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STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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NH DIVISION OF Public Health Services
Improving health, preventing disease, reducing costs for all

Nicholas A. Toumpas
Commissioner

Marcella J. Bobinsky
Acting Director

November 17, 2015

Her Excellency Governor Margaret Wood Hassan
and the Honorable Executive Council
State House
Concord, NH 03301

Sole Source

REQUESTED ACTION

Authorize the Department of Health and Human Services, Division of Public Health Services to enter into a **sole source** agreement with the Public Health Institute, 555 12th Street 10th FL, Oakland, CA 94607-4046 to provide analytical laboratory testing services in an amount not to exceed $69,780 effective upon Governor and Executive Council approval, through June 30, 2017. 100% General Funds

Funds are available in the following accounts for State Fiscal Year 2016 and State Fiscal Year 2017 upon the availability and continued appropriation of funds, with the ability to adjust encumbrances between State Fiscal Years through the Budget Office without further Governor and Executive Council approval, if needed and justified.

05-95-90-902510-51700000 HEALTH AND SOCIAL SERVICES, DEPT OF HEALTH AND HUMAN SERVICES, HHS: DIVISION OF PUBLIC HEALTH, BUREAU OF INFECTIOUS DISEASE CONTROL, DISEASE CONTROL

Fiscal Year	Class	Title	Activity Code	Amount
2016	547-500394	Disease Control Emergencies	90027021	$69,780
2017	547-500394	Disease Control Emergencies	90027021	$0
			Total:	**$69,780**

EXPLANATION

This agreement is **sole source** because the Public Health Institute has extensive technical expertise in measuring perfluorochemicals in human serum. This is highly specialized testing. The Department identified only two laboratories with the technical capability and combined capacity to assist in the testing and analysis of human serum. The two laboratories were contacted and contracts were negotiated. This agreement represents the second of the two (2) contracts for which the Department seeks Governor and Executive Council approval. The first contract was approved by the Governor and Executive Council on November 18, 2015 (Item #11).

The purpose of this agreement is to conduct analytical laboratory testing services to measure perfluorochemicals (PFC) in human serum collected as a result of potential exposure to perfluorochemical-contaminated drinking water at the Pease Tradeport.

Perfluorochemicals are a group of chemicals used to make fluoropolymer coatings and products that resist heat, oil, stains, grease, and water. They were also an ingredient in fire-fighting foam used at the Pease Tradeport. Fluoropolymer coatings can be used in products such as clothing, furniture, adhesives, food packaging, heat resistant non-stick cooking surfaces, and the insulation of electrical wire. Many chemicals in this group are a concern as they are slow to break down in the environment and can accumulate in human tissues. Scientific studies are ongoing to better understand what, if any, health effects are associated with exposure to perfluorochemicals.

The Centers for Disease Control and Prevention has conducted tests for the Department for the presence of perfluorochemicals in specimens that were collected from the aforementioned location. However, the Centers for Disease Control and Prevention has reached its capacity for conducting these tests. The Department identified two laboratories with the technical capability and combined capacity to assist in the testing and analysis of human serum. The two laboratories were contacted and contracts were negotiated.

Should the Governor and Executive Council determine not to approve this request, then the New Hampshire Division of Public Health Services will not have access to PFC exposure information for the Pease Tradeport population and community members will not receive their expected individual test results.

Area Served: Statewide

Source of Funds: 100% General

Respectfully submitted

Marcella J. Bobinsky
Acting Director

Approved by:
Nicholas A. Toumpas
Commissioner

Subject: PFC Exposure Assessment Services

Notice: This agreement and all of its attachments shall become public upon submission to Governor and Executive Council for approval. Any information that is private, confidential or proprietary must be clearly identified to the agency and agreed to in writing prior to signing the contract.

AGREEMENT

The State of New Hampshire and the Contractor hereby mutually agree as follows:

GENERAL PROVISIONS

1. IDENTIFICATION.

1.1 State Agency Name Department of Health and Human Services		1.2 State Agency Address 129 Pleasant Street Concord, NH 03301-3857	
1.3 Contractor Name Public Health Institute		1.4 Contractor Address 555 12th Street 10th Floor Oakland, CA 94607-4046	
1.5 Contractor Phone Number (510) 285-5500	1.6 Account Number 05-95-90-902510-51700000	1.7 Completion Date June 30, 2017	1.8 Price Limitation $69,780
1.9 Contracting Officer for State Agency Eric Borrin, Director		1.10 State Agency Telephone Number 603-271-9558	
1.11 Contractor Signature		1.12 Name and Title of Contractor Signatory Joanna Gomes Director, Bid & Proposal	

1.13 Acknowledgement: State of California, County of Alameda

On 10/28/2015, before the undersigned officer, personally appeared the person identified in block 1.12, or satisfactorily proven to be the person whose name is signed in block 1.11, and acknowledged that s/he executed this document in the capacity indicated in block I.12.

1.13.1 Signature of Notary Public or Justice of the Peace [Seal]

LISA K. STAUBER
COMM. #2103461
Notary Public - California
Alameda County
My Comm. Expires Mar. 16, 2019

1.13.2 Name and Title of Notary or Justice of the Peace
Lisa K. Stauber, Notary Public

1.14 State Agency Signature Date: 11/19/15	1.15 Name and Title of State Agency Signatory Brook Dupee / Bureau Chief

1.16 Approval by the N.H. Department of Administration, Division of Personnel *(if applicable)*

By: Director, On:

1.17 Approval by the Attorney General (Form, Substance and Execution) *(if applicable)*

By: Megan A. Yale-Attorney On: 11/25/15

1.18 Approval by the Governor and Executive Council *(if applicable)*

By: On:

2. EMPLOYMENT OF CONTRACTOR/SERVICES TO BE PERFORMED. The State of New Hampshire, acting through the agency identified in block 1.1 ("State"), engages contractor identified in block 1.3 ("Contractor") to perform, and the Contractor shall perform, the work or sale of goods, or both, identified and more particularly described in the attached EXHIBIT A which is incorporated herein by reference ("Services").

3. EFFECTIVE DATE/COMPLETION OF SERVICES.
3.1 Notwithstanding any provision of this Agreement to the contrary, and subject to the approval of the Governor and Executive Council of the State of New Hampshire, if applicable, this Agreement, and all obligations of the parties hereunder, shall become effective on the date the Governor and Executive Council approve this Agreement as indicated in block 1.18, unless no such approval is required, in which case the Agreement shall become effective on the date the Agreement is signed by the State Agency as shown in block 1.14 ("Effective Date").
3.2 If the Contractor commences the Services prior to the Effective Date, all Services performed by the Contractor prior to the Effective Date shall be performed at the sole risk of the Contractor, and in the event that this Agreement does not become effective, the State shall have no liability to the Contractor, including without limitation, any obligation to pay the Contractor for any costs incurred or Services performed. Contractor must complete all Services by the Completion Date specified in block 1.7.

4. CONDITIONAL NATURE OF AGREEMENT.
Notwithstanding any provision of this Agreement to the contrary, all obligations of the State hereunder, including, without limitation, the continuance of payments hereunder, are contingent upon the availability and continued appropriation of funds, and in no event shall the State be liable for any payments hereunder in excess of such available appropriated funds. In the event of a reduction or termination of appropriated funds, the State shall have the right to withhold payment until such funds become available, if ever, and shall have the right to terminate this Agreement immediately upon giving the Contractor notice of such termination. The State shall not be required to transfer funds from any other account to the Account identified in block 1.6 in the event funds in that Account are reduced or unavailable.

5. CONTRACT PRICE/PRICE LIMITATION/ PAYMENT.
5.1 The contract price, method of payment, and terms of payment are identified and more particularly described in EXHIBIT B which is incorporated herein by reference.
5.2 The payment by the State of the contract price shall be the only and the complete reimbursement to the Contractor for all expenses, of whatever nature incurred by the Contractor in the performance hereof, and shall be the only and the complete compensation to the Contractor for the Services. The State shall have no liability to the Contractor other than the contract price.
5.3 The State reserves the right to offset from any amounts otherwise payable to the Contractor under this Agreement those liquidated amounts required or permitted by N.H. RSA 80:7 through RSA 80:7-c or any other provision of law.
5.4 Notwithstanding any provision in this Agreement to the contrary, and notwithstanding unexpected circumstances, in no event shall the total of all payments authorized, or actually made hereunder, exceed the Price Limitation set forth in block 1.8.

6. COMPLIANCE BY CONTRACTOR WITH LAWS AND REGULATIONS/ EQUAL EMPLOYMENT OPPORTUNITY.
6.1 In connection with the performance of the Services, the Contractor shall comply with all statutes, laws, regulations, and orders of federal, state, county or municipal authorities which impose any obligation or duty upon the Contractor, including, but not limited to, civil rights and equal opportunity laws. This may include the requirement to utilize auxiliary aids and services to ensure that persons with communication disabilities, including vision, hearing and speech, can communicate with, receive information from, and convey information to the Contractor. In addition, the Contractor shall comply with all applicable copyright laws.
6.2 During the term of this Agreement, the Contractor shall not discriminate against employees or applicants for employment because of race, color, religion, creed, age, sex, handicap, sexual orientation, or national origin and will take affirmative action to prevent such discrimination.
6.3 If this Agreement is funded in any part by monies of the United States, the Contractor shall comply with all the provisions of Executive Order No. 11246 ("Equal Employment Opportunity"), as supplemented by the regulations of the United States Department of Labor (41 C.F.R. Part 60), and with any rules, regulations and guidelines as the State of New Hampshire or the United States issue to implement these regulations. The Contractor further agrees to permit the State or United States access to any of the Contractor's books, records and accounts for the purpose of ascertaining compliance with all rules, regulations and orders, and the covenants, terms and conditions of this Agreement.

7. PERSONNEL.
7.1 The Contractor shall at its own expense provide all personnel necessary to perform the Services. The Contractor warrants that all personnel engaged in the Services shall be qualified to perform the Services, and shall be properly licensed and otherwise authorized to do so under all applicable laws.
7.2 Unless otherwise authorized in writing, during the term of this Agreement, and for a period of six (6) months after the Completion Date in block 1.7, the Contractor shall not hire, and shall not permit any subcontractor or other person, firm or corporation with whom it is engaged in a combined effort to perform the Services to hire, any person who is a State employee or official, who is materially involved in the procurement, administration or performance of this

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Agreement. This provision shall survive termination of this Agreement.
7.3 The Contracting Officer specified in block 1.9, or his or her successor, shall be the State's representative. In the event of any dispute concerning the interpretation of this Agreement, the Contracting Officer's decision shall be final for the State.

8. EVENT OF DEFAULT/REMEDIES.
8.1 Any one or more of the following acts or omissions of the Contractor shall constitute an event of default hereunder ("Event of Default"):
8.1.1 failure to perform the Services satisfactorily or on schedule;
8.1.2 failure to submit any report required hereunder; and/or
8.1.3 failure to perform any other covenant, term or condition of this Agreement.
8.2 Upon the occurrence of any Event of Default, the State may take any one, or more, or all, of the following actions:
8.2.1 give the Contractor a written notice specifying the Event of Default and requiring it to be remedied within, in the absence of a greater or lesser specification of time, thirty (30) days from the date of the notice; and if the Event of Default is not timely remedied, terminate this Agreement, effective two (2) days after giving the Contractor notice of termination;
8.2.2 give the Contractor a written notice specifying the Event of Default and suspending all payments to be made under this Agreement and ordering that the portion of the contract price which would otherwise accrue to the Contractor during the period from the date of such notice until such time as the State determines that the Contractor has cured the Event of Default shall never be paid to the Contractor;
8.2.3 set off against any other obligations the State may owe to the Contractor any damages the State suffers by reason of any Event of Default; and/or
8.2.4 treat the Agreement as breached and pursue any of its remedies at law or in equity, or both.

