

Date: September 3, 2019

Change Request for OMB Control No. 0923-0061 (expiration date 08/31/2022)

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

Justification

This is a nonmaterial/non-substantive change request for OMB Control No. 0923-0061 (expiration date 08/31/2022).

The Pease Community Advisory Panel (CAP) has recommended that the leftover blood from the NH PFC Blood Testing Program be brought into the Pease Study with participant consent. The NH State Epi has asked ATSDR to re-consent participants to retain leftover blood, as the original NH consent said that the bloods would be destroyed after the blood testing program was over. After the Pease enrollment is completed NH DHHS can destroy the samples for which Pease participants declined saving, or for those who did not enroll in the Pease Study. NH DHHS will be making a public announcement to this fact.

Proposed Changes are reflected in the revised: (1) Appendix E (IRB Approval memos), (2) body of the Pease Study Protocol, and in (3) Protocol Attachment 9b (Informed Consent Packet), as described below:

Information Collection Documents	Requested Change	Justification
Appendix E. IRB Approval Memos 20190903	1. During the OMB review, ATSDR submitted 4 IRB amendments after initial IRB approval was obtained on 05/23/2019. The fourth and final amendment approval reflects the current changes requested to allow ATSDR to obtain leftover bloods from the New Hampshire Department of Health and Human Services (NH DHHS) Pease PFC Blood Testing Program, 2015-2017.	During the course of OMB review, ATSDR amended the research protocol and submitted to CDC IRB for approval.
Protocol 20190823	2. Dissemination statement on the front page of the protocol deleted. 3. Added sentence about the leftover blood samples from the 2015-17 NH DHHS PFC Blood Testing Program; those that will consent will have their samples stored for future testing by ATSDR. Others will have those samples discarded (p. 52).	Protocol changes are consistent with the Pease CAP and the NH State Epidemiologists recommendations.
Attachment 9b. Informed Consent Packet 20190823	4. Attachment 9b is modified to allow participants to consent or not consent for ATSDR to receive their leftover blood samples from the 2015-17 NH DHHS Pease PFC Blood Testing Program for future testing by ATSDR.	

The requested time burden to the respondents and the data collection methods remain unchanged.