

June 15, 2020

Change Request for OMB Control No. 0923-0059: Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs)

Justification/Brief Explanation for the Change Request

Background: ATSDR suspended its PFAS EA activities for three of eight sites when the COVID-19 pandemic began in the United States. Restarting PFAS EA field work will require that precautions be put in place to ensure that staff, contractors, and members of the public are protected from COVID-19. This plan is based on interim CDC guidance for non-COVID-19 public health activities that require face-to-face interaction during the COVID-19 pandemic and will be used to outline practices for conducting PFAS EA activities <https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-covid-19-client-interaction.html>.

Since that time, the agency has developed its restart plan in collaboration with, and reviewed and approved by, the CDC Office of Safety, Security, and Asset Management (OSSAM), CDC Leadership, the CDC Emergency Operation Center (EOC) Joint Information Center (JIC), and a CDC EOC COVID-19 Task Force which included members from the National Institute for Occupational Safety and Health (NIOSH).

ATSDR plans for resumption of field work activities will be determined on a site by site basis. Work at the sites will be staggered. Decisions about when to restart activities will be made in consultation with regional ATSDR staff as well as state and local public health officials.

The Request: This is a non-material/non-substantive change request for “Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs)” (OMB Control No. 0923-0059; expiration date June 30, 2022). This change request reflects modifications to the currently approved information collection request (ICR) and reflects the need to practice social distancing to the extent possible, such as changing from in-person contact to virtual meetings and telephone interviews. Where necessary, ATSDR has modified its scripts and forms to let the public know of the COVID-19 precautions that the agency is implementing.

Our goal is to announce our resumption of activities on June 23, 2020, and we are requesting approval of this non-substantive change prior to that date.

Summary of the Restart Plan: Appropriate safety precautions, including the use of all appropriate personal protective equipment (PPE), will be implemented to keep the EA team and participants safe during the EA process. Appendix J, the PFAS EA Restart Plan, has been included that outlines the additional procedures that will be implemented during recruitment, field work and community meetings to ensure that the EAs are completed in compliance with state, local and CDC requirements.

The activities that will be modified include:

- Holding virtual community meetings, including the kickoff meeting and possibly the presentation of results. Small group sessions (less than 10 participants) may be held as needed following applicable local, state and CDC guidelines in place at the time of the meeting.
- Ensuring that social distancing and the use of PPE are employed to comply with local, state and CDC COVID-19 guidelines during door-to-door recruitment.
- Adding information to the recruitment letters to reassure potential EA participants that all local, state and CDC COVID-19 guidelines will be followed during the EA testing.

- Asking participants about their and their family’s health/COVID-19-status during their appointment reminder phone call and prior to beginning the testing process.
- Monitoring the temperature of EA team members (CDC/ATSDR and contractor staff) twice daily and taking participant’s temperatures prior to entering the EA testing facility.
- Administering the exposure questionnaire over the phone instead of at the testing facility to reduce exposure time: consent form administration and collection of biological samples will occur at the testing location.

Below is the change request cross-walk table. Attached please find the revised protocol and modified forms and appendices. The overall number of respondents and requested burden hours remain the same.

As such, we would appreciate your expedited consideration of this request.

Attachment	Requested Change	Justification
<i>Protocol Body</i>	1. Appendix J (PFAS EA Restart Plan) has been indexed in the protocol table of contents. A text box has been added to the beginning of the protocol outlining proposed changes to original procedures.	1. Appendix J documents the precautions that ATSDR is undertaking to protect the public and its workers from COVID-19.
<i>(Appendix A1 unchanged)</i>	N/A	N/A
<i>(Appendices A2-A4) Household Recruitment Letter; Eligibility Screener; Environmental Recruitment Script</i>	2. Recruitment materials will include information on procedures that CDC/ATSDR will be taking to address concerns associated with COVID-19.	2. The recruitment materials will provide information to potential participants on the procedures that CDC/ATSDR will take to comply with local, state and CDC guidelines at the time of EA field activities.
<i>(Appendices B1-B5 unchanged)</i>	N/A	N/A
<i>(Appendix B6) Biological Tracking Form</i>	3. The biological tracking form is modified to include a screening for COVID-19 and a temperature check.	3. A screening for self-reported COVID-19 symptoms and a temperature check will be conducted prior to participants entering the testing facility.
<i>(Appendices C-G unchanged)</i>	N/A	N/A
<i>(Appendix H) Site Health and Safety Plan</i>	4. A statement is included that indicates PPE requirements and safety procedures are outlined in Appendix J.	4. The Site Health and Safety Plan provides a reference to the Restart Plan in Appendix J.
<i>(Appendix I) Data Management Plan</i>	5. The Data Management Plan indicates that the questionnaire may be conducted onsite or via the telephone.	5. To reduce the time participants spend in the testing facility, the questionnaire will be administered over the phone.
<i>(Appendix J) Restart Plan</i>	6. The restart plan provides methodology for safely completing EA field activities in compliance with state, local and CDC COVID-19 guidelines in place at the time the EAs are conducted.	6. Policies and procedures must be followed to modify activities to address concerns associated with COVID-19. Procedures will comply with the guidance in place at the time an activity is conducted.