9. DATA/ACCESS/CONFIDENTIALITY/ PRESERVATION.
9.1 As used in this Agreement, the word "data" shall mean all information and things developed or obtained during the performance of, or acquired or developed by reason of, this Agreement, including, but not limited to, all studies, reports, files, formulae, surveys, maps, charts, sound recordings, video recordings, pictorial reproductions, drawings, analyses, graphic representations, computer programs, computer printouts, notes, letters, memoranda, papers, and documents, all whether finished or unfinished.
9.2 All data and any property which has been received from the State or purchased with funds provided for that purpose under this Agreement, shall be the property of the State, and shall be returned to the State upon demand or upon termination of this Agreement for any reason.
9.3 Confidentiality of data shall be governed by N.H. RSA chapter 91-A or other existing law. Disclosure of data requires prior written approval of the State.

10. TERMINATION. In the event of an early termination of this Agreement for any reason other than the completion of the Services, the Contractor shall deliver to the Contracting Officer, not later than fifteen (15) days after the date of termination, a report ("Termination Report") describing in detail all Services performed, and the contract price earned, to and including the date of termination. The form, subject matter, content, and number of copies of the Termination Report shall be identical to those of any Final Report described in the attached EXHIBIT A.

11. CONTRACTOR'S RELATION TO THE STATE. In the performance of this Agreement the Contractor is in all respects an independent contractor, and is neither an agent nor an employee of the State. Neither the Contractor nor any of its officers, employees, agents or members shall have authority to bind the State or receive any benefits, workers' compensation or other emoluments provided by the State to its employees.

12. ASSIGNMENT/DELEGATION/SUBCONTRACTS. The Contractor shall not assign, or otherwise transfer any interest in this Agreement without the prior written notice and consent of the State. None of the Services shall be subcontracted by the Contractor without the prior written notice and consent of the State.

13. INDEMNIFICATION. The Contractor shall defend, indemnify and hold harmless the State, its officers and employees, from and against any and all losses suffered by the State, its officers and employees, and any and all claims, liabilities or penalties asserted against the State, its officers and employees, by or on behalf of any person, on account of, based or resulting from, arising out of (or which may be claimed to arise out of) the acts or omissions of the Contractor. Notwithstanding the foregoing, nothing herein contained shall be deemed to constitute a waiver of the sovereign immunity of the State, which immunity is hereby reserved to the State. This covenant in paragraph 13 shall survive the termination of this Agreement.

14. INSURANCE.
14.1 The Contractor shall, at its sole expense, obtain and maintain in force, and shall require any subcontractor or assignee to obtain and maintain in force, the following insurance:
14.1.1 comprehensive general liability insurance against all claims of bodily injury, death or property damage, in amounts of not less than $1,000,000per occurrence and $2,000,000 aggregate ; and
14.1.2 special cause of loss coverage form covering all property subject to subparagraph 9.2 herein, in an amount not less than 80% of the whole replacement value of the property.
14.2 The policies described in subparagraph 14.1 herein shall be on policy forms and endorsements approved for use in the State of New Hampshire by the N.H. Department of Insurance, and issued by insurers licensed in the State of New Hampshire.

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14.3 The Contractor shall furnish to the Contracting Officer identified in block 1.9, or his or her successor, a certificate(s) of insurance for all insurance required under this Agreement. Contractor shall also furnish to the Contracting Officer identified in block 1.9, or his or her successor, certificate(s) of insurance for all renewal(s) of insurance required under this Agreement no later than thirty (30) days prior to the expiration date of each of the insurance policies. The certificate(s) of insurance and any renewals thereof shall be attached and are incorporated herein by reference. Each certificate(s) of insurance shall contain a clause requiring the insurer to provide the Contracting Officer identified in block 1.9, or his or her successor, no less than thirty (30) days prior written notice of cancellation or modification of the policy.

15. WORKERS' COMPENSATION.
15.1 By signing this agreement, the Contractor agrees, certifies and warrants that the Contractor is in compliance with or exempt from, the requirements of N.H. RSA chapter 281-A *("Workers' Compensation").*
15.2 To the extent the Contractor is subject to the requirements of N.H. RSA chapter 281-A, Contractor shall maintain, and require any subcontractor or assignee to secure and maintain, payment of Workers' Compensation in connection with activities which the person proposes to undertake pursuant to this Agreement. Contractor shall furnish the Contracting Officer identified in block 1.9, or his or her successor, proof of Workers' Compensation in the manner described in N.H. RSA chapter 281-A and any applicable renewal(s) thereof, which shall be attached and are incorporated herein by reference. The State shall not be responsible for payment of any Workers' Compensation premiums or for any other claim or benefit for Contractor, or any subcontractor or employee of Contractor, which might arise under applicable State of New Hampshire Workers' Compensation laws in connection with the performance of the Services under this Agreement.

16. WAIVER OF BREACH. No failure by the State to enforce any provisions hereof after any Event of Default shall be deemed a waiver of its rights with regard to that Event of Default, or any subsequent Event of Default. No express failure to enforce any Event of Default shall be deemed a waiver of the right of the State to enforce each and all of the provisions hereof upon any further or other Event of Default on the part of the Contractor.

17. NOTICE. Any notice by a party hereto to the other party shall be deemed to have been duly delivered or given at the time of mailing by certified mail, postage prepaid, in a United States Post Office addressed to the parties at the addresses given in blocks 1.2 and 1.4, herein.

18. AMENDMENT. This Agreement may be amended, waived or discharged only by an instrument in writing signed by the parties hereto and only after approval of such amendment, waiver or discharge by the Governor and Executive Council of the State of New Hampshire unless no such approval is required under the circumstances pursuant to State law, rule or policy.

19. CONSTRUCTION OF AGREEMENT AND TERMS. This Agreement shall be construed in accordance with the laws of the State of New Hampshire, and is binding upon and inures to the benefit of the parties and their respective successors and assigns. The wording used in this Agreement is the wording chosen by the parties to express their mutual intent, and no rule of construction shall be applied against or in favor of any party.

20. THIRD PARTIES. The parties hereto do not intend to benefit any third parties and this Agreement shall not be construed to confer any such benefit.

21. HEADINGS. The headings throughout the Agreement are for reference purposes only, and the words contained therein shall in no way be held to explain, modify, amplify or aid in the interpretation, construction or meaning of the provisions of this Agreement.

22. SPECIAL PROVISIONS. Additional provisions set forth in the attached EXHIBIT C are incorporated herein by reference.

23. SEVERABILITY. In the event any of the provisions of this Agreement are held by a court of competent jurisdiction to be contrary to any state or federal law, the remaining provisions of this Agreement will remain in full force and effect.

24. ENTIRE AGREEMENT. This Agreement, which may be executed in a number of counterparts, each of which shall be deemed an original, constitutes the entire Agreement and understanding between the parties, and supersedes all prior Agreements and understandings relating hereto.

Contractor Initials
Date 10/28/15

Scope of Services

1. Provisions Applicable to All Services

1.1. The Contractor agrees that, to the extent future legislative action by the New Hampshire General Court or federal or state court orders may have an impact on the Services described herein, the State Agency has the right to modify Service priorities and expenditure requirements under this Agreement so as to achieve compliance therewith.

2. Scope of Services

2.1. The Contractor shall conduct analytical laboratory testing services to measure perfluorochemicals (PFC) in human serum, in accordance with the methodology outlined in Exhibit A-1, Standard Operating Procedures (SOP) for:

2.1.1. perfluorooctane sulfonamide

2.1.2. 2-(N-ethyl-perfluorooctane sulfonamido) acetate

2.1.3. 2-(N-methyl-perfluorooctane sulfonamido) acetate

2.1.4. perfluorohexane sulfonate

2.1.5. perfluorodecanoate

2.1.6. perfluoroundecanoate

2.1.7. perfluorononanoate

2.1.8. perfluorooctanoate

2.1.9. perfluorooctane sulfonate

2.2. The Contractor shall report all testing results and associated quality control measures, which shall include but not be limited to:

2.2.1. Identification of appropriate detection limits.

2.2.2. Quality assurance measures practiced during testing.

3. Reporting

3.1. The Contractor shall provide reports of testing results to the Department within twelve (12) weeks of receiving human serum samples from the Department.

3.2. The Contractor shall send reports in Section 3.1 to the Department electronically in the following forms:

3.2.1. PDF.

3.2.2. Excel Spreadsheet.

Status: Final

Written by: Miaomiao Wang, Ph.D.
Human Environmental Monitoring Section

June-Soo Park, Ph.D., Supervisor
Human Environmental Monitoring Section

Approved by:

Bruce LaBelle, Ph.D., Chief
Environmental Chemistry Laboratory

Carol Wortham, Quality AssuranceOfficer
Environmental Chemistry Laboratory

Analysis of 12 Perfluorinated Compounds (PFCs) in Serum Samples using Online Solid Phase Extraction - High Performance Liquid Chromatography – Turbo Ion Spray – Tandem Mass Spectrometry (online SPE-HPLC-TIS-MS/MS)

1. SCOPE AND APPLICABILITY

The method described in this SOP, adapted from the CDC SOP for PFCs (Method code 6304.01), utilizes an online Solid Phase Extraction - High Performance Liquid Chromatograph-Turbo ion Spray – Tandem Mass Spectrometry (online SPE-HPLC-TIS-MS/MS) system to analyze 12 PFCs in serum samples. Briefly, a serum sample is first mixed with formic acid for protein denaturation. The mixture is further extracted by online SPE system using a C18 cartridge. The analytes of interest are purified and concentrated on the SPE column, and separated by a C8 HPLC column before entering the MS/MS system, operating in negative-ion spray ionization mode. Analytes are quantified using a calibration curve constructed for each batch with the ratio of the peak area of target quad 1 and quad 3 ions (a.k.a. Q1/Q3 ions) over internal standard peak area vs. known concentration. Rapid and sensitive detection is achieved for the target compounds.

1.1. Reportable Range

The linear range of the standard calibration curves and the method limit of detection (LOD) determine the reportable range of results. The reportable range must be within the range of the calibration curves. Samples with concentrations exceeding the highest reportable limit may be diluted and re-analyzed. The LOD, LOQ and linear range for each analyte are summarized in Table1.

1.1.1. Limit of Detection (LOD) and Limit of Quantitation (LOQ)

The limit of detection (LOD) and limit of quantitation (LOQ) are determined for each analyte by replicate analysis of 20 blanks and calculating the standard deviation. The formal LOD is defined as 3*STDEV. The LOQ is defined as 5*STDEV (CDC SOP 6304.01). This is updated on a per batch basis.

2. DEFINITIONS

Abbreviations/ Acronyms for the PFC's are listed in Table 2.

3. PRINCIPLE

The method described in this SOP, adapted from the CDC SOP for PFCs (Method code 6304.01), utilizes an online Solid Phase Extraction - High Performance Liquid Chromatograph-Turbo ion Spray – Tandem Mass Spectrometry (online SPE-HPLC-TIS-MS/MS) system to analyze 12 PFCs in serum samples.

3.1. Clinical Relevance

Perfluorinated compounds (PFCs) are a group of molecules in which all bonds of the alkyl chain are carbon-fluorine bonds except for the terminal functional group. The analytes of interest include perfluorinated carboxylic acids, perfluorinated carboxyl amides and perfluorinatedsulfonates. PFCs have been used widely in industrial and consumer products, such as protective coatings for carpets, furniture, apparel and paper, insecticide formulations, surfactants, fluoropolymer manufacture and fluoropolymer dispersions[1]. Among the PFCs of interest, PFOS (perfluorooctanesulfonate) and PFOA (perfluorooctanoic acid) have been widely found in wildlife and in humans, indicating widespread exposure to the environment and the general population[2]. Both PFOS and PFOA have demonstrated toxicity in lab animals (causing adverse effects on reproduction, development, fatty acid metabolism and liver) as well as adverse effects on human health. Therefore, PFCs are of increasing environmental concern. In 1999 the USEPA began an investigation on PFCs after receiving data on PFOS persistence. In May 2000, 3M, the sole manufacturer of PFOS in the United States and the principal manufacturer worldwide, announced that it was discontinuing its perfluoroctanyl chemistries, including PFOS. In June 2000, the EPA identified possible health concerns with respect to PFOA and fluorinated telomers[3].In June 2000, the USEPA identified possible health concerns with respect to PFOA and fluorinated telomers[4]. The Fourth National Report on Human Exposure to Environmental Chemicals, published by the CDC, shows measurable serum concentrations of several PFCs in samples collected from 2003-2004[4-5].

