on these fixed numbers the remainder of the table was interpolated based on the following assumptions:  
*Italicized* numbers indicate numbers indirectly calculated and interpolated. We assume the following:

- Wave One: 95% eligibility and 70% response from the fixed cohort that will require agency recruitment efforts.
- Wave Two and Wave Three: We assume 95% eligibility and 80% response since these people are already interested and are self-volunteering to take part. They are not part of a statistical sample requiring recruitment. We assume that fewer one in five (20%) may change his/her mind after hearing the informed consent information.

\* Estimates align with Table A.12.1 and Table A.12.2 annualized results and with assumptions made in Section A.12. Enrollment will occur in three waves. Wave One will first prioritize recruitment of interested and eligible cohort members from the Pease PFC Blood Testing Program. If sample size goals are not met for the exposure group, Wave Two will recruit additional exposed community members who are eligible but did not enroll in the Pease PFC Blood Testing Program. Wave Three will recruit the referent group.

‡ Wave One adult and child estimates are generalized from Table B.1.1, by assuming equal distribution across ages within each age sub-total and adding 4 years to each age. For example, a child who is Age 0 in 2015 is eligible at Age 4 in 2019. The 164 children in the 3-5 year age group in 2015 are assumed to be evenly distributed as 54 3-year olds, 55 4-year olds, and 55 5-year olds, who would now be 7, 8, and 9 year olds in 2019. We use the same method for the 31 individuals in the 12-19 year age group to estimate the number of children in 2015 who will be adults 18 years and older in 2019. We distribute the 31 as follows: 3 12-year olds and 4 13-year olds in 2015 would be classified as children 16 and 17 years old in 2019. This would yield 373 Wave One children and 1,205 Wave One adults to be screened. Therefore, all 1,578 from 2015 are assumed to be age-eligible for the Pease Study and would be screened for additional eligibility criteria and willingness to participate. Since the demographics for the 258 cohort members are not reported by the NH DHHS,<sup>5</sup> we assume the same proportion of adults to children as reported for the 2015 cohort (76.4% adults and 23.6% children), which results in 1,403 adults and 433 children screened for eligibility, or 1,836 screened for eligibility in all.

ATSDR assumes that the Pease Study populations will be very similar in demographics to the 2015 Pease PFC Blood Testing Program (**Table B.1.1**); however, eligibility criteria will be slightly

<sup>5</sup> [https://www.bedfordnh.org/DocumentCenter/View/2472/PFC-Blood-Testing-Aggregate-Results-Overview\\_FINAL\\_100517](https://www.bedfordnh.org/DocumentCenter/View/2472/PFC-Blood-Testing-Aggregate-Results-Overview_FINAL_100517)

different for the purposes of this research (see **Pease Study Protocol Section 3.2** and description below).

**Adult Eligibility:** Adults will be 18 years or older at enrollment. To restrict this study to drinking water exposures, any adult occupationally exposed to PFAS will not be eligible for the study (i.e. ever firefighters or in chemical manufacture). This restriction applies to both the exposure and the referent group.

**Child Eligibility:** Children will be 4-17 years of age at enrollment. Ideally for the child study, the parent should be the mother, who can best answer some survey questions about the child's exposures and about the mother's pregnancy and breastfeeding history. A parent can enroll with more than one child. In this case, ATSDR will enroll each child separately along with his or her parent. Parents, if eligible, may also enroll in the adult study. Children whose birth mothers were occupationally exposed will not be eligible. This restriction applies to both the exposure and the referent group.

**Exposure Group Eligibility (Adults and Children):** For the exposure groups (n=1,350 total), ATSDR will enroll 1,000 adults and 350 children. Eligible participants had to work at, live on, or attend childcare at the former Pease Air Force Base or the Pease International Tradeport, or live in a nearby home that was served by a PFAS-contaminated private well. Drinking water exposures must have occurred at some time between 2004 and May 2014, after which remediation of the public water supply occurred.

**Referent Group Eligibility (Adults and Children):** For the referent groups (n=275 total), ATSDR will enroll 100 adults and 175 children. Eligible participants, never exposed to PFAS-contaminated drinking water from Pease, will come from other areas of Portsmouth, NH. Birth mothers of referent children likewise must never have had PFAS drinking water exposure. See **Attachments 6c and 7c**.

