

October 6, 2020

Change Request #2 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

We are requesting an expedited review of this non-substantive change request to start the Multi-Site Study by the end of October/early November, having added COVID-19 safety precautions procedures to the approved information collection request (ICR). Our changes are based on the language approved by OMB for the Pease Study (OMB Control No. 0923-0061; exp. date 08/31/2022) on 09/30/2020.

The original shutdown and ongoing resurgence in the COVID-19 pandemic has impacted plans for field work and study collection in a number of communities and has likely negatively impacted interest in the study. The longer study recruitment is delayed, the more difficult it will be to achieve reasonable study participation in those communities due to perceived delays, lack of government commitment, and potential interference with the holiday season, adding to the difficulty of recruitment. Starting the study in communities with low infection rates by the end of October/early November would be optimal for recruitment in those sites. It is therefore imperative to provide our investigators with approvals and tools to commence study activities.

While the COVID situation remains fluid, ATSDR is fully committed to provide approvals and support to awardees that are in position to initiate the field work on this high priority project.

There are no changes to the approved number of respondents or annualized time burden.

Attachment	Revisions	Justification
<i>Multi-site study protocol</i>	<ul style="list-style-type: none">• Added summary of protocol changes related to COVID-19 (page 2)	<ul style="list-style-type: none">• Changes reflect efforts to prevent the spread of COVID-19
<i>(M_Att12_Manual of Procedures)</i>	<ul style="list-style-type: none">• Changed version date• Added information on COVID-19 health and safety precautions (page 10-11)• Added a Health and Safety plan (pages 17-19)• Added reference to COVID-19 safety precautions (page 29)• Added information on conducting interviews given COVID-19 (page 44, 50, 51)• Added a COVID-19 Preparedness Plan (98-102)	<ul style="list-style-type: none">• Changes reflect efforts to prevent the spread of COVID-19

<i>(M_Att04_ElgblyScreeningScript)</i>	<ul style="list-style-type: none"> Added information on COVID-19 health and safety precautions (page 1) 	<ul style="list-style-type: none"> Changes reflect efforts to prevent the spread of COVID-19
<i>(M_Att07a_ApptReminderCard)</i>	<ul style="list-style-type: none"> Added information on COVID-19 health and safety precautions (pages 2-3) 	<ul style="list-style-type: none"> Changes reflect efforts to prevent the spread of COVID-19
<i>(M_Att07b_InformedConsentPacket)</i>	<ul style="list-style-type: none"> Added information on COVID-19 health and safety precautions (pages 3-4, 9, 13-15,) Updated language to include guardian in addition to parent (page 9) Added information on the option of conducting the interview via telephone (page 14) Updated the volume of blood to be collected (page 16) 	<ul style="list-style-type: none"> Changes reflect efforts to prevent the spread of COVID-19 The selection of laboratories informed the adjustments to the blood sample volumes Minor wording updates
<i>(M_Att08_AppointmentReminderTelScript)</i>	<ul style="list-style-type: none"> Added information on COVID-19 health and safety precautions (pages 2-3) 	<ul style="list-style-type: none"> Changes reflect efforts to prevent the spread of COVID-19
<i>(M_Att09_ApptTrackingForm)</i>	<ul style="list-style-type: none"> Added information on COVID-19 health and safety precautions (pages 1-2) Added line for no temperature or reported symptoms (page 3) 	<ul style="list-style-type: none"> Changes reflect efforts to prevent the spread of COVID-19