3.2. Specificity

The current method is highly selective because it requires the analytes to elute at specific times; precursor ions have specific mass/charge ratios; and the specific product ions formed from the precursor ion must have specific mass/charge ratios.

4. SAFETY

Standard safety protective equipment should be utilized when performing this procedure.

4.1. Reagent Toxicity or Carcinogenicity

Some of the reagents used are toxic. Special care should be taken to avoid contact with eyes and skin. Personal protective equipment (PPE) such as eye protection, gloves, lab coats, long pants, and shoes that fully cover the foot should be worn. Avoid use of

organic solvents in the vicinity of an open flame and use solvents only in well-ventilated areas.

4.2. Microbiological Hazards

Serum samples, being human body fluids pose the possibility of being contaminated with various microbiological hazards. Appropriate measures should be taken to avoid any direct contact with biological specimens (use of PPE, biohazard hoods). Any residual biological material should be appropriately labeled and prepared for disposalafter analysis, according to the current version of the Waste Disposal SOP. All disposable laboratory supplies must also be placed in a "biohazardous" bag for disposal. The Hepatitis B vaccination series is required for laboratory workers who are exposed to human fluids and tissues. Laboratory personnel handling human fluids and tissues are required to take the "Blood borne Pathogens Training" classes.

4.3. Mechanical Hazards

There are only minimal mechanical hazards when performing this procedure using standard safety practices. Generally, only qualified technicians should perform the electronic maintenance and repair of the instruments. Avoid contact with the heated surface of the mass spectrometer.

4.4. Training Requirement

Training on the online SPE-HPLC-MS/MS system is required before operating the system. Users of the method must be knowledgeable in the principles of this method. Users must have demonstrated knowledge of the procedures and must have documented competency prior to independent analysis. The competency can be demonstratedthrough the successful analysis of standard reference materials, certified reference materials, or any other sample whose composition is known and has been verified.

4.5. Disposal of Wastes

4.5.1. Liquid Wastes

Solvents and reagents are disposed of in appropriate containers labeled with hazardous waste labels filled out properly during accumulation and storage and temporarily stored in one of the chemical fume hoods. When full,liquid waste bottles are taken to the red solvent cabinet in room 144 for disposal according to ECL's Chemical Hygiene Plan and the current version of the Waste Disposal SOP.

4.5.2. Solid Wastes

Containers, glassware, etc., that come in direct contact with the specimen are collected in clear plastic bags and when full,bags are taken to the biological hazardous waste bin in room 144 to be disposed as biohazardous wastes. To ensure proper compliance with safety measures, laboratory personnel are required to attend annual safety training classes.

5. INTERFERENCES

Most interferences are eliminated in the online SPE-HPLC process, and based on the analysis of Q1/Q3 ions and retention time. However, there are two known interferences present, one for PFOS and the other for PFHxS. For PFOS, the 499/80 ion pair has a background in blank serum, thus 499/99 is used to quantitate the analyte. For PFHxS, in certain serum samples such as pregnant women, relatively higher levels of pregnandiolsulfonate isomers might interfere with the ion pair 399/80, which is generally used to quantitate PFHxS. Thus for these serums, the ion pair 399/119 is used instead[6].

6. COLLECTION, STORAGE, HANDLING, ACCEPTABILITY AND TRACKING OF SPECIMENS

Original samples are accepted or rejected by staff when they arrive at the laboratory. The criteria for rejecting a sample include the following: sample container does not contain enough sample (less than 100 µL serum); sample container is unlabeled, or the label is damaged; sample sealing is damaged; or serum has been compromised. Any rejected sample will be documented and the client will be informed.

6.1. Sample Collection and Storage

Preferably, at least 0.5 mL of serum should be collected in labeled standard collection containers, frozen at -20oC or below within 4 hours of collection, and transferred to the laboratory as soon as possible. The preferred sample collection containers are made of polypropylene or polyethylene. However, glass containers may be used if the specimens are to be analyzed for other environmental chemicals for which storage in polypropylene may be a problem. Teflon-coated materials should be avoided. If the analysis is not performed immediately, samples should be stored at -20°C or below.

6.2. Sample Handling

For specimen handling conditions, follow procedures outlined in the current ECL Serum Collection and Handling SOP. In general, serum specimens should be transported frozen (dry ice), or cold (ice or blue ice) if less than 24 hours of transportation time is expected. Special care must be taken in packing to protect collection vials from breakage during shipment.

Prior to analysis, the samples are thawed, vortexed, aliquoted, and the residual specimen is stored at -20°C until use. The integrity of samples are not effected by several rounds of thawing/refreezing cycles.

6.3. Sample Receiving Documents

Analysts should not accept samples for analysis unless they are accompanied by all appropriate paperwork. Please refer to the current version of the Sample Handling and Chain of Custody SOP for detailed procedures):

(1) Sample Analysis Request (SAR)

(2) Authorization Request Form (ARF)

(3) ECL Sample Receipt Form

(4) Sample Receipt Checklist

(5) Sample Information Form

6.4. Specimen Storage and Handling during Testing

Serum samples are stored in the walk-in -20°C freezer in room 144. Serum samples may be stored overnight in a refrigerator at 4°C to expedite thawing prior to aliquoting the sample.

Samples should be re-frozen at -20°C after aliquoting and stored until ready to analyze.

6.5. Procedures for Specimen Accountability and Tracking

6.5.1. Sample Recordkeeping

Samples to be analyzed are retrieved from LIMS first. The analyst would log in to the LIMS interface, select all the samples that would be included in one particular batch, and create a run sequence together with QC samples. This sequence will be saved as .txt file and later be exported to the instrument software to create the run batch. Standard record keeping systems (e.g., notebooks, sample logs, data files) should be employed to keep track of all specimens.

7. EQUIPMENT AND INSTRUMENT SETUP

7.1. Equipment

(1) Symbiosis TM Pharma system with Mistral CS Cool (includes autosampler and online SPE-HPLC, system ID SY82617) (IChrom, Plainsboro, NJ)

(2) ABSciex API 4000 QTrap mass spectrometer (ABSciex, Foster city, CA)

(3) BETASIL C8 column (3 mm x 50 mm, 5 µm) (Thermo Electron Corporation, Bellefonte, PA)

(4) Betasil C8 precolumn (3 mm x 10 mm, 5 µm), and in-line filter (2 µm)

(5) Thermo Scientific Orion Star TM series pH meter (Thermo Scientific, 166 Cummings Center, Beverly, MA)

(6) Variable volume micropipettes with tip ejector (Rainin Instruments, Emeryville, CA)

7.2. Instrument Configuration

7.2.1. Online SPE- HPLC Configuration

Symbiosis™Pharma for Analyst system is used for online serum sample preparation and HPLC separation. The system is controlled by Symbiosis™Pharma for Analyst software which interfaces directly with the Analyst software for the API-4000 QTRAP. Main parts of the system include the

autosampler, HPD Standard (high pressure dispenser) and HPD mix for sample preparation, and the gradient pumps.

Betasil C8 column (3 mm x 50mm, 5µm, Thermo Electron Corporation, Bellefonte, PA) is used for sample separation, preceded by a Betasil C8 precolumn (3 mm x 10mm), and an online 2-µm frit filter. The gradient pump flow is 300 µL/min. The parameters for HPLC are shown in Table 3. Due to the presence of contaminant PFCs in gradient pump parts, a second Betasil C8 column is inserted between the HPLC pump and the right clamp valve. Thus, the contaminants from the Teflon parts of the pump will need to go through the length of the column twice, resulting in a delay in the elution time fortheanalytes. With scheduled MRM acquisition method, the contaminants can be completely eliminated from interfering with the analyte signals.

7.2.2. Mass Spectrometer Configuration

Mass spectroscopic analyses are conducted on the API 4000 tandem mass spectrometer in the negative ion electrospray mode. The parameters in general for the vaporizations and ionization of the samples are listed in Table 4.

Optimized parameters used for each individual analyte, including precursor (Q1) and product (Q3) ion masses, are summarized in Table 5.

8. STANDARDS AND REAGENTS USED

Note: Chemicals or consumables that are deemed equivalent can be substituted for those specified in this section. For example, we use LCMS grade solvents. Equivalent grade or higher grade solvents from other manufacturers can be substituted.

8.1. Standards

All standard stock solutions are purchased from Wellington Laboratories (Guelph, Ontario, Canada) and received as 50 µg/mL stock in methanol in amber ampules. The catalog number for each standard is listed in Table 2. The internal standards are a stock mixture which contains 10 isotope labeled PFC compounds(MPFAC-MXA, Wellington laboratories), and isotope labeled N-EtFOSAA (d5-N-EtFOSAA).

8.2. Reagents and Consumables

The method has been validated using the chemicals, solvents, and expendables listed in Table 6. Equivalent products from other manufacturers may be used with the exception of the SPE cartridges.

8.3. Working Solutions Preparation

Note: All prepared solutions must be properly labeled with solution name, concentration, analyst initials, date prepared, and expiration date, as applicable.

- HPLC Aqueous Mobile Phase: 2mM Ammonium Acetate Buffer

To make 1 L of HPLC aqueous mobile phase, measure out 0.154 ± 0.002 g Ammonium Acetate using an analytical balance. Dissolve in 1000mL of HPLC grade water. Prepare as needed and store at room temperature for up to three months. The solution is transferred to labeled mobile phase containers for usage.

- HPLC Organic Mobile Phase: 2mM Ammonium Acetate in 80% methanol/Acetonitrile.

  To make 1 L of HPLC organic mobile phase, measure out 0.154 ± 0.002 g Ammonium Acetate using an analytical balance. Dissolve in 800 mL HPLC grade Methanol and 200mL Acetonitrile. Prepare as needed and store at room temperature for up to three months. The solution is transferred to labeled mobile phase containers for usage.

- Organic Solvent for SPE column regeneration, 100% Acetonitrile

- Solid Phase extraction (SPE) Acidic wash solution, 0.1 M Formic Acid (FA).

  To make 500 mL of SPE acidic wash solution, add 2,143 µL of 88% Formic Acid to 498 mL HPLC grade water. Prepare as needed and store at room temperature for up to three months.

- Basic Wash, 0.3% Ammonium Hydroxide in Water

  To make 500 mL of SPE basic wash solution, add 5 mL 30% ammonia solution to 495 mL HPLC grade water. Prepare as needed and store at room temperature for up to three months.

8.4. Standards Preparation

Note: All prepared standards must be properly labeled with solution name, concentration, analyst initials, date prepared, and expiration date, as applicable.

8.4.1. Stock Solutions

All standard stock solutions are purchased from Wellington Laboratories (Guelph, Ontario, Canada) and received as 50 µg/mL stock in methanol in amber ampules.

8.4.2. Calibration Standards

Calibration standards are prepared in methanol from the Wellington standard stock solutions. Stock standard S9 is prepared directly from the stock solutions, and standards S1 to S8 are prepared by serial dilutions so the final concentrations in serum from Standard 1 to Standard 8 are 0.043 to 108 ng/mL for PFOS, and 0.01 to 25 ng/mL for all other analytes. Table 7 shows the concentrations of each standard in the spike stock solutions and in serum after spike along with preparation information. The spiking solutions are stored for up to one year at -20°C in 1-mL aliquots in polypropylene cryogenic vials until use.

8.4.3. Internal Standard Spiking Solution

The internal standard spiking solution is prepared in methanol directly from a methanol-based stock solution (MPFAC-MXA and d5-N-EtFOSAA, Wellington laboratories) that contains 2000 ng/mL of the following isotopically-labeled internal standards,

MPFHxS,MPFOS, MPFBA, MPFHxA, MPFOA, MPFNA, MPFNA, MPFDA, MPFUdA, and MPFDoA.MPFHxS is 2 ^{18}O labeled, MPFOS, MPFBA, MPFOA, and MPFNA are 4 ^{13}C labeled, and the rest are 2 ^{13}C labeled.

and 50 µg/mL of N-EtFOSAA, ^{2}D labeled. The final IS spiking solution contains 40ng/mL of each mass-labeled internal standard. Please refer to Table 8 for IS preparation.

