Date September 7, 2021

From Denise M. Marshall
Reliance Officer, Human Research Protection Office

Subject IRB Approval of Amendment #9 to CDC Protocol 7161, "Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH (Pease Study - Proof of Concept)" (Expedited)

To Marian Pavuk, PhD, MD
ATSDR/DTHHS

CDC's IRB-Committee 2 has reviewed and approved your request to amend protocol 7161, “Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH (Pease Study - Proof of Concept)”.

These changes included the following:

Study Protocol:

1. Updated method for PFAS measurements (Kato et al., 2018).
2. PFAS analytes that will not be measured in Pease were removed from the list: PFOSA, Et_PFOSA-AcOH, PFBuS, PFHpA, and PFDoA [Section 3.6.Biochemical Analyses, p.44].
3. Three additional PFAS analytes that have been included in 2017-8 NHANES (Oxanonane, Adona, and GenX) but will not be measured in Pease due to all reference ranges below limit of detection (LOD) [p. 44]

Att 3 BiochemAnalPlan

4. Updated PFAS analytes to be measured; PFOSA, Et-PFOSA-AcOH, PFBuS, PFHpA, and PFDoA were deleted.

Att 24 PFASChemReport

5. Added thank you to participants as the first sentence.
6. Noted that the results of adults and children 12-19 years old will now be compared to 2017-2018 NHANES.
7. Updated link to ATSDR PFAS information.
8. Updated 50th and 95th percentiles for NHANES 2017-2018 PFAS reference ranges in children 12-19 and adults 20+ year old in template Table 1 and added link.

9. Three PFAS analytes (PFNA, PFDA, and PFUnDA) inadvertently didn't copy in Table 1 to page 3 from the originally approved version and are now listed to be consistent with the protocol.
10. Note was added that all reference ranges for these analytes were below the limits of detection (LOD).

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), under categories 2a, 2b, 3, 4, 5, and 7 to previously approved research during the period (of one year or less) for which approval is authorized.

Any problems of a serious nature must be brought to the immediate attention of the CDC IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for CDC IRB approval before they are implemented.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-7570 or e-mail: huma@cdc.gov.

cc: NCEH/ATSDR Human Studies