### Sampling Methods

Recruitment methods, described in the **Pease Study Protocol Section 3.5**, will not involve statistical methods. Trained study staff and contractors from ATSDR will recruit, screen for eligibility, and enroll a convenience sample of participants in three waves.

To set up the operational procedures needed to achieve recruitment goals, ATSDR is planning for the possibility that not all of the past participants of the 2015 Pease PFC Blood Testing Program will enroll in the exposure group. **Table B.1.2** shows the estimated totals and counts of adults and children required to achieve the stated sample size goals.

- In Wave One, NH DHHS will assist ATSDR by sending out letters of invitation to its former blood testing program participants (**Attachments 6a&6b**). ATSDR assumes that all 1,836 cohort members of the Pease PFC Blood Testing Program will be screened for eligibility (**Attachment 6c**). Thus, ATSDR estimates that 90.4 percent of the exposure

group will be screened and enrolled in Wave One (n=1,221=933 adults + 288 children; %=1,221/1,350\*100), that is, will be past participants of the 2015-7 Pease PFC Blood Testing Program.

- In Wave Two and Wave Three, recruits will be instructed to volunteer after ATSDR opens those waves to enrollment in recruitment flyers (**Attachments 7a,7b,7d&7e**).
  - Wave Two Enrollment: To achieve the desired sample size for the exposure group, ATSDR will screen and recruit additional people who were eligible for the Pease PFC Blood Testing Program but did not take part (**Attachment 7c**).
    - ATSDR estimates it will screen at least 170 exposed people in Wave Two to get 129 eligible (67 adults and 62 children).
  - Wave Three Enrollment: The referent group will be recruited in Wave Three, which can occur concurrently with Wave One and Wave Two (**Attachment 7c**).
    - ATSDR will screen at least 362 unexposed people (132 adults and 230 children) in Wave Three to get 275 eligible (100 adults and 175 children).

Steps in screening are:

- Administer the eligibility screening scripts and schedule appointments (**Attachments 6c&7c**).
- Begin tracking the recruitment process (**Attachment 8**).
- Mail out appointment packets (**Attachment 9**), which will contain the following documents to keep and read before their appointments:
  - Appointment reminder cards (**Attachment 9a**), with instructions on how to prepare for the appointment
  - Informed consent packets (**Attachment 9b**),
    - Privacy Act Statement (**Attachment 9b1**)
    - Parental Permission and Child Assent Forms (**Attachment 9b2**)
    - Parental Consent to Release Student Information (**Attachment 9b3**)
    - Adult Consent Form (**Attachment 9b4**)
    - Parent/Child/Adult Permission for Medical Record Abstraction (**Attachment 9b5**)
  - Study Fact Sheet (**Attachment 9c**)
- Encourage participation with appointment reminder calls (**Attachments 10&11**).

### Sample Size Justification

The power calculations specifically for the **Pease Study Protocol** is found in detail in **Section 3.3** and **Attachment 4**. A summary is presented here.

Adult Study



**Table B.1.3** presents minimum detectable difference calculations assuming that 1,000 adults from Pease and 100 referent adults will participate in the study (**Attachment 4**). The calculations also assume a type 1 error of .05 and a type 2 error of .20. There is sufficient power to detect mean differences in total cholesterol, uric acid, and ALT based on estimated from other epidemiological studies. For categorical outcomes such as hyperuricemia and hypertension, ORs below 2.0 are detectable. For health outcomes such as hypercholesterolemia, thyroid disease, elevated liver enzymes, cardiovascular disease and osteoarthritis, ORs between 2.0 and 3.0 are detectable, though these ORs are larger than those typically documented to be statistically significant in most environmental epidemiology studies. In addition, several epidemiological studies of adults exposed to PFAS that reported robust statistical associations with these health outcomes had similar or smaller sample sizes, e.g., NHANES studies (Nelson 2010, Wen 2013), a C8 longitudinal study (Fitz-Simon 2013), a C8 immune study (Looker 2014), and studies in China (Fu 2014) and Korea (Ji 2012).

Table B.1.3. Minimum Detectable Effects for Pease Adult Study of 1,000 Exposed and 100 Referents.