9. METHOD PROCEDURE

9.1. Batch QC Requirements

9.1.1. QC Materials

QC Materials are prepared by spiking natural stock standards into serum directly Table 9 shows the concentration of each analyte spiked into the QC Materials.The QC materials were prepared in bulk using calf serum (Gibco, Grand Island, NY). The target ranges for the pools were set to encompass the expected concentration ranges in human populations. Two aliquots of 25 mL of blank calf serum were spiked with the appropriate amounts of PFC standards in order to obtain two concentration levels (low-QCL, and high-QCH) for each analyte (please refer Table 10 for QC concentrations). Large batches are prepared, aliquoted and stored at -20°C for up to two years.

Addingtionally, a Standard Reference Materials (SRM) from the National Institute of Standard and Technology (NIST) containing four of the analytes (PFOS, PFOA, PFNA and PFHxS) is prepared per instructions and analyzed with samples in every batch. The measured values are compared with the listed expected values for accuracy, and the measured values need to be between 75% to 125% of the expected values.

9.1.2. Characterization of QC Materials

At the very beginning of setting up this method, a minimum of 20 runs of QCs must be completed over a 1-month period. In each run, duplicate results of QCL, and QCH should be obtained. The results are compiled and compared with the theoretical values. QC limits are established as ±3*SD (standard deviation) according to the Levey-Jennings chart. After setting up the valid method, QC samples are analyzed along with unknown samples in order to monitor accuracy and precision throughout the analysis batch. For each batch, a maximum of 40 unknown samples are run with 2 each of randomly placed QCHs, QCLs, SRMs, and serum blanks, so that the batch can be finished within one day. QC values and limits are established and plotted in the QC data file by date for each analyte.

9.2. Instrument QC requirements

9.2.1. Calibration Curve

Eight calibration standards are analyzed daily and processed together within each running batch for quantitative analysis from lowest to highest. The calibration curve is constructed usinganalyte area ratios (analyte area/internal standard area) vs. standard concentrations and a linear regression is performed. The unknown concentration of ananalyte is calculated using the calibration curve. The area of the corresponding Q1/Q3 ion pair is used in the quantitation calculation. Correlation coefficients of 0.98 to 0.99 are generally obtained. Correlation coefficients above 0.97 will be acceptable for quantificationpurposes. If for a certain analyte the correlation coefficient of the calibration curve is below 0.97, the sample will be re-analyzed if serum samples are still available.

There are several possible corrective actions that would be done if the correlation coefficients drop below 0.97. First, flush the system and replace the SPE cartridge plate if needed. If this does not solve the problem, then replace the pre-column and filter, and consult with the supervisor.

9.2.2. Mass Spectrometer Calibration

The API 4000 QTRAP mass spectrometer is tuned at least once per year using a polypropylene glycol (PPG) solution according to the instructions in the operator's manual. This is performed by the manufacturer's technicians and monitored with the QC samples analyzed.

9.2.3. Calibration Verification

Manufacturer Requirements

Calibration verification is not required by the manufacturer. However, it is performed after any substantial change in the method or instrumentation (e.g., new internal standard, change in instrumentation) which may lead to changes in instrument response. Calibration verification is performed by injecting QC materials and evaluating data according to the standard QC validation procedures as needed by certified technitians from the instrument manufacturer.

CLIA Requirements

According to the CLIA regulations (CLIA_Clinical Laboratory Improvement amendment_brochure#3), Calibration verification must be performed at least once every 6 months by the analyst and include one low and one high value QCs (QCL and QCH).

Documentation of Calibration Verification

All calibration verification runs and results shall be appropriately reviewed and documented. This is done with the technicians when they are servicing the instrument. QC results are documented as Validation data packages and both hard copies and electronic files are available.

Additional Verification Requirements

None.

9.2.4. Proficiency Testing (PT)

A Round Robin test that includes collaboratinglaboratories is performed twice every year.We participate in the AMAP program and run proficiency test samples from CDC two times per year. The data are kept together with QC data in the Validation data package.

9.3. Sample Preparation And Analysis

9.3.1. Sample Preparation

- **Unknown, QC, SRM, Blank and Standard Preparation**

  Note: For each batch analysis, at least one blank, 2 QC materials (low and high), SRM material, and eight calibration standards must be included.

  Remove serum samples, QCs,SRM, and blank from the freezer and thaw at ambient temperature. Vortex after thawing. Label polypropylene snap-cap autosampler vials with appropriate sample names (unknowns, QCs,SRM, blank and standards). Aliquot 100 µL of each unknown sample, SRMs, and QC material into the corresponding autosampler vials.100 µL of blank (calf serum) should be aliquoted into vials for the standards and the blank.

  Add 25 µL of native standard solutions (S1 to S8) to 8 corresponding standard vials.

  Add 300µL 0.1M formic acid to all vials containing unknown samples, blank, SRMs, and QC. Add 275µL 0.1M Formic acid to the standard vials. Finally, add 25 µL of internal isotope-labeled standard into all of the above vials. Mix well.

9.3.2. Sample Analysis

- **Building Batch Files**

  In the symbiosis software, go to "Batches" and click on "import bactches". Import the saved .txt file that was exported from LIMS, with the sample names, sample collectors ID and ECL numbers. Edit the batch by entering method to be used, data file name, injection volume, sample vial positions, and cartridge positions for each sample. Save the batch file. The batch file is also exported as an excel file and saved in the "Batch" folder. Then put the prepared samples to the autosampler tray in Symbiosis.

- **Automated SPE-HPLC-MS/MS Analysis Procedure**

  The Symbiosis Pharma system was installed and is maintained by a certified engineer from Spark-Holland, the company that manufactured

the Symbiosis system. All installation and maintenance documents are located in the Symbiosis Instrument Maintenance Folder that is located on the computer table beside the instrument.

The tubing diagram (Fig. 1) illustrates the online SPE-HPLC system. During each sample preparation process, a C18 HD 7 µm, 10 mm X 1 mm cartridge is picked up by the left clamp valve (LCV), conditioned first by 300 µL 0.3% NH3-H2O and then by 2 mL acetonitrile. Then the cartridge is equilibrated by 2 mL 0.1 M Formic Acid. For sample clean up, 400 µL of the sample (containing 100 µl serum sample) is injected into the 1 mL sample loop, loaded onto the SPE cartridge using 2 mL 0.1M Formic Acid, at 1 mL/min flow rate. Then the cartridge is washed with 1.5 mL 40% methanol/60% 0.1M Formic Acid. After sample clean up, the cartridge is moved to the right clamp valve (RCV) for sample elution via the changing of valves so the gradient pump is connected to the cartridge. The elution time is 13 minutes for the transfer of analytes from the cartridge to the LC column, and after that the gradient pump is switched directly to the LC column. For a detailed understanding of each step, please see Figure 1 and the following step-wise descriptions.

Starting from the API 4000 Analyst software, open the Symbiosis software, then perform the following steps:

(1) Go to direct control, select gradient pump control, start from 0.1 mL/min flow rate with a 50:50 mixture of gradient A and B, then submit the flow rate and start the gradient pump. Gradually increase the flow to 0.3 mL/min by 0.1 mL/min increments.

(2) Change the organice solvent ratio, and purge the solvent lines using 90% organic phase gradient.

(3) Go to the Analyst software, click on equilibration, and equilibrate the system using the acquisitionmethod in use.

- **Starting the SPE-HPLC/MS/MS Run**

  After the equilibration is done, double check the sample names and positions, then submit the batch from symbiosis to Analyst software. Press "Run" in the Analyst software if it is the first run of the day. If it is not the first run, the batch will run automatically in the Analyst interface after submitting.

9.4. Data Analysis

9.4.1. Electronic Data Acquisition System/Software Requirements

As outlined in section 9.3, all samples are queued for analysis in Symbiosis (the control software for the online-SPE-HPLC system) and then submitted to the Analyst Software of the API 4000 qtrapmass spectrometer workstation. Mass spectrometry data arecollected and stored using the Analyst software. During sample preparation and analysis, samples are identified by their Collector ID and ECL number. The collector ID is used by the collector to provide the

demographic data recorded by the sample collectors and assigned to one specific ECL number. The ECL number is used to identidy sample analysis information.. All raw data files are processed using the API 4000 qtrapAnalyst software and are archived for future reference. The Analyst software identifies the appropriate peak based on the Q1/Q3 ion pairs and the chromatographic retention time and subsequently integrates the peak area. It also allows manual peak identification and area integration. If there is a shift or mismatch between the retention time and the target Q1/Q3 ions, reject the results. The raw data (peak area, peak height, retention time, analyte name, multiple reaction monitoring (MRM) transition name, and ratio of analyteareavs. internal standard area) arearchived under appropriate project anddate.This information is exported as text (.txt) files, and then saved as Excel (.xls) files.

9.4.2. Processing Data

Based on a chromatogramfrom a calibration standard, the quantitation method is built for the current acquisition method; the corresponding quantitation method and acquisition method are named with the same date. Then, all raw data files are analyzed using the Quantitation Wizard application in the Analyst software, which allows both automatic and manual peak selection and area integration. Each peak is double-checked manually for correct identification and integration, and manual integarsion is used for those peaks that were not automatically integrated.In the Analyst data processing interface, columns are listed as Internal standards, values. etc. Calibration samples are identified as "standards", and the theoretical concentration is copied in the result file to obtain the calibration curve. Samples are identified as "Unknown". The concentration of corresponding Internal Standard is also copied to the column. A calibration curve is calculated with a correlation coefficient and R-squaredvalueis obtained. Sample concentration of each analyteis calculated using that analyte's calibration curve. The result file is exported as a .txt file in the analyst results folder by choosing "export" from the software interface, and later converted to Excel format using a built-in lab macro programfor data analysis. No manual calculation is involved in the data processing; the concentrations of unknowns are calculated by the Analyst software using the following formulas:

$$A_{unk}/A_{is}=R \times C_{unk}/C_{is}$$

$$C_{unk} = A_{unk}/A_{is} \times C_{is} /R$$

WhereA_{unk} is the signal area of the unknown analyte, A_{is} is the signal area of the corresponding IS, C_{unk} is the concentration of the unknown analyte and C_{is} is the concentration of the corresponding IS. R is the slope of the calibration curve for the specific analyte.

The calibration curve is linear for all analytes in the calibration range (generally R^2>0.97). The upper limit of the linear range is determined by the highest standard analyzed in the method. Unknown samples whose concentrations exceed the highest standard concentration must be diluted, so that the concentration of the sample is within the calibration range, and re-analyzed. The low end of the linear range is limited by the method LOD. Samples whose

concentrations are below the method LOQ (or the concentration of the lowest standard in the calibration curve) are reported as less than LOQ (< LOQ).

9.4.3. Evaluation of Quality Control Results

- **Accuracy**
  The accuracy of the method is determined by enriching serum samples with known concentrations of PFCs and comparing the calculated and expected concentrations. To examine their consistency over the range of levels encountered in serum, 2 concentration levels are tested and measured in 7 independent runs. The recovery rate calculations are shown in Table 9. Also, QC samples from other laboratories are being tested and results compared between laboratories. Proficiency test samples from the AMAP program and from CDC are recerviced and analyzed 2-3 times per year.

- **Precision - In-house QC sample**
  The precision of this method is reflected in the variance of two quality control (QC) pools over time (at least 20 independent runs over a period of two weeks). The coefficient of variation (CV) of the repeated measurements of these QC pools, which reflects both inter- and intra-day variations, is used to estimate precision.

  Table 10 shows the mean QC concentrations and CV%, for QCL and QCH.

Standard criteria for run rejection based on statistical probabilities are used to declare a run either in-control or out-of-control.

Three levels of QC are run together with the samples. The criteria are

(1) If results of all QC levels are within 2SD limits, accept the run.

(2) If one of the QC resultsis outside a 2SD limit: reject the run if one of the following rules is violated:

- Extreme outlier: result is beyond the characterization mean 4SD
- 1 3S rule: one result is outside a 3SD limit
- 2 2S rule: two results are outside the 2SD limit.
- 10 X-bar rule: current and previous 9 run results are on same side of the characterization mean.
- R 4S rule: two consecutive standardized run results (either within one batch or between two different batches) differ by more than 4SD (standardized results are used because different pools have different means). Since runs have single measurements per pool for two pools, comparison of results for the R 4S rule will be with the previous result within run or the last result of the previous run.

