

July 20, 2020

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)

Justification/Brief Explanation for the Change Request

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
<i>Multi-site study protocol</i>	<ul style="list-style-type: none"> • Changed version date • Corrected sample size numbers • Added approved language on heavy metals/neurobehavioral outcomes in children (Section 3.8.6; page 56) 	<ul style="list-style-type: none"> • Language on metals/neuro added per OMB request • Corrected error in sample size numbers. Protocol had incorrect numbers from a previous version
<i>(M_Att12_Manual of Procedures)</i>	<ul style="list-style-type: none"> • Changed version date • Updated OMB numbers / exp. dates, number of participants updated. • Added for the whole blood collection “trace metals pre-screened 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 	<ul style="list-style-type: none"> • Post-OMB approval updates • Consistency with Pease MOP
<i>(M_Att04_ElgblyScreeningScript)</i>	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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

	<p>target study area.</p> <ul style="list-style-type: none"> • 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 	<p>drinking water exposures.</p> <ul style="list-style-type: none"> • Editorial changes were made to improve the flow and readability of the screening script.
<p>(M_Att15_ChldQstnnr_LongForm)</p>	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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
<p>(M_Att16_AdltQstnr)</p>	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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

