

Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH

(OMB Control No. 0923-0061, exp. date 08/31/2022)

Justification/Brief Explanation for Change Request

The Request: This is a non-material/non-substantive change request for “Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH” (OMB Control No. 0923-0061; expiration date August 31, 2022). This change request reflects modifications to the currently approved information collection request (ICR) and incorporates the need to practice social distancing to the extent possible, such as changing from in-person contact to virtual meetings and telephone interviews. Where necessary, ATSDR has modified its scripts and forms to let the public know of the COVID-19 precautions that the agency is implementing.

The program is requesting an expedited review to restart the Pease study as soon as possible. The shutdown of the study over the last several months has likely impacted community interest in the study. The longer study recruitment is delayed, the harder it will be to achieve reasonable study participation by the community. Moreover, if the study restart is delayed much further, it will begin to interfere with the holiday season, adding to the difficulty of recruitment. Restarting the study by the end of September at the latest would be optimal for recruitment.

Background: ATSDR and contractors suspended the Pease Study activities when the COVID-19 pandemic began in the United States. Restarting Pease Study 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 <https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-covid-19-client-interaction.html>.

Since that time, the program has developed the Pease restart plan in collaboration with and reviewed and approved by CDC Leadership and the CDC Emergency Operation Center (EOC) Joint Information Center (JIC).

Summary of the Restart Plan: Appendix G, the Pease Restart Plan, in Attachment 14, the Manual of Procedures, has been included and outlines the additional procedures that will be implemented during recruitment, field work, and community meetings to ensure that the Pease study activities are completed in compliance with state, local, and CDC requirements.

The activities that will be modified include:

- Holding virtual community assistance panel (CAP) meetings on a quarterly basis. In addition, in order to improve study participation recruitment, meetings of small groups (e.g., “lunch and learn”) may be held at businesses and colleges/universities at the Pease Tradeport, and at community organizations in Portsmouth, as needed. Media and community outreach activities

will be held online or structured to ensure less than 10 participants at a time in accordance with applicable local, state and CDC guidelines in place at the time of the events.

- 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 Pease study contractor staff twice daily and taking participant's temperatures prior to entering the Pease study office.
- Administering the questionnaire over the phone instead of at the Pease study office to reduce the participant's time in the Pease study office: consent form administration and collection of biological samples will occur at the Pease study office.
- Ensure proper use of PPE when participants and examiners are not able to be socially distance when conducting neurobehavioral tests and body measurements

Below is the change request cross-walk table. Attached please find the revised protocol and modified forms and appendices. The overall number of respondents and requested burden hours remain the same.

Attachment	Revisions	Justification
P_Att14 PeaseManualofProcedures_20200729	<ul style="list-style-type: none"> • Updated date (cover page and footer) • Minor grammatical and formatting changes (pages 6, 29, 34, 35, & 46) • Added information on COVID-19 safety precautions (pages 8-9) • Added general health and safety plan (pages 15-17) • Added information on the selected laboratories (page 27) • Added reference to COVID-19 safety precautions and health and safety plan (page 27) • Adjusted blood sample volumes (page 27) • Added sample collection tube information (page 27) • Changed freezer temperature for storage of samples (page 28) • Deleted table on whole blood processing (page 29) • Added preferred pipet information (pages 29-30) • Replaced cryovials with vials (page 30) • Replaced the blood processing table with additional information on serum and blood processing aliquots (pages 30-32) • Removed email for sample logistics (page 35) • Added shipping address for PFAS samples (page 35) • Added clarification that the CDC Biorepository will only store reserve samples (page 35) • Added information on an option for a phone interview (page 40) • Updated internal document reference (page 46) 	<ul style="list-style-type: none"> • Minor grammatical updates • Changes reflect efforts to prevent the spread of COVID-19 • The selection of laboratories informed the adjustments to the blood sample volumes and additional information on sample collection and storage • Updated sample logistics information

