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** |
| *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** **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 | * Post-OMB approval updates * Consistency with Pease MOP |
| *(M\_Att04\_ElgbltyScreeningScript)* | * 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 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 | * 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 drinking water exposures. * Editorial changes were made to improve the flow and readability of the screening script. |
| *(M\_Att15\_ ChldQstnnr\_LongForm)* | * 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\_AdltQstnnr)* | * 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 |