9.4.4. Remedial Actions for QC Failure

If the QC results or the calibrations failed to meet acceptable criteria, operations are suspended until the source or cause of failure is identified and corrected. If the source of failure is easily identifiable (e.g., failure of the mass spectrometer or a pipetting error), the problem is immediately corrected and samples are reanalyzed. Otherwise, fresh reagents are prepared and the mass spectrometer is cleaned. Before beginning another analytical run, several QC materials (in the case of QC failure) or calibration standards (in the case of calibration failure) are analyzed. After calibration or quality control has been reestablished, analytical runs may be resumed.

All errors and steps to correct those errors must be documented and reviewed by analysts to prevent further occurrences of this error.

9.5. Data Reporting

9.5.1. Sample Information

Sample collector IDs and ECL numbers are retrieved from the LIMS system, selected as a run sequence, and exported into the Symbiosis software (the software that controls the on-line SPE-HPLC system) as part of a batch file. The batch file is also exported as an Excel file in the sample queue folderis printed and dated for the record. The batch file is then submitted to Analyst (the mass spectrometer control software). After MS data collection and peak integration, the whole batch file is saved as a.wiff file, archived, and then processed by Analyst. The result file (.rdb) is saved, exported as a text file (.txt), and data isfurther processed for reporting.

9.5.2. Data Maintenance

Raw files are saved in the LCMS computer hard drive and automatically backed up onto an external hard drive every week. All sample and analytical data are entered into a specific lab database (LIMS) and checked for transcription errors and overall validity. Once a specific project was done, the complete samples data will be compiled and QC evaluated. Analyzed data from completed studies are saved on the analyst's work station and on the intranet hard drive (L).

Process for Reporting Results

The sample analysis results will be reported according to the current version of the Procedures for the Distribution of Laboratory Sample Analysis Reports SOP. All results must be reviewed by a peer and/or the supervisor prior to release to the requester. Briefly, the Laboratory Sample Analysis Report, which is a complilation of the sample data, will be sent electronically in PDF format to the requester and cc'ed to ECLLIMS as soon as possible. Hard copies of the report may also be sent by fax or by mail. The original Laboratory Sample Analyses Report and data package should be filed by the supervisor or chemist in ECL's designated place in the main office. The sample custodian will prepare the file indicating the ECL number and authorization number after the samples are logged in. Finally, the clerical staff will shift the original Laboratory Sample

Analysis Report and data package files from the office to ECL's storage cabinets for future reference and archiving.

The data from analytical runs of unknowns are initially reviewed by the laboratory supervisor. Data should be reported using correct forms together with required raw data.

9.6. Method Performance

Precision - Inter-laboratory QC samples (Round Robin tests results)

The precision of this method is validated by testing blind samples from collaborating laboratories at the CDC that contain certain PFC analytes. Independent runs over a period of two weeks are measured. The coefficient of variation (CV) between the experimental average and the CDC experimental average demonstrates the inter-laboratory variations, and also serves as precision validation of the method.

Table 11 summarizes the proficiency tests results.

10. MAINTENANCE AND TROUBLESHOOTING

10.1. Maintenance

API 4000 Linear TRAP Mass Spectrometer

Preventive maintenance is done by a qualified engineer once per year. In addition, to ensure proper performance of the system, periodic maintenance of the system may be required.The skimmer plate is cleaned periodically by taking it outside of the interface housing and wiping/rinsing with methanol. The routine maintenance procedures are documented in the API 4000 QTRAP Maintenance Notebook.

Rough pump oil is checked regularly for oil leaks and oil level.

Symbiosis online SPE-HPLCPreventive maintenance is done by a qualified engineer once per year. Performance maintenance procedures are also performed if there is a change in system performance (sensitivity and/or S/N ratio).

For daily maintenance checks, the pressure of the gradient pump at standard flow rate at a 20:80 organic to aqueous phase ratio is recorded daily in a excel file of sample log and checked for consistency by comparing the values,before each batch analysis to prevent possible bubble interference.

The inline frit and the pre-column are replaced periodically when there is deterioration in peak shape/sensitivity, such as peak broadening or tailing.

Before submitting the batch for analysis, the column is equilibrated with the current method for 30 min. The HPLC column is also washed with 90% organic phase gradient after each batch or before a new batch is submitted for analysis. A sample run flow chart is documented together with each batch that is analyzed and kept in the sample documentation folder.

The C18 HD cartridge tray is replaced as needed, generally after using each cartridge four times.

10.2. Troubleshooting

Fluctuation in HPLC pressure: First check to see if there is any leaking in the tubing system. Also refer to the injection log, flush the system with isoproponal, replace inline filter, precolumn, and column as needed.

Injection volume: Check if all solvent levels are good. check if the injection syringe is still working fine by repeating injections. Replace with new one if needed.

Drop in signal sensitivity: First, switch to LC MS only mode, to see if Mass spec is still working fine. Check if the spray needle is clean. If not, replace needle.

11. REFERENCES

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TABLES

Table 1. LOD, LOQ, linear range and reportable range of the analytes (based on July 2012).

ng/mL	PFNA	PFHpA	PFDeA	PFDoA	PFOS	PFOA	PFBS	PFOSA	Me-PFOSA-AcOH	Et-PFOSA-AcOH	PFHxS	PFUA
LOD	0.08	0.06	0.03	0.04	0.08	0.30	0.02	0.01	0.01	0.01	0.01	0.01
LOQ	0.13	0.10	0.05	0.06	0.14	0.50	0.04	0.01	0.02	0.02	0.02	0.02
Linear Range	0.08-50	0.06-50	0.03-50	0.04-50	0.08-215	0.30-50	0.02-50	0.01-50	0.01-50	0.01-50	0.01-50	0.01-50
Report-able Range	0.13-50	0.10-50	0.05-50	0.06-50	0.14-215	0.50-50	0.04-50	0.01-50	0.02-50	0.02-50	0.02-50	0.02-50

Table 2. PFCs included in this analysis.

Analyte Full Name	Abbreviation	Catalogue Number	Molecular Formula	Standard Source
Perfluoroheptanoic acid	PFHpA	PFHpA	CF_3-$(CF_2)_5$-CO_2H	Wellington Laboratories
Perfluorooctanoic acid	PFOA	PFOA	CF_3-$(CF_2)_6$-CO_2H	Wellington Laboratories
Perfluorononanoic acid	PFNA	PFNA	CF_3-$(CF_2)_7$-CO_2H	Wellington Laboratories
Perfluorodecanoic acid	PFDA	PFDA	CF_3-$(CF_2)_8$-CO_2H	Wellington Laboratories
Perfluoroundodecanoic acid	PFUA	PFUdA	CF_3-$(CF_2)_9$-CO_2H	Wellington Laboratories
Perfluorododecanoic acid	PFDoA	PFDoA	CF_3-$(CF_2)_{10}$-CO_2H	Wellington Laboratories
perfluorobutanesulfonate	PFBS	L-PFBS	CF_3-$(CF_2)_3$-SO_3H	Wellington Laboratories
perfluorohexanesulfonate	PFHxS	L-PFHxS	CF_3-$(CF_2)_5$-SO_3H	Wellington Laboratories
perfluorooctanesulfonate	PFOS	L-PFOS	CF_3-$(CF_2)_7$-SO_3H	Wellington Laboratories
perfluorooctanesulfonamide	PFOSA	FOSA	CF_3-$(CF_2)_7$-SO_2NH_2	Wellington Laboratories
2-(N-methyl-perfluoro-octane sulfoamido) acetic acid	Me-PFOSA	N-MeFOSAA	CF_3-$(CF_2)_7$-SO_2NH-CH_3	Wellington Laboratories
2-(N-ethyl-perfluorooctanesulfoamido) acetic acid	Et-PFOSA	N-EtFOSAA	CF_3-$(CF_2)_7$-SO2NH-CH2CH3	Wellington Laboratories

Table 3. HPLC parameters for sample preparation and separation.

Time (min)	0	2	4	8	12	26	26.5	27	28	28.5	30	30.5	33
Flow (mL/min)	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Percentage of Organic Phase	20	30	30	55	55	93	93	100	100	30	30	20	20

Table 4. Parameters for the vaporization and ionization of the samples.

Curtain Gas (CUR)	28 psi
Collision Gas (CAD)	High
IonSpray Voltage (IS)	-4200V
Temperature	300°C
Ion Source Gas 1 (GS1)	40 psi
Ion Source Gas 2 (GS2)	40 psi
Entrance Potential (EP)	-10 V
Collision Cell Exit Potential (CXP)	-15V

Table 5.Optimized acquisition parameters for individual analytes.

Analyte	**Q1**	**Q3**	**DP (volts)**	**CE (volts)**
PFNA	463	419	-30	-16
PFHpA	363	318.6	-75	-14
PFDA	513	469	-50	-16
PFDoA	613	569	-30	-20
PFOS-2	498	99	-95	-72
PFOA	413	369	-50	-14
PFBS	299	80	-70	-80
PFOS-3	498	130	-95	-62
PFOSA	498	78	-60	-85
Me-PFOSA-AcOH	570	512	-45	-30
Et-PFOSA-AcOH	584	526	-45	-30
PFHxS-1	399	99	-70	-80
PFHxS-2	399	80	-70	-85
PFHxS-3	399	119	-70	-85
PFOS-1	498	80	-95	-100
PFOA-13C-IS	417	372	-70	-14
PFOS-13C-IS	503	99	-95	-85
PFUA	563	519	-30	-17
MPFHxS-13C-IS	403	103	-70	-85
MPFNA-13C-IS	468	423	-30	-16
MPFDA-13C-IS	515	470	-50	-16
MPFUA-13C-IS	565	520	-30	-17
MPFDoA-13C-IS	615	570	-30	-20
D5-N-EtFOSA	589	419	-45	-30

10/28/15
Contractor Initial, Date

Table 6. List of consumables.

Chemicals/Solvents/Expendables	Manufacturer/Grade/Cat No.
Solvents	
Acetonitrile	JT Baker, LCMS, JT-9829-2
Water	JT Baker, HPLC, JT-4218-3
Methanol	JT Baker, LCMS, JT9830-3
Chemicals	
30% ammonia water	JT Baker, JT-9726-2
Formic Acid	JT Baker, JT0128-1
Glacial Acetic Acid	JT Baker, glacial, JT-9515-3
SPE sorbents	
Cartridge tray containing 96 HySphere C18 HD, 7 µm, 10 mm x 2 mm	IChrom, Plainsboro, NJ, 822609
Vials and caps	
800 µL polypropylene autosampler vials with polyethylene snap caps (TARGET crimp snap vials)	Lab Depot, Darsonville, GA, NSC_C4011-14 (vial) and NSC_C4011-50G (cap)
1.8 mL polypropylene cryovials	Nunccryotube, Fisher Scientific, Houston, TX
3.6 mL polypropylene cryovials	Nunccryotube, Fisher Scientific, Houston, TX
Labware and others	
pipette tips	Rainin Instruments, assorted kinds and sizes
Assorted glass and polypropylene labware	VWR international, GL45 glass bottles

Table 7 Calibration Stock mix S8 preparation from original Stock solutions

Calibration Stock S8 preparation

	1	2	3	4	5	6	7	8	9	10	11	12	13
Analytes	PFOSA	Me-PFOSA-AcOH	Et-PFOSA-AcOH	PFHxS	PFOS	PFOA	PFHpA	PFNA	PFDeA	PFBuS	PFUdA	PFDoA	PFHxA
Original Stock(ug/ml)	50	50	50	50	50	50	50	50	50	50	50	50	50
volume of stock to prepare 25mL S8	50	50	50	50	215	50	50	50	50	50	50	50	50

Table 8 Calibration standards preparation by serial dilutions, and final concentrations in S1-S8

Calibration standards preparation: S6 and S7 are diluted from S8. S1-S5 are diluted from S6.

