

Memorandum

Date November 16, 2021

From Felecia Peterson IRB Analyst Human Research Protection Office

- Subject IRB Approval of New CDC Protocol 7360.0, "Evaluating the Association between Serum Concentrations of Per- and Polyfluoroalkyl Substances (PFAS) and Symptoms and Diagnoses of Selected Acute Viral Illnesses" (Expedited)
- To Melanie Buser, MPH NCEH/OA/OD

CDC's IRB-Committee 2 has reviewed the request for approval of new protocol 7360.0, "Evaluating the Association between Serum Concentrations of Per- and Polyfluoroalkyl Substances (PFAS) and Symptoms and Diagnoses of Selected Acute Viral Illnesses". The protocol was reviewed and approved in accordance with the expedited review process outlined in (§45 CFR §46.110(b)(1)), categories 4, and 5. You are required to close out expedited protocols as soon as CDC staff are no longer engaged in the research activity. The Human Research Protection Office (HRPO) may follow up with you periodically to check the status of CDC's engagement in this research activity.

The IRB determined that the study poses minimal risk to subjects. The IRB approves the additional protections for children and pregnant women involved in research, as described in 45 CFR 46 subparts D and B. The IRB approves the inclusion of children (§45 CFR 46.404), with child assent and parent permission, as well as pregnant women is justifiable and permitted. Prisoners will not be eligible to participate in this study.

This approval confirms that CDC's IRB-Committee 2 has determined that a Certificate of Confidentiality applies to this study and protects the privacy of individuals who are subjects of this research, pursuant to subsection 301(d) of the Public Health Service Act.

If other institutions involved in this protocol are being awarded CDC funds through the CDC Office Financial Resources (OFR), you are required to send a copy of this IRB approval to the CDC OFR award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided OFR with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office at (404) 639-7570 or email at <u>huma@cdc.gov</u>).

cc: NCEH/ATSDR Human Subjects mailbox