DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date September 12, 2018

From Jerrell Little
IRB-Committee 2 Administrator
Human Research Protection Office

Subject CDC IRB Approval of New Protocol 7161.0, "Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH (Pease Study - Proof of Concept)" (Expedited)

To MARIAN PAVUK, PhD, MD
ATSDR/DTHHS

CDC's IRB-Committee 2 has reviewed the request for approval of new protocol 7161.0, "Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH (Pease Study - Proof of Concept)" and has approved the protocol for the maximum allowable period of one year. CDC IRB approval will expire on 8/26/2019. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 2a, 2b, 4, and 7.

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.

The IRB determined that the study poses minimal risk to subjects. The IRB approved the inclusion of pregnant women under 45 CFR 46.204 and the inclusion of children under 45 CFR 46.404.

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

As a reminder, the IRB must review and approve all human subjects' research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request at least six weeks before the protocol's expiration date of **8/26/2019**.

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.

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 huma@cdc.gov).

CC:
NCEH/ATSDR Human Subjects

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Date November 20, 2018

From Jerrell Little
IRB-Committee 2 Administrator
Human Research Protection Office

Subject IRB Approval of Amendment to CDC Protocol 7161, "Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH (Pease Study - Proof of Concept)" (Expedited)

To Marian Pavuk, PhD, MD
ATSDR/DTHHS

CDC's IRB-Committee 2 has reviewed and approved your request to amend protocol 7161, "Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH (Pease Study - Proof of Concept)". These changes included the following:

The Manual of procedures (MOP, Attachment 14; placeholder in the original submission) has been prepared and revised; especially the section on data management and security (Section 13). Changes in sample volumes (Attachment 3) reflect input and revisions from NCEH/DLS.

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), under categories 2a, 2b, 4, and 7 to previously approved research during the period (of one year or less) for which approval is authorized.

Reminder: IRB approval of protocol #7161 will still expire on 8/26/2019.

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

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-7570 or e-mail: huma@cdc.gov.

cc:
NCEH/ATSDR Human Studies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Date March 5, 2019

From Jerrell Little
IRB-Committee 2 Administrator
Human Research Protection Office

Subject IRB Approval of Amendment to CDC Protocol 7161, "Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH (Pease Study - Proof of Concept)" (Expedited)

To Marian Pavuk, PhD, MD
ATSDR/DTHHS

CDC's IRB-Committee 2 has reviewed and approved your request to amend protocol 7161, "Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH (Pease Study - Proof of Concept)". These changes included the following:

1. Informed Consent package (Attachment 9b) contains changes reflecting requirements to conversion to 2018 Common Rule. This affects the storage and future use of collected biospecimens (see p. 7-8, 12, 19-20, 22 tracked changes document).

2. Corresponding changes in the study protocol with additions on the future use of stored biospecimens (p. 55-56 tracked changes document).

3. Text message script added in Attachment 10. Allowing contractor to send a short reminder text in addition to reminder telephone call about the upcoming appointment to a cell phone number on record (no additional burden). Corresponding change also made in the protocol (p. 35).

In addition,

1. CDC research partner was added; Abt Associates were awarded contract to conduct the study, see form 1370.

2. We also request this outside institution to rely on CDC IRB approval; see form 1372.

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), under categories 2a, 2b, and 7 to previously approved research during the period (of one year or less) for which approval is authorized.

Reminder: IRB approval of protocol #7161 will still expire on 8/26/2019.

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

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-7570 or e-mail: huma@cdc.gov.

cc:
NCEH/ATSDR Human Studies