		S1	S2	S3	S4	S5	S6	S7	Stock (S8)
Concentrations in standards	PFOS final concentration in spike (ng/mL)	0.172	0.86	1.72	8.6	17.2	86	172	430
	other analytes final concentration in spike (ng/mL)	0.04	0.2	0.4	2	4	20	40	100
serial dilution to prepare standards	volume of S8/S6	2	10	20	100	200	***400***	***400***	***1000***
	Volume of MeOH	998	990	980	900	800	***1600***	***600***	***0***

Table 9 Internal standard preparation and concentration

internal standards spiking solution (mass labeled)

Stock name	labeled compounds in stock	stock in MeOH(ng/ml)	final in serum (ng/ml)	final in spike stock(ng/ml)	volume to prepare 20ml spike stock (ul)
MPFAC-MXA	MPFOA-13C(4)	2000	10	40	400
	MPFOS-13C(4)	2000	10	40	
	MPFBA-13C(4)	2000	10	40	
	MPFHxA-13C(2)	2000	10	40	
	MPFHxS-18O(2)	2000	10	40	
	MPFNA-13C(4)	2000	10	40	
	MPFDA-13C(2)	2000	10	40	
	MPFUdA-13C(2)	2000	10	40	
	MPFDoA-13C(2)	2000	10	40	
d5-N-EtFOSAA	d5-NEtPFOSAA	50000	10	40	16
	MeOH(mL)				19.6

Table 10. Final concentration of analyte spikes in QC materials.

	QCL (ng/mL)	QCH (ng/mL)
PFOSA	1.5	3.9
Me-PFOSA-AcOH	1.7	4.3
Et-PFOSA-ACOH	1.2	4.6
PFHxS	2.9	9.3
PFBS	2.9	9.3
PFOS	7	30
PFOA	3	10.4
PFHpA	1.6	5.6
PFNA	2.8	9.3
PFDA	3	9.5
PFUA	2.2	6.8
PFDoA	1.8	4.9

Table 11. Recovery rates of analytes.

Recovery (%)												
	PFNA	**PFHpA**	**PFDeA**	**PFDoA**	**PFOS**	**PFOA**	**PFBS**	**PFOSA**	**Me-PFOSA-AcOH**	**Et-PFOSA-AcOH**	**PFHxS**	**PFUA**
Range	87.0-114.0	97.1-150.8	76.3-109.5	38.0-84.1	92.5-107.5	88.7-102.9	85.9-101.5	79.2-96.2	65.6-72.8	87.9-98.5	88.3-118.3	76.4-136.9
Mean	107.5	121.8	58.3	58.3	99.5	97.9	97.2	89.7	70.0	93.8	109.1	97.6
Range	76.8-111.4	74.1-157.3	80.4-132.3	44.3-96.2	81.3-120.1	80.9-111	86.9-118.7	72.3-123.8	79.1-105.2	105-135	94-151	76.4-136
Mean	98.7	126.9	104.2	71.0	100.4	101.2	105.4	106.7	88.5	117.5	130.0	113.0

Table 12. CV of analytes for QC materials.

CV (%)												
	PFNA	**PFHpA**	**PFDeA**	**PFDoA**	**PFOS**	**PFOA**	**PFBS**	**PFOSA**	**Me-PFOSA-AcOH**	**Et-PFOSA-AcOH**	**PFHxS**	**PFUdA**
QC Low	9.3	17.4	7.4	15.9	7.7	6.7	28.1	22.1	24.9	22.5	10.9	16.3
QC High	8.2	13.4	11.0	6.7	5.9	9.9	25.2	25.1	22.4	17.9	14.2	7.1

Figures

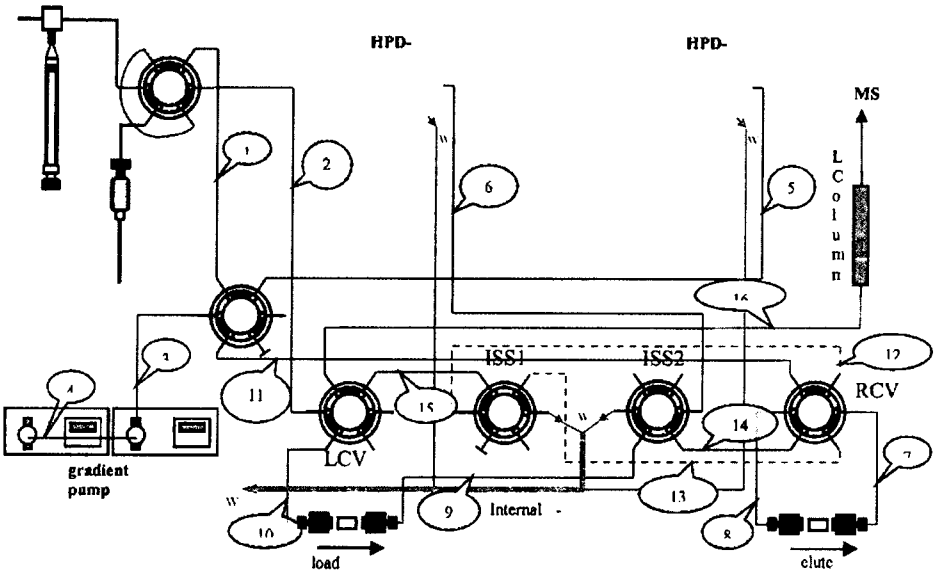

Figure 1. Online SPE-HPLC flow chart.

The Method for SPE clean-up and HPLC-MS/MS acquisitions is shown step-wise as follows:

1) Move cartridge from left clamp to right clamp (the right clamp is located between lines 7 and 8, connected to RCV (right clamp valve), and the left clamp is between lines 9 and 10, connected to LCV (left clamp valve))

2) Load new cartridge into left clamp (after the first sample)

3) Send contact closure signal to HPLC/MS/MS; flow path 4, 3, 11, 12, 15, 16

4) Begin HPLC gradient elution by-pass MS/MS (to waste)

5) Condition left cartridge, first with 300 0.3% NH_3H_2O, then with 2 mL acetonitrile, 2 mL/min (HPD mix, flow path 5, 1, sampling loop, 2, 10, cartridge, 9, waste)

6) Equilibrate left cartridge (2 mL 0.1M Formic Acid, 2 mL/min) (flow path same as 5)

7) Load Sample (400 µL injected, loaded to sampling loop with 2 mL 0.1M Formic Acid, 1 mL/min) (flow path same as 5)

8) Cartridge Wash (1 mL 80% 0.1M formic acid/20% MeOH, 1 mL/min) (flow path same as 5)

9) Begin HPLC gradient elution to MS/MS (flow path 4, 3, 11, 8, cartridge, 7, 12, 15, 16 to HPLC column and MS/MS)

10) After 13 minutes, bypass cartridge HPLC elution (flow path 4, 3, 11, 12, 15, 16 to HPLC column and MS/MS)

11) Cartridge flush (500 µL MeOH, 2 mL/min), return to tray (flow path HPD single, 6, 14, 8, cartridge, 7, 13 to waste)

12. REVISION HISTORY

Revision	Date	Responsible Person	Description of Change
0	February 5, 2014	Miaomiao Wang	Revision New Issue in New Format

13. ANNUAL REVIEW

Signatures	Date
[signature]	9/24/15

Read and Understood by:

Signature/Date	Signature/Date
Signature/Date	Signature/Date
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Method and Conditions Precedent to Payment

1. The State shall pay the Contractor an amount not to exceed the Price Limitation, block 1.8, for the services provided by the Contractor pursuant to Exhibit A, Scope of Services.
2. This Contract is funded by general funds. Funds available to implement this agreement are conditioned upon continued support of the program by the State government and continued appropriation of general funds.
3. Payment for said services shall be made as follows:
   3.1. The Contractor will submit an invoice on Contractor letterhead by the tenth (10^{th}) working day of each month, which identifies and requests payment for testing services completed in accordance with Exhibit A, Scope of Services.
   3.2. The test results provided in accordance with Exhibit A, Scope of Services shall be paid on a fee-for-service basis at the rate of $174.45 per test, which includes:
      3.2.1. The $150.00 fee per test.
      3.2.2. The 16.3% indirect cost per test.
   3.3. The State shall make payment to the Contractor within thirty (30) days of receipt of each invoice for Contractor services provided pursuant to this Agreement.
   3.4. The invoice must be submitted by mail or e-mail to:

      NH Public Health Laboratories
      29 Hazen Drive
      Concord, NH 03301
      Attn: Julianne Nassif
      E-mail: Julianne.nassif@dhhs.state.nh.us
4. A final payment request shall be submitted no later than forty (40) days from the Form P37, General Provisions, Contract Completion Date, Block 1.7.
5. Notwithstanding anything to the contrary herein, the Contractor agrees that funding under this Contract may be withheld, in whole or in part, in the event of noncompliance with any State or Federal law, rule or regulation applicable to the services provided, or if the said services have not been completed in accordance with the terms and conditions of this Agreement.

Contractor Initials:
Date: 10/28/15

SPECIAL PROVISIONS

Contractors Obligations: The Contractor covenants and agrees that all funds received by the Contractor under the Contract shall be used only as payment to the Contractor for services provided to eligible individuals and, in the furtherance of the aforesaid covenants, the Contractor hereby covenants and agrees as follows:

1. **Compliance with Federal and State Laws:** If the Contractor is permitted to determine the eligibility of individuals such eligibility determination shall be made in accordance with applicable federal and state laws, regulations, orders, guidelines, policies and procedures.

2. **Time and Manner of Determination:** Eligibility determinations shall be made on forms provided by the Department for that purpose and shall be made and remade at such times as are prescribed by the Department.

3. **Documentation:** In addition to the determination forms required by the Department, the Contractor shall maintain a data file on each recipient of services hereunder, which file shall include all information necessary to support an eligibility determination and such other information as the Department requests. The Contractor shall furnish the Department with all forms and documentation regarding eligibility determinations that the Department may request or require.

4. **Fair Hearings:** The Contractor understands that all applicants for services hereunder, as well as individuals declared ineligible have a right to a fair hearing regarding that determination. The Contractor hereby covenants and agrees that all applicants for services shall be permitted to fill out an application form and that each applicant or re-applicant shall be informed of his/her right to a fair hearing in accordance with Department regulations.

5. **Gratuities or Kickbacks:** The Contractor agrees that it is a breach of this Contract to accept or make a payment, gratuity or offer of employment on behalf of the Contractor, any Sub-Contractor or the State in order to influence the performance of the Scope of Work detailed in Exhibit A of this Contract. The State may terminate this Contract and any sub-contract or sub-agreement if it is determined that payments, gratuities or offers of employment of any kind were offered or received by any officials, officers, employees or agents of the Contractor or Sub-Contractor.

6. **Retroactive Payments:** Notwithstanding anything to the contrary contained in the Contract or in any other document, contract or understanding, it is expressly understood and agreed by the parties hereto, that no payments will be made hereunder to reimburse the Contractor for costs incurred for any purpose or for any services provided to any individual prior to the Effective Date of the Contract and no payments shall be made for expenses incurred by the Contractor for any services provided prior to the date on which the individual applies for services or (except as otherwise provided by the federal regulations) prior to a determination that the individual is eligible for such services.

7. **Conditions of Purchase:** Notwithstanding anything to the contrary contained in the Contract, nothing herein contained shall be deemed to obligate or require the Department to purchase services hereunder at a rate which reimburses the Contractor in excess of the Contractors costs, at a rate which exceeds the amounts reasonable and necessary to assure the quality of such service, or at a rate which exceeds the rate charged by the Contractor to ineligible individuals or other third party funders for such service. If at any time during the term of this Contract or after receipt of the Final Expenditure Report hereunder, the Department shall determine that the Contractor has used payments hereunder to reimburse items of expense other than such costs, or has received payment in excess of such costs or in excess of such rates charged by the Contractor to ineligible individuals or other third party funders, the Department may elect to:
   7.1. Renegotiate the rates for payment hereunder, in which event new rates shall be established;
   7.2. Deduct from any future payment to the Contractor the amount of any prior reimbursement in excess of costs;

7.3. Demand repayment of the excess payment by the Contractor in which event failure to make such repayment shall constitute an Event of Default hereunder. When the Contractor is permitted to determine the eligibility of individuals for services, the Contractor agrees to reimburse the Department for all funds paid by the Department to the Contractor for services provided to any individual who is found by the Department to be ineligible for such services at any time during the period of retention of records established herein.

