DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date May 23, 2019 (Revised: Inclusion of Certificate of Confidentiality)

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

Subject CDC IRB Approval of New Protocol 7207.0, "Human health effects of drinking water exposures to per- and poly-fluoroalkyl substances (PFAS): A multi-site cross-sectional study." (Expedited)

To Marian Pavuk, PhD, MD
ATSDR/DTHHS

CDC's IRB-Committee 2 has reviewed the request for approval of new protocol 7207.0, "Human health effects of drinking water exposures to per- and poly-fluoroalkyl substances (PFAS): A multi-site cross-sectional study." The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 2a, 2b, 3, 5 and 7. The Human Research Protection Office (HRPO) will request an administrative check-in every two years from the date of approval to determine the status of this protocol.

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

This approval confirms that CDC's IRB-Committee *2* has confirmed 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.

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 HS mailbox

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Date December 27, 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:

In response to the ICRO review for Paperwork Reduction Act (PRA). The ICRO Desk Officer requested that the introductory paragraph for Attachment 6a be revised to align with that in Attachment 6b.

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.

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cc:
NCEH/ATSDR Human Studies

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Date September 3, 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:

Protocol

1. *Deleted 'draft' in protocol title (p.1)*
2. *Deleted detailed list of attachment titles in the table of contents (p. 6-12)*
3. *Revised justification for the inclusion of health outcomes (p. 16-17)*
4. *Clarified 'ever firefighter' meaning (p. 20, 29)*
5. *Updated total number of participants in NH biomonitoring program (p.21)*
6. *Added reference for NH DHHS; added 'PFAS in drinking water' (p. 30)*
7. *Corrected reference spelling (p.33)*
8. *Added forms requesting permission to release child's educational records (Att19b-c; p.47, 50)*
9. *Updated language for added forms requesting permission to release medical records (Att20b-c; p.49)*
10. *Revised sentence on future test results reporting (p.60)*
11. *Added sentence and reference on PBPK modeling on PFHxS (p.61, p.71)*
12. *Added more detail on selection and information bias (p. 64)*
13. *Listed Att24 (p.65)*
14. *Modified list of attachments based on OMB request to create new forms (p. 77)*

Attachments

15. *Att05 – Accepted changes and language suggested by OMB in Communication Plan forms.*
16. *Att09b - Revised language on future use of stored samples per OMB request; restored originally approved language to conform with the CDC IRB approval on study risks.*
17. *Att17, Att17a, Att18 – In all questionnaires the instructions to reviewers were provided to record, but do not read response options aloud for "Don't Know" and "Refused.".*

In children questionnaires (Att17-17a) we revised sentence on parent/guardian on p.1 and removed a few open ended questions on treatment of ADHD/ADD and behavioral problems from the children questionnaires (Section E.1.o and E.1.q.). We added autism question in Sections E.1.o and G.4.l. We revised question on ever pregnant (E.6 and E.7).

In adult questionnaire (Att18), the date of birth was replaced with age in adult questionnaire for consistency with children questionnaires. The question on pregnancy was also revised for consistency (E. 15, 17). Choices for diabetes response were also revised for consistency with other questionnaires (E.1.m).

18. *Att19 - Converted letter to serve as request form to get medical records per OMB request*
19. *Att20b - Created new form per OMB request for child school abstractions; replaced old Att20b with new file*
20. *Att20c - Relabeled old Att20b to Att20c.*
21. *Att24 – Deleted language about unusual exposure from the results report for PFAS.*

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), under categories 2a, 2b, 3, 4, 5, and 7 to previously approved research during the period (of one year or less) for which approval is authorized.

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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
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and Prevention (CDC)

Date September 3, 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:

Protocol
1. Dissemination statement on the front page of the protocol deleted.
2. Added sentence about the leftover blood samples from the 2015-17 NH DHHS PFC Blood Testing Program; those that will consent will have their samples stored for future testing by ATSDR. Others will have those samples discarded (p. 52).
3. Attachment 9b is modified to allow participants to consent or not consent for ATSDR to receive their leftover blood samples from the 2015-17 NH DHHS PFC Blood Testing Program
Attachments
3. Att09b - Consent form for both children and adults have consent added to store samples from NH DHHS PFC blood testing program for future testing by ATSDR.

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), under categories 2a, 2b, 3, 4, 5, and 7 to previously approved research during the period (of one year or less) for which approval is authorized.

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