<b>Endpoint</b>	<b><math>\alpha = .05, \beta = .20</math></b>
Mean difference in:	
Total cholesterol	12.4 mg/dL
Uric acid	0.46 mg/dL
ALT	5.92 IU/L
Uric acid (mean difference)	0.46 mg/dL
Odd Ratios (OR) for:	
Hyperuricemia	OR=1.96
Elevated GGT (>55 IU/L, men; >38 IU/L, women)	OR=2.26
Hypercholesterolemia	OR=2.21
Thyroid disease	OR=3.03
Elevated ALT (>45 IU/L, men; >34 IU/L, women)	OR=2.43
Cardiovascular disease	OR=2.31
Hypertension	OR=1.83
Thyroid disease	OR=3.03
Osteoarthritis	OR=2.83
Osteoporosis	OR=3.44
Rheumatoid arthritis	OR=4.65
Ulcerative colitis	OR= 8.0
Based on Protocol Attachment 4 Table 2.	

## Child Study

Minimum detectable differences were calculated with type 1 (“ $\alpha$  error”) set at .05 and type 2 error (“ $\beta$  error”) set at .20. Sample sizes per stratum group were calculated. It was considered important that a study have a total sample size so that exposures could be categorized into tertiles (i.e., reference level, medium level, and high level) or quartiles (i.e., reference level, low, medium and high) (**Attachment 4**).

Studies were selected that were considered the most representative of U.S. populations exposed via drinking water to PFOA, PFOS and/or PFHxS as a result of the migration of these PFAS chemicals into ground water or surface water sources from the use of aqueous film forming foam (AFFF). The PFAS serum results from the Pease PFC Blood Testing Program were used as representative PFAS serum levels.

Studies conducted using NHANES data had PFOA and PFHxS serum levels similar to or lower than those observed at Pease. Therefore the PFOS, PFOA and PFHxS results in the NHANES studies were used in many of the minimum detectable difference calculations. For those outcomes not included in NHANES studies, the C8 studies were used. Where applicable studies from Taiwan or other major industrialized countries were also used.

Table B.1.4. Minimum Detectable Effects for Pease Child Study of 350 Exposed and 175 Referents.

Endpoint	$\alpha = .05, \beta = .20$
Mean difference in:	
Total cholesterol	9.8 mg/dL
Uric acid	0.40 mg/dL
eGFR	9.3 mL/min/1.73 m <sup>2</sup>
IGF - 1	22.5 ng/mL
TT <sub>4</sub>	0.37 $\mu$ g/dL*
Wechsler Full Scale IQ	3.4 points*
Odds Ratio (OR) for:	
Hypercholesterolemia	OR = 2.00
Hypertension	OR = 2.12
Overweight/Obese	OR = 2.18
Hyperuricemia	OR = 2.30
ADHD <sup>†</sup>	OR = 2.47
Asthma	OR = 2.56
Atopic dermatitis	OR = 2.49

## B.2. Procedures for the Collection of Information

At the appointment, enrollment and data collection procedures are described in the **Pease Study Protocol Section 3.5.3, Section 3.6**, and in the Manual of Procedures for staff and contractor training (**Attachment 14**). Steps in enrollment are:

- Administration of informed consent, parental permission, and child assent (**Attachment 9b**).
- Update participant contact information, if needed (**Attachment 12**).
- Record participant medication list (**Attachment 13**).
- Take body and blood pressure measures (**Attachment 15**).
- Collect blood and urine biospecimens (**Attachment 16**).
- Administer questionnaire (**Attachment 17, 17a, 18**).
- (For children and parents) Administer the neurobehavioral test battery (**Attachment 20**).

After the appointment, ATSDR will seek:

- Medical record verification for self-reported conditions noted in the questionnaire (**Attachment 19, 19a, 19b**).
- Education record verification to compare to the results of the children's neurobehavioral assessments and their parents' assessments of their children (**Attachment 20b, 20c**).

## B.3. Methods to Maximize Response Rates and Deal with Non-response

The **Pease Study Protocol Section 3.2.1** describes the estimated number of eligible children and assumptions about participation rates needed to achieve statistical goals:

“Assuming that a minimum of about 500 children attended the two day-care centers at Pease before June 2014 and would be aged 4–17 years in 2018, we would require a participation rate of about 70% to recruit 350 Pease children into the study. Such a participation rate is possible given the high visibility of the study, strong interest in the community, and the commitment of the Pease CAP and associated organizations to conduct outreach for the study.

It would also be feasible to recruit at least 175 children in the same age range from the schools in Portsmouth, NH, who were unexposed to the PFAS-contaminated drinking water at the Pease Tradeport and whose parents did not work at the Pease Tradeport or have occupational exposures to PFAS.”

