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.

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| **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
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| *(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
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| *(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.
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| *(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
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| (*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
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