Change Request for "Human Health Effects of Drinking Water Exposures to Per- and Polyfluoroalkyl Substances (PFAS): A Multi-site Cross-sectional Study" (OMB Control No. 0923-0063; exp. date 05/31/2023)

<u>Justification/Brief Explanation for the Change Request</u>

These non-substantial changes for the Multi-site Study (MSS) fall into three categories. First, changes were made to maintain consistency with the Pease Study (OMB Control No. 0923-0061; exp. date 08/31/2022) as the MSS expands on the work done in the Pease Study. Second, changes were made to reflect the differences in PFAS exposure between the Pease site (non-residential drinking water) and the MSS sites (residential drinking water). Third, the remainder of changes were made based on suggestions from OMB.

Attachment	Revisions	Justification		
Multi-site study protocol	 Changed version date Corrected sample size numbers Added approved language on heavy metals/neurobehavioral outcomes in children (Section 3.8.6; page 56) 	 Language on metals/neuro added per OMB request Corrected error in sample size numbers. Protocol had incorrect numbers from a previous version 		
(M_Att12_Manual of Procedures)	 Changed version date Updated OMB numbers / exp. dates, number of participants updated. Added for the whole blood collection "trace metals prescreened vials provided by CDC"; also the labels provided by CDC (Section 10.1; page 23) All other supplies and equipment for blood collection to be obtained by grantees (study investigators); deleted provided by contractor Blood collection updated as if the same labs as for Pease for consistency 	 Post-OMB approval updates Consistency with Pease MOP 		
(M_Att04_ElgbltyScr eeningScript)	 Changes for improved readability Added wording for type of contact (inbound call/outbound call) Added question about how the potential participant learned about the study Added questions about residing in the 	 These changes were made based on feedback from the 7 MSS sites to adjust the eligibility script to accommodate the site-specific needs. New questions differ from Pease questionnaire because the Pease study does not follow residential 		

	 target study area. Added examples of PFAS manufacturing (Scotch Guard/Teflon) Differentiate between mailing address vs home address Question added about texting study information to provided cell phone number Added question about other adults who used to be part of the household who have moved away Added questions about parent/guardian/birth mother of enrolled child Changed wording on interviewing over the phone 	drinking water exposures. • Editorial changes were made to improve the flow and readability of the screening script.
(M_Att15_ ChldQstnnr_LongFor m)	 Added question about household income and health insurance Questions added about current and past addresses in study area Questions added about source of tap water, tap and bottled, and general water consumption Questions added about water filtration Revised medical condition tables Added word "grandparents" to question about blood relatives 	 Household income and health insurance questions were added to remain consistent with Pease questionnaire. New questions were added based on feedback from 7 MSS sites to reflect their site-specific circumstances New questions differ from Pease questionnaire because the Pease study does not follow residential drinking water exposures. Revised medical condition tables into disease classification groups as requested by OMB
(M_Att16_AdltQstnn r)	 Added question about household income and health insurance Questions added about prior PFAS testing Added question about firefighting training exercises Questions added about current and past addresses in study area Questions added about source of tap water, tap and bottled, and general water consumption Questions added about water filtration Questions about previous address in study area and past water consumption Revised medical condition tables Added question on oral contraception 	 Household income and health insurance questions were added to remain consistent with Pease questionnaire. New questions were added based on feedback from 7 MSS sites to reflect their site-specific circumstances New questions differ from Pease questionnaire because the Pease study does not follow residential drinking water exposures. Revised medical condition tables into disease classification groups as requested by OMB Oral contraceptive question added for consistency with child's questionnaire