The **Pease Study Protocol Section 3.2.2** describes the estimated number of eligible adults and assumptions about participation rates needed to achieve statistical goals:

“Apart from the occupational exposure exclusion, the study will recruit adults who participated in the Pease PFC Blood Testing Program. Adults who did not participate in the biomonitoring program but meet eligibility criteria could also enroll in the current study in order to meet sample size requirements. About 1,430 adults have participated in this program. A participation rate of 70% would result in a sample size of about 1,000. In addition, for some of the outcomes of interest, e.g., serum level of total cholesterol, hyperuricemia, and cardiovascular disease, a sample size of 1,000 would be sufficient for PFAS serum levels categorized into quartiles.

The study will recruit a comparison population of 100 adults, unexposed to the contaminated drinking water at Pease, consisting of adults aged  $\geq 18$  years, taking into account the age distribution of the adults who participated in the Pease PFC Blood Testing Program.”

In order to maximize participation in the Pease Study, ATSDR will provide the flexibility to schedule or re-schedule office or home visits within the study period (**Pease Study Protocol Section 3.5.3**).

- Interested recruits who are unable or unwilling to come to the study office, will be offered an in-home appointment by trained study staff to complete the study. Interested recruits who request or require a home interview, blood draw, and urine collection, must reside within a one-hour drive from the study office.
- Study staff will give the interested recruit a reminder telephone call one to two days before the scheduled appointment (**Attachment 10**).
  - The study staff will make up to five contact attempts to an interested recruit who misses an appointment in order to reschedule the appointment and maximize the number of completed appointments (**Attachment 11**).

When the data are collected, ATSDR will perform non-response bias analyses.

## B.4. Test of Procedures or Methods to be Undertaken

The **Pease Study Protocol** will serve as the proof of concept research study. One of the main goals of the research study is to evaluate the study procedures and methods to identify any issues that need to be addressed before embarking on a multi-site study.

ATSDR will use the proof of concept study experience to refine questions, minimize burden, and improve utility. Some of the proposed data/information collection instruments have been based on those successfully used in the “Anniston Community Health Survey: Follow up and Dioxin Analyses (ACHS-II)” (OMB Control No. 0923-0049; discontinued 11/12/2015) (**Attachments 12, 13, 15, 16**).

The Pease Study questionnaires (**Attachments 17, 17a, 18**) were developed specifically for the unique PFAS exposure scenarios at Pease; therefore, ATSDR will use this proof of concept experience to see if questionnaire refinement will be recommended for the multi-site protocol. Additionally, eligibility screeners (**Attachments 6c, 7c**), medical records request and abstraction forms (**Attachments 19, 19a, 19b**), and the school records request and abstraction form (**Attachments 20b, 20c**) are new forms to be tested for ease of use and utility.

## B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Table B.5.1. Personnel Consulted on Statistical Design

Name	Title	Affiliation	Phone	Email
<i>FEDERAL AGENCY</i>				
Marian Pavuk, MD, PhD	Senior Epidemiologist, PI Pease Study	ATSDR	(770) 488-3671	<a href="mailto:fsh8@cdc.gov">fsh8@cdc.gov</a>
Frank Bove, DSc	Senior Epidemiologist, PI Pease Study	ATSDR	(770) 488-3809	<a href="mailto:fjb0@cdc.gov">fjb0@cdc.gov</a>

Table B.5.2. Personnel Responsible for Collection and Analysis of Information

Name	Title	Affiliation	Phone	Email
Marian Pavuk, MD, PhD	Senior Epidemiologist, PI Pease Study	ATSDR	(770) 488-3671	<a href="mailto:fsh8@cdc.gov">fsh8@cdc.gov</a>
Frank Bove, DSc	Senior Epidemiologist, PI Pease Study	ATSDR	(770) 488-3809	<a href="mailto:fjb0@cdc.gov">fjb0@cdc.gov</a>
Michael Lewin, MS	Mathematical Statistician	ATSDR	(770) 488-3812	<a href="mailto:mdl0@cdc.gov">mdl0@cdc.gov</a>
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## References

Agency for Toxic Substances and Disease Registry (ATSDR). Feasibility Assessment for Epidemiological Studies at Pease International Tradeport. Portsmouth, New Hampshire. November 2017. **Appendix C** available at:

