DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date December 11, 2019

From Jerrell Little
IRB Administrator
Human Research Protection Office

Subject CDC IRB Approval of Amendment #2 to CDC Protocol #7207, "Human health effects of drinking water exposures to per- and poly-fluoroalkyl substances (PFAS): A multi-site cross-sectional study " (Expedited)

To Marian Pavuk
ATSDR/DTHHS

CDC's IRB-Committee 2 has reviewed and approved your request to amend protocol #7207, "Human health effects of drinking water exposures to per- and poly-fluoroalkyl substances (PFAS): A multi-site cross-sectional study". The modification includes the following changes:

Following the OMB review and approval as well as activities related to preparation and start of data collection on the proof of concept Pease Study the changes were made in number of documents. We have revised the Multi-site Study protocol and information collection materials to reflect the changes made to the Pease protocol.

Protocol

1. Date revised to reflect current submission (p.1)

2. Updated the site selection criteria (Sections 1.1.3 and 2.3) and text reflecting the Notice of Funding Opportunity (NOFO) process and the fact that the selection has occurred (p. 7 and p. 12).
3. Added information on the seven research partners awarded the cooperative agreement to conduct the Multi-site Study and the location where they each will conduct their work (Section 2.3, p. 14-15).
4. Updated and rephrased Section 2.4 General Approach for Study Recruitment to reflect that awardees have propose sampling methodologies as described in the protocol (p. 15-17).
5. Added "2" for section 2.5 (p. 17)

6. Added sentence specifying that each awardee will attempt to meet a target recruitment of 300 children; also added 'minimum' in the proposed sample size of 2,000 (Section 3.3.1, p. 27).
7. Added sentence specifying that each awardee will attempt to meet a target recruitment of 1,000 adults; also added 'minimum' in the proposed sample size of 6,000 (Section 3.3.2, p. 30).
8. Updated text and the table in the Section 3.6.5.1.1 Child/Parent Neurobehavioral Assessments. After the pilot testing and review by child psychologist a few subtests of the NEPSY-II test were removed to keep proposed testing at no more than 90 min per child participant. Subtest removed: Auditory Attention and Response, Inhibition, Word List Interference, and Sentence Repetition.; Affect Recognition replaced Theory of Mind (p. 42).
9. Added information on two approaches to assess the potential and magnitude of possible selection bias and information biases (p. 58).
10. Added Attachment 3c Sampling and Recruitment Strategies Across Sites to the list of attachments (p. 72).

Att1 Investigators and Key Study Personnel

1. Revised to reflect the cooperative agreement primary investigators.

Att7b Consent Package

2. Updated headings for study principal investigators at study site institution and ATSDR as well as the number of ***children (n=300) and adults (n=1000) taking part in the*** study (p.3, 9 and p.13)
3. Added "or guardians" when referencing parents (p. 3)
4. Rephrased eligibility regarding prisoners/house arrest (p. 3, 13)
5. Replaced ATSDR investigators with the site study investigators for questions about study (p.4 and p14), release of school records (p. 12), and in permission for medical record abstraction (p. 21).
6. Rephrased risks of the study paragraph (p.4 and p.14) and other blood tests (p.6 and p.16).
7. Deleted "and urinary" when referencing PFAS analyses (p. 4
8. Added "potential" to study overview/purpose (p. 5, 15)
9. Replaced "consent" with "permission" (p. 7, 17)
10. Revised language regarding reporting of results (p. 7-8, 17)

11. Added a rephrased bullet point requiring permission for any future genetic testing (p.8 and p.17).
12. Replaced “match” with “might relate” (p. 9)
13. Corrected number of digits in the SSN numbers (p.10 and p.19).
14. Updated consent for children and adults for additional uses of leftover biospecimen in new studies that are related to PFAS and are not about PFAS (p. 11, 20).
15. Deleted phrase “Study methods will inform the design of future studies” (p. 13)
16. Deleted phrasing on ability to meet participants at their home (p.13)
17. Added in a bullet regarding target sample size and age criteria (p.13)
18. Added in a bullet regarding past participation in PFAS biomonitoring programs (p. 15)
19. Deleted “child’s” from PFAS Measure in Blood section (p. 16)
20. Added “may” in Use of Collected Information section (p.17)
21. Replaced “/” with “and” (p. 19)
22. Added Parkinson disease, allergies, infertility, eczema, and preeclampsia in permission for medical abstraction to be consistent with changes in medical abstraction forms Att19a and Att19b (p.21).