RECORDS: MAINTENANCE, RETENTION, AUDIT, DISCLOSURE AND CONFIDENTIALITY:

8. **Maintenance of Records:** In addition to the eligibility records specified above, the Contractor covenants and agrees to maintain the following records during the Contract Period:
   8.1. Fiscal Records: books, records, documents and other data evidencing and reflecting all costs and other expenses incurred by the Contractor in the performance of the Contract, and all income received or collected by the Contractor during the Contract Period, said records to be maintained in accordance with accounting procedures and practices which sufficiently and properly reflect all such costs and expenses, and which are acceptable to the Department, and to include, without limitation, all ledgers, books, records, and original evidence of costs such as purchase requisitions and orders, vouchers, requisitions for materials, inventories, valuations of in-kind contributions, labor time cards, payrolls, and other records requested or required by the Department.
   8.2. Statistical Records: Statistical, enrollment, attendance or visit records for each recipient of services during the Contract Period, which records shall include all records of application and eligibility (including all forms required to determine eligibility for each such recipient), records regarding the provision of services and all invoices submitted to the Department to obtain payment for such services.
   8.3. Medical Records: Where appropriate and as prescribed by the Department regulations, the Contractor shall retain medical records on each patient/recipient of services.

9. **Audit:** Contractor shall submit an annual audit to the Department within 60 days after the close of the agency fiscal year. It is recommended that the report be prepared in accordance with the provision of Office of Management and Budget Circular A-133, "Audits of States, Local Governments, and Non Profit Organizations" and the provisions of Standards for Audit of Governmental Organizations, Programs, Activities and Functions, issued by the US General Accounting Office (GAO standards) as they pertain to financial compliance audits.
   9.1. Audit and Review: During the term of this Contract and the period for retention hereunder, the Department, the United States Department of Health and Human Services, and any of their designated representatives shall have access to all reports and records maintained pursuant to the Contract for purposes of audit, examination, excerpts and transcripts.
   9.2. Audit Liabilities: In addition to and not in any way in limitation of obligations of the Contract, it is understood and agreed by the Contractor that the Contractor shall be held liable for any state or federal audit exceptions and shall return to the Department, all payments made under the Contract to which exception has been taken or which have been disallowed because of such an exception.

10. **Confidentiality of Records:** All information, reports, and records maintained hereunder or collected in connection with the performance of the services and the Contract shall be confidential and shall not be disclosed by the Contractor, provided however, that pursuant to state laws and the regulations of the Department regarding the use and disclosure of such information, disclosure may be made to public officials requiring such information in connection with their official duties and for purposes directly connected to the administration of the services and the Contract; and provided further, that the use or disclosure by any party of any information concerning a recipient for any purpose not directly connected with the administration of the Department or the Contractor's responsibilities with respect to purchased services hereunder is prohibited except on written consent of the recipient, his attorney or guardian.

Notwithstanding anything to the contrary contained herein the covenants and conditions contained in the Paragraph shall survive the termination of the Contract for any reason whatsoever.

11. **Reports:** Fiscal and Statistical: The Contractor agrees to submit the following reports at the following times if requested by the Department.
    11.1. Interim Financial Reports: Written interim financial reports containing a detailed description of all costs and non-allowable expenses incurred by the Contractor to the date of the report and containing such other information as shall be deemed satisfactory by the Department to justify the rate of payment hereunder. Such Financial Reports shall be submitted on the form designated by the Department or deemed satisfactory by the Department.
    11.2. Final Report: A final report shall be submitted within thirty (30) days after the end of the term of this Contract. The Final Report shall be in a form satisfactory to the Department and shall contain a summary statement of progress toward goals and objectives stated in the Proposal and other information required by the Department.

12. **Completion of Services:** Disallowance of Costs: Upon the purchase by the Department of the maximum number of units provided for in the Contract and upon payment of the price limitation hereunder, the Contract and all the obligations of the parties hereunder (except such obligations as, by the terms of the Contract are to be performed after the end of the term of this Contract and/or survive the termination of the Contract) shall terminate, provided however, that if, upon review of the Final Expenditure Report the Department shall disallow any expenses claimed by the Contractor as costs hereunder the Department shall retain the right, at its discretion, to deduct the amount of such expenses as are disallowed or to recover such sums from the Contractor.

13. **Credits:** All documents, notices, press releases, research reports and other materials prepared during or resulting from the performance of the services of the Contract shall include the following statement:
    13.1. The preparation of this (report, document etc.) was financed under a Contract with the State of New Hampshire, Department of Health and Human Services, with funds provided in part by the State of New Hampshire and/or such other funding sources as were available or required, e.g., the United States Department of Health and Human Services.

14. **Prior Approval and Copyright Ownership:** All materials (written, video, audio) produced or purchased under the contract shall have prior approval from DHHS before printing, production, distribution or use. The DHHS will retain copyright ownership for any and all original materials produced, including, but not limited to, brochures, resource directories, protocols or guidelines, posters, or reports. Contractor shall not reproduce any materials produced under the contract without prior written approval from DHHS.

15. **Operation of Facilities: Compliance with Laws and Regulations:** In the operation of any facilities for providing services, the Contractor shall comply with all laws, orders and regulations of federal, state, county and municipal authorities and with any direction of any Public Officer or officers pursuant to laws which shall impose an order or duty upon the contractor with respect to the operation of the facility or the provision of the services at such facility. If any governmental license or permit shall be required for the operation of the said facility or the performance of the said services, the Contractor will procure said license or permit, and will at all times comply with the terms and conditions of each such license or permit. In connection with the foregoing requirements, the Contractor hereby covenants and agrees that, during the term of this Contract the facilities shall comply with all rules, orders, regulations, and requirements of the State Office of the Fire Marshal and the local fire protection agency, and shall be in conformance with local building and zoning codes, by-laws and regulations.

16. **Equal Employment Opportunity Plan (EEOP):** The Contractor will provide an Equal Employment Opportunity Plan (EEOP) to the Office for Civil Rights, Office of Justice Programs (OCR), if it has received a single award of $500,000 or more. If the recipient receives $25,000 or more and has 50 or

more employees, it will maintain a current EEOP on file and submit an EEOP Certification Form to the OCR, certifying that its EEOP is on file. For recipients receiving less than $25,000, or public grantees with fewer than 50 employees, regardless of the amount of the award, the recipient will provide an EEOP Certification Form to the OCR certifying it is not required to submit or maintain an EEOP. Non-profit organizations, Indian Tribes, and medical and educational institutions are exempt from the EEOP requirement, but are required to submit a certification form to the OCR to claim the exemption. EEOP Certification Forms are available at: http://www.ojp.usdoj/about/ocr/pdfs/cert.pdf.

17. **Limited English Proficiency (LEP):** As clarified by Executive Order 13166, Improving Access to Services for persons with Limited English Proficiency, and resulting agency guidance, national origin discrimination includes discrimination on the basis of limited English proficiency (LEP). To ensure compliance with the Omnibus Crime Control and Safe Streets Act of 1968 and Title VI of the Civil Rights Act of 1964, Contractors must take reasonable steps to ensure that LEP persons have meaningful access to its programs.

18. **Pilot Program for Enhancement of Contractor Employee Whistleblower Protections:** The following shall apply to all contracts that exceed the Simplified Acquisition Threshold as defined in 48 CFR 2.101 (currently, $150,000)

CONTRACTOR EMPLOYEE WHISTLEBLOWER RIGHTS AND REQUIREMENT TO INFORM EMPLOYEES OF WHISTLEBLOWER RIGHTS (SEP 2013)

(a) This contract and employees working on this contract will be subject to the whistleblower rights and remedies in the pilot program on Contractor employee whistleblower protections established at 41 U.S.C. 4712 by section 828 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239) and FAR 3.908.

(b) The Contractor shall inform its employees in writing, in the predominant language of the workforce, of employee whistleblower rights and protections under 41 U.S.C. 4712, as described in section 3.908 of the Federal Acquisition Regulation.

(c) The Contractor shall insert the substance of this clause, including this paragraph (c), in all subcontracts over the simplified acquisition threshold.

19. **Subcontractors:** DHHS recognizes that the Contractor may choose to use subcontractors with greater expertise to perform certain health care services or functions for efficiency or convenience, but the Contractor shall retain the responsibility and accountability for the function(s). Prior to subcontracting, the Contractor shall evaluate the subcontractor's ability to perform the delegated function(s). This is accomplished through a written agreement that specifies activities and reporting responsibilities of the subcontractor and provides for revoking the delegation or imposing sanctions if the subcontractor's performance is not adequate. Subcontractors are subject to the same contractual conditions as the Contractor and the Contractor is responsible to ensure subcontractor compliance with those conditions.
When the Contractor delegates a function to a subcontractor, the Contractor shall do the following:
    19.1. Evaluate the prospective subcontractor's ability to perform the activities, before delegating the function
    19.2. Have a written agreement with the subcontractor that specifies activities and reporting responsibilities and how sanctions/revocation will be managed if the subcontractor's performance is not adequate
    19.3. Monitor the subcontractor's performance on an ongoing basis

19.4. Provide to DHHS an annual schedule identifying all subcontractors, delegated functions and responsibilities, and when the subcontractor's performance will be reviewed
19.5. DHHS shall, at its discretion, review and approve all subcontracts.

If the Contractor identifies deficiencies or areas for improvement are identified, the Contractor shall take corrective action.

DEFINITIONS
As used in the Contract, the following terms shall have the following meanings:

COSTS: Shall mean those direct and indirect items of expense determined by the Department to be allowable and reimbursable in accordance with cost and accounting principles established in accordance with state and federal laws, regulations, rules and orders.

DEPARTMENT: NH Department of Health and Human Services.

FINANCIAL MANAGEMENT GUIDELINES: Shall mean that section of the Contractor Manual which is entitled "Financial Management Guidelines" and which contains the regulations governing the financial activities of contractor agencies which have contracted with the State of NH to receive funds.

PROPOSAL: If applicable, shall mean the document submitted by the Contractor on a form or forms required by the Department and containing a description of the Services to be provided to eligible individuals by the Contractor in accordance with the terms and conditions of the Contract and setting forth the total cost and sources of revenue for each service to be provided under the Contract.

UNIT: For each service that the Contractor is to provide to eligible individuals hereunder, shall mean that period of time or that specified activity determined by the Department and specified in Exhibit B of the Contract.

FEDERAL/STATE LAW: Wherever federal or state laws, regulations, rules, orders, and policies, etc. are referred to in the Contract, the said reference shall be deemed to mean all such laws, regulations, etc. as they may be amended or revised from the time to time.

CONTRACTOR MANUAL: Shall mean that document prepared by the NH Department of Administrative Services containing a compilation of all regulations promulgated pursuant to the New Hampshire Administrative Procedures Act. NH RSA Ch 541-A, for the purpose of implementing State of NH and federal regulations promulgated thereunder.

SUPPLANTING OTHER FEDERAL FUNDS: The Contractor guarantees that funds provided under this Contract will not supplant any existing federal funds available for these services.

REVISIONS TO GENERAL PROVISIONS

1. Subparagraph 4 of the General Provisions of this contract, Conditional Nature of Agreement, is replaced as follows:

   4. CONDITIONAL NATURE OF AGREEMENT.
   Notwithstanding any provision of this Agreement to the contrary, all obligations of the State hereunder, including without limitation, the continuance of payments, in whole or in part, under this Agreement are contingent upon continued appropriation or availability of funds, including any subsequent changes to the appropriation or availability of funds affected by any state or federal legislative or executive action that reduces, eliminates, or otherwise modifies the appropriation or availability of funding for this Agreement and the Scope of Services provided in Exhibit A, Scope of Services, in whole or in part. In no event shall the State be liable for any payments hereunder in excess of appropriated or available funds. In the event of a reduction, termination or modification of appropriated or available funds, the State shall have the right to withhold payment until such funds become available, if ever. The State shall have the right to reduce, terminate or modify services under this Agreement immediately upon giving the Contractor notice of such reduction, termination or modification. The State shall not be required to transfer funds from any other source or account into the Account(s) identified in block 1.6 of the General Provisions, Account Number, or any other account, in the event funds are reduced or unavailable.