[https://www.atsdr.cdc.gov/sites/pease/documents/Pease\\_Feasibility\\_Assessment\\_November-2017\\_508.pdf](https://www.atsdr.cdc.gov/sites/pease/documents/Pease_Feasibility_Assessment_November-2017_508.pdf)

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# List of Appendices and Protocol Attachments

Appendix A. Authorizing Legislation

Appendix B. 60-day Federal Register Notice

Appendix B1. Public Comments and Program Responses

Appendix C. ATSDR Pease Feasibility Assessment

Appendix D. Privacy Impact Assessment

Appendix E. IRB Approval Memo

Appendix F: Data Sharing and Disclosure Review

## Pease Study Protocol and Attachments

Attachment 1. Investigators and Key Study Personnel

Attachment 2. PFAS Serum Levels, Pease vs. External Populations

Attachment 2a. Pease serum PFAS levels in  $\mu\text{g/L}$ , by age groups, 2018

Attachment 2b. Serum PFAS levels in  $\mu\text{g/L}$ , children aged <12 years, Pease vs. comparisons

Attachment 2c. Serum PFAS levels in  $\mu\text{g/L}$ , aged  $\geq 12$  years, Pease vs. NHANES

Attachment 3. Biochemical Analytical Plan in Children and Adults

Attachment 4. Justification for Sample Size Calculations

Attachment 4a. Sample Size for Child Study

Attachment 4b. Sample Size for Adult Study

Attachment 5 – Pease Study Communication Plan

Attachment 5a. Pease Study Communication Plan Objectives

Attachment 5b. Pease Study Overarching Communication Messages

Attachment 5c. Pease Study Press Release – Launch

Attachment 5d. Pease Study Website Flyer

Attachment 5e. Pease Study Public Service Announcement

Attachment 6 – Wave One - NH DHHS Invitation Letters for Study Roll Out

Attachment 6a – NH DHHS Child Invitation Letter

Attachment 6b – NH DHHS Adult Invitation Letter

Attachment 6c – Wave One Eligibility Screening Script

Attachment 7 – Waves Two and Three Recruitment Materials

Attachment 7a – Wave Two Flyer to Recruit Additional Exposed Children

Attachment 7b – Wave Two Flyer to Recruit Additional Exposed Adults

Attachment 7c – Wave Two or Wave Three Eligibility Screening Script  
Attachment 7d – Wave Three Child Flyer for Referent Recruitment  
Attachment 7e – Wave Three Adult Flyer for Referent Recruitment  
Attachment 8 – Recruitment Tracking Form  
Attachment 9 – Appointment Packet  
Attachment 9a – Appointment Reminder Card  
Attachment 9b – Informed Consent Packet  
Attachment 9b1 – Privacy Act Statement  
Attachment 9b2 – Parental Permission and Child Assent Forms  
Attachment 9b3 – Parental Consent to Release Student Information  
Attachment 9b4 – Adult Consent Form  
Attachment 9b5 – Parent/Child/Adult Permission for Medical Record Abstraction  
Attachment 9c – Study Fact Sheet  
Attachment 10 – Appointment Reminder Telephone Script  
Attachment 11 – Appointment Tracking Form  
Attachment 12 – Update Contact Information Hardcopy Form  
Attachment 13 – Medication List  
Attachment 14 – Manual of Procedures  
Attachment 15 – Body and Blood Pressure Measures Form  
Attachment 16 – Blood Draw and Urine Collection Form  
Attachment 17 – Child Questionnaire – Long Form  
Attachment 17a – Child Questionnaire – Short Form  
Attachment 18 – Adult Questionnaire  
Attachment 19 – Request for Medical Record Abstraction  
Attachment 19a – Medical Record Abstraction Form - Adult  
Attachment 19b – Medical Record Abstraction Form - Child  
Attachment 20 – Child/Parent Neurobehavioral Test Battery  
Attachment 20a – NBT Time Estimation Table, by Age in Years  
Attachment 20b – Request for Child School Record Abstraction  
Attachment 20c – Child School Record Abstraction Form  
Attachment 21 – Body and Blood Pressure Measurements Report  
Attachment 22 – Advance Reporting Script for Clinical Tests  
Attachment 22a – Advance Clinical Test Report Tracking Form  
Attachment 22b – Letter Report of Critical Values



Attachment 23 - Clinical Test Results Report

Attachment 24 - PFAS Results Report

Attachment 24a - ATSDR PFAS Factsheet