Att7c Study Fact Sheet

1. Numerous language changes made to align with previously approved fact sheet for the Pease Study (p.1-5)
2. information regarding site-specific sample size was added (p.1)
3. An overview of the potential reasons for being excluded from the study was added (p.1-2)
4. Information on what the participant can expect on the day of the appointment has been added (p. 2)

Att12 Manual of Procedures

1. Date on title page updated, as well as in the document footer.

2. Updated table of contents to add appendix F (p. 2-8)
3. Inserted updated blood pressure guideline table (p. 21-22)
4. Updated blood collection procedure guidelines (p. 24)
5. Updated Serum Materials and Equipment list (p. 25)
6. Updated number of vials needed (p. 26)
7. Updated blood collection procedure guidelines (p.27)
8. Updated number of centrifuges needed (p. 29)
9. Updated shipping address to CDC Biorepository (p. 35)
10. Revised HIPPA to HIPAA (p.39)
11. Deleted two extra steps in 11.4B (p. 41)
12. Added sample questions from the Pease questionnaire to replace Anniston samples (p. 44-47)
13. Removed “Not sure” as a potential response (p. 48)
14. Added “paper” to indicate questionnaire format (p.48)
15. Removed text regarding different font styles, as they are not being used in the Pease questionnaire (p. 48-50)
16. Deleted “Nested Questions” section (p. 50-51)
17. Changed information regarding the telephone contact quality control information (p. 52)
18. Replaced “CATI” with “REDCap” (p.52)
19. Added Appendix F-CDC IRB Consent Form (p. 77-96)

Att15 Child Questionnaire - Long Form

1. Question modified to specify how many times the participant has donated blood (C5; p.5).
2. Added autism (point m.) and deleted ‘how is child treated for behavioral problems’ (modified per OMB’s request on Pease questionnaire) (F1; p.14).
3. Added autism (H4; p. 17) and renumbered “n” due to the addition.

Att15a Child Questionnaire – Short Form

1. Added autism (point m.), deleted ‘how is child treated for behavioral problems’ (modified per OMB’s request on Pease questionnaire) (F1; p.8).
2. Added autism (G1; p. 10) and renumbered “d” due to the addition.

Att16 Adult Questionnaire

1. Modified order of the first two questions: What is your age is now question A1 and what is your sex is question A2 (p.1).
2. Participants are asked how many times they donated blood (C3; p.5).

Att17a Medical Record Abstraction Form - Child

1. Several health outcomes were added in the form to be consistent with the questionnaire, specifically autism, pregnancy induced hypertension/preeclampsia, (p. 2) and gestational diabetes (p.3). Renumbered due to the addition of autism (p.2).

Att17b Medical Record Abstraction Form - Adult

1. Several health outcomes were added in the form to be consistent with the questionnaire, specifically Parkinson disease (p. 2), atopic dermatitis/eczema, allergies, infertility, pregnancy induced hypertension/preeclampsia, and gestational diabetes (p. 3). Renumbered due to addition of Parkinson disease.

Att18. Child/Parent Neurobehavioral Test Battery

1. Updated NEPSY-II subtests battery following the pilot testing. Subtest removed: Auditory Attention and Response, Inhibition, Word List Interference, and Sentence Repetition.; Affect Recognition replaced Theory of Mind (p. 2-5). Description of Affect Recognition added (p.4)

Att18a. Neurobehavioral Test Battery – Time Estimation Table, by Age in years

1. Updated table removing subtests and revising time estimates for NEPSY-II subtest.

Att19 - Body and Blood Pressure Measures Report

1. Replaced 'OR' with 'AND' for hypertensive crises and for elevated blood pressure in the status section.

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

Reminder: IRB approval of protocol #7207 will still expire on 4/2/2021.

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 HS Mailbox (CDC)