	<ul style="list-style-type: none"> Added an appendix to describe the Pease Study Restart Plan (pages 74-79) 	
P_Att09a_ApptReminderCard_20200729_trackchanges	<ul style="list-style-type: none"> Added information on COVID-19 health and safety precautions (page 3) 	<ul style="list-style-type: none"> Changes reflect efforts to prevent the spread of COVID-19
Pease Study Protocol 20191122_clean_COVID insert 20200622	<ul style="list-style-type: none"> Updated date (page 1) Added summary of protocol changes related to COVID-19 (page 2) Added details on IRB and OMB approval (page 12) 	<ul style="list-style-type: none"> Changes reflect efforts to prevent the spread of COVID-19
P_Att11_ApptTrackingForm_20200729	<ul style="list-style-type: none"> Added document title (page 1) Added information on COVID-19 health and safety precautions (pages 1-2) Added line for no temperature or reported symptoms (page 3) 	<ul style="list-style-type: none"> Changes reflect efforts to prevent the spread of COVID-19
P_Att10_AppointmentReminderTelScript_20200729_trackchanges	<ul style="list-style-type: none"> Added reminder about residential, occupational, and medical history (pages 2-3) Added information on COVID-19 health and safety precautions (pages 2-3) 	<ul style="list-style-type: none"> Changes for consistency between Pease and Multi-site Study Changes reflect efforts to prevent the spread of COVID-19
P_Att07c WaveTwoorWaveThreeElgbltyScreeningScript_20200729	<ul style="list-style-type: none"> Added information on COVID-19 health and safety precautions (pages 1-2) Minor grammatical and formatting changes (pages 3-4 & 6-7) Added option of conducting the interview via telephone (page 4) Added question to schedule telephone interview for interested participants (page 4) Corrected reference to juvenile detention from prison (page 5) 	<ul style="list-style-type: none"> Changes reflect efforts to prevent the spread of COVID-19 Updated reference to juvenile detention Minor grammatical updates Changes for consistency between Pease and Multi-site Study
P_Att06c WaveOneElgbltyScreeningScript_20200729_trackchanges	<ul style="list-style-type: none"> Updated OMB approval number (page 1) Added information on COVID-19 health and safety precautions (page 1) Minor grammatical and formatting changes (pages 2-4) 	<ul style="list-style-type: none"> Changes reflect efforts to prevent the spread of COVID-19 Minor grammatical updates

	<ul style="list-style-type: none"> • Added option of conducting the interview via telephone (page 2) • Added question to schedule telephone interview for interested participants (page 2-3) • Removed confirmation of eligibility after question #4 (page 4) • Corrected reference to juvenile detention from prison (page 4) 	<ul style="list-style-type: none"> • Added OMB approval number • Updated reference to juvenile detention • Changes for consistency between Pease and Multi-site Study
P_Att09c_StudyFactSheet_20200729_trackchanges	<ul style="list-style-type: none"> • Added information on the option of conducting the interview via telephone (page 3) • Added information on COVID-19 health and safety precautions (page 4) • Added CDC Protocol Number (page 4) 	<ul style="list-style-type: none"> • Changes reflect efforts to prevent the spread of COVID-19 • Added CDC protocol number
P_Att06_WaveOne_NHDDHHSInvitationLetterStudyRollout_20200729_trackchanges	<ul style="list-style-type: none"> • Added CDC Protocol Number (page 2-3) • Added information on COVID-19 health and safety precautions (page 2-3) • Changed ATSDR contact (page 2-3) 	<ul style="list-style-type: none"> • Changes reflect efforts to prevent the spread of COVID-19 • Added CDC protocol number • Updated contact information
P_Att09b_InformedConsentPacket_20200729_trackchanges	<ul style="list-style-type: none"> • Added information on COVID-19 health and safety precautions (pages 4, 10, 14-16,) • Updated language to include guardian in addition to parent (page 10) • Added information on the option of conducting the interview via telephone (page 15) • Added clarification that ATSDR will collect biospecimens at the study office (page 15) • Updated the volume of blood to be collected (page 17-18) 	<ul style="list-style-type: none"> • Changes reflect efforts to prevent the spread of COVID-19 • The selection of laboratories informed the adjustments to the blood sample volumes • Minor wording updates