2. Subparagraph 10 of the General Provisions of this contract, Termination, is amended by adding the following language;

   10.1 The State may terminate the Agreement at any time for any reason, at the sole discretion of the State, 30 days after giving the Contractor written notice that the State is exercising its option to terminate the Agreement.

   10.2 In the event of early termination, the Contractor shall, within 15 days of notice of early termination, develop and submit to the State a Transition Plan for services under the Agreement, including but not limited to, identifying the present and future needs of clients receiving services under the Agreement and establishes a process to meet those needs.

   10.3 The Contractor shall fully cooperate with the State and shall promptly provide detailed information to support the Transition Plan including, but not limited to, any information or data requested by the State related to the termination of the Agreement and Transition Plan and shall provide ongoing communication and revisions of the Transition Plan to the State as requested.

   10.4 In the event that services under the Agreement, including but not limited to clients receiving services under the Agreement are transitioned to having services delivered by another entity including contracted providers or the State, the Contractor shall provide a process for uninterrupted delivery of services in the Transition Plan.

   10.5 The Contractor shall establish a method of notifying clients and other affected individuals about the transition. The Contractor shall include the proposed communications in its Transition Plan submitted to the State as described above.

3. The Department reserves the right to renew the Contract for up to four (4) years, subject to the continued availability of funds, satisfactory performance of services and approval by the Governor and Executive Council.

CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS

The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of Sections 5151-5160 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701 et seq.), and further agrees to have the Contractor's representative, as identified in Sections 1.11 and 1.12 of the General Provisions execute the following Certification:

ALTERNATIVE I - FOR GRANTEES OTHER THAN INDIVIDUALS

US DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTRACTORS
US DEPARTMENT OF EDUCATION - CONTRACTORS
US DEPARTMENT OF AGRICULTURE - CONTRACTORS

This certification is required by the regulations implementing Sections 5151-5160 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701 et seq.). The January 31, 1989 regulations were amended and published as Part II of the May 25, 1990 Federal Register (pages 21681-21691), and require certification by grantees (and by inference, sub-grantees and sub-contractors), prior to award, that they will maintain a drug-free workplace. Section 3017.630(c) of the regulation provides that a grantee (and by inference, sub-grantees and sub-contractors) that is a State may elect to make one certification to the Department in each federal fiscal year in lieu of certificates for each grant during the federal fiscal year covered by the certification. The certificate set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or government wide suspension or debarment. Contractors using this form should send it to:

Commissioner
NH Department of Health and Human Services
129 Pleasant Street,
Concord, NH 03301-6505

1. The grantee certifies that it will or will continue to provide a drug-free workplace by:
   - 1.1. Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;
   - 1.2. Establishing an ongoing drug-free awareness program to inform employees about
     - 1.2.1. The dangers of drug abuse in the workplace;
     - 1.2.2. The grantee's policy of maintaining a drug-free workplace;
     - 1.2.3. Any available drug counseling, rehabilitation, and employee assistance programs; and
     - 1.2.4. The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;
   - 1.3. Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);
   - 1.4. Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will
     - 1.4.1. Abide by the terms of the statement; and
     - 1.4.2. Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;
   - 1.5. Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph 1.4.2 from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer on whose grant activity the convicted employee was working, unless the Federal agency

has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

1.6. Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph 1.4.2, with respect to any employee who is so convicted

1.6.1. Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

1.6.2. Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

1.7. Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs 1.1, 1.2, 1.3, 1.4, 1.5, and 1.6.

2. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant.

Place of Performance (street address, city, county, state, zip code) (list each location)

Check ☒ if there are workplaces on file that are not identified here.

Contractor Name:

10/28/15
Date

Name:
Title: Director, BCP

CERTIFICATION REGARDING LOBBYING

The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of Section 319 of Public Law 101-121, Government wide Guidance for New Restrictions on Lobbying, and 31 U.S.C. 1352, and further agrees to have the Contractor's representative, as identified in Sections 1.11 and 1.12 of the General Provisions execute the following Certification:

US DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTRACTORS
US DEPARTMENT OF EDUCATION - CONTRACTORS
US DEPARTMENT OF AGRICULTURE - CONTRACTORS

Programs (indicate applicable program covered):
*Temporary Assistance to Needy Families under Title IV-A
*Child Support Enforcement Program under Title IV-D
*Social Services Block Grant Program under Title XX
*Medicaid Program under Title XIX
*Community Services Block Grant under Title VI
*Child Care Development Block Grant under Title IV

The undersigned certifies, to the best of his or her knowledge and belief, that:

1. No Federal appropriated funds have been paid or will be paid by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement (and by specific mention sub-grantee or sub-contractor).

2. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement (and by specific mention sub-grantee or sub-contractor), the undersigned shall complete and submit Standard Form LLL, (Disclosure Form to Report Lobbying, in accordance with its instructions, attached and identified as Standard Exhibit E-I.)

3. The undersigned shall require that the language of this certification be included in the award document for sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by Section 1352, Title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Contractor Name:

10/28/15
Date

Name:
Title: Director

CERTIFICATION REGARDING DEBARMENT, SUSPENSION AND OTHER RESPONSIBILITY MATTERS

The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of Executive Office of the President, Executive Order 12549 and 45 CFR Part 76 regarding Debarment, Suspension, and Other Responsibility Matters, and further agrees to have the Contractor's representative, as identified in Sections 1.11 and 1.12 of the General Provisions execute the following Certification:

INSTRUCTIONS FOR CERTIFICATION

1. By signing and submitting this proposal (contract), the prospective primary participant is providing the certification set out below.

2. The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. If necessary, the prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the NH Department of Health and Human Services' (DHHS) determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

3. The certification in this clause is a material representation of fact upon which reliance was placed when DHHS determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, DHHS may terminate this transaction for cause or default.

4. The prospective primary participant shall provide immediate written notice to the DHHS agency to whom this proposal (contract) is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

5. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549: 45 CFR Part 76. See the attached definitions.

6. The prospective primary participant agrees by submitting this proposal (contract) that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by DHHS.

7. The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions," provided by DHHS, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or involuntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List (of excluded parties).

9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and

information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal government, DHHS may terminate this transaction for cause or default.

PRIMARY COVERED TRANSACTIONS

11. The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:
    11.1. are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
    11.2. have not within a three-year period preceding this proposal (contract) been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or a contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
    11.3. are not presently indicted for otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (I)(b) of this certification; and
    11.4. have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.

12. Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal (contract).

LOWER TIER COVERED TRANSACTIONS

13. By signing and submitting this lower tier proposal (contract), the prospective lower tier participant, as defined in 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:
    13.1. are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
    13.2. where the prospective lower tier participant is unable to certify to any of the above, such prospective participant shall attach an explanation to this proposal (contract).

14. The prospective lower tier participant further agrees by submitting this proposal (contract) that it will include this clause entitled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion - Lower Tier Covered Transactions," without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Contractor Name:

10/28/15
Date

Name: Joanna Jones
Title: Director

CERTIFICATION OF COMPLIANCE WITH REQUIREMENTS PERTAINING TO FEDERAL NONDISCRIMINATION, EQUAL TREATMENT OF FAITH-BASED ORGANIZATIONS AND WHISTLEBLOWER PROTECTIONS

The Contractor identified in Section 1.3 of the General Provisions agrees by signature of the Contractor's representative as identified in Sections 1.11 and 1.12 of the General Provisions, to execute the following certification:

Contractor will comply, and will require any subgrantees or subcontractors to comply, with any applicable federal nondiscrimination requirements, which may include:

- the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. Section 3789d) which prohibits recipients of federal funding under this statute from discriminating, either in employment practices or in the delivery of services or benefits, on the basis of race, color, religion, national origin, and sex. The Act requires certain recipients to produce an Equal Employment Opportunity Plan;

- the Juvenile Justice Delinquency Prevention Act of 2002 (42 U.S.C. Section 5672(b)) which adopts by reference, the civil rights obligations of the Safe Streets Act. Recipients of federal funding under this statute are prohibited from discriminating, either in employment practices or in the delivery of services or benefits, on the basis of race, color, religion, national origin, and sex. The Act includes Equal Employment Opportunity Plan requirements;

- the Civil Rights Act of 1964 (42 U.S.C. Section 2000d, which prohibits recipients of federal financial assistance from discriminating on the basis of race, color, or national origin in any program or activity);

- the Rehabilitation Act of 1973 (29 U.S.C. Section 794), which prohibits recipients of Federal financial assistance from discriminating on the basis of disability, in regard to employment and the delivery of services or benefits, in any program or activity;

- the Americans with Disabilities Act of 1990 (42 U.S.C. Sections 12131-34), which prohibits discrimination and ensures equal opportunity for persons with disabilities in employment, State and local government services, public accommodations, commercial facilities, and transportation;

- the Education Amendments of 1972 (20 U.S.C. Sections 1681, 1683, 1685-86), which prohibits discrimination on the basis of sex in federally assisted education programs;

- the Age Discrimination Act of 1975 (42 U.S.C. Sections 6106-07), which prohibits discrimination on the basis of age in programs or activities receiving Federal financial assistance. It does not include employment discrimination;

- 28 C.F.R. pt. 31 (U.S. Department of Justice Regulations – OJJDP Grant Programs); 28 C.F.R. pt. 42 (U.S. Department of Justice Regulations – Nondiscrimination; Equal Employment Opportunity; Policies and Procedures); Executive Order No. 13279 (equal protection of the laws for faith-based and community organizations); Executive Order No. 13559, which provide fundamental principles and policy-making criteria for partnerships with faith-based and neighborhood organizations;

- 28 C.F.R. pt. 38 (U.S. Department of Justice Regulations – Equal Treatment for Faith-Based Organizations); and Whistleblower protections 41 U.S.C. §4712 and The National Defense Authorization Act (NDAA) for Fiscal Year 2013 (Pub. L. 112-239, enacted January 2, 2013) the Pilot Program for Enhancement of Contract Employee Whistleblower Protections, which protects employees against reprisal for certain whistle blowing activities in connection with federal grants and contracts.

The certificate set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or government wide suspension or debarment.

In the event a Federal or State court or Federal or State administrative agency makes a finding of discrimination after a due process hearing on the grounds of race, color, religion, national origin, or sex against a recipient of funds, the recipient will forward a copy of the finding to the Office for Civil Rights, to the applicable contracting agency or division within the Department of Health and Human Services, and to the Department of Health and Human Services Office of the Ombudsman.

The Contractor identified in Section 1.3 of the General Provisions agrees by signature of the Contractor's representative as identified in Sections 1.11 and 1.12 of the General Provisions, to execute the following certification:

1. By signing and submitting this proposal (contract) the Contractor agrees to comply with the provisions indicated above.

Contractor Name:

10/28/15
Date

Name:
Title: Director

CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE

Public Law 103-227, Part C - Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1000 per day and/or the imposition of an administrative compliance order on the responsible entity.

The Contractor identified in Section 1.3 of the General Provisions agrees, by signature of the Contractor's representative as identified in Section 1.11 and 1.12 of the General Provisions, to execute the following certification:

1. By signing and submitting this contract, the Contractor agrees to make reasonable efforts to comply with all applicable provisions of Public Law 103-227, Part C, known as the Pro-Children Act of 1994.

Contractor Name:

10/28/15
Date

Name:
Title: Director

HEALTH INSURANCE PORTABLITY ACT
BUSINESS ASSOCIATE AGREEMENT

The Contractor identified in Section 1.3 of the General Provisions of the Agreement agrees to comply with the Health Insurance Portability and Accountability Act, Public Law 104-191 and with the Standards for Privacy and Security of Individually Identifiable Health Information, 45 CFR Parts 160 and 164 applicable to business associates. As defined herein, "Business Associate" shall mean the Contractor and subcontractors and agents of the Contractor that receive, use or have access to protected health information under this Agreement and "Covered Entity" shall mean the State of New Hampshire, Department of Health and Human Services.

(1) Definitions.

a. "Breach" shall have the same meaning as the term "Breach" in section 164.402 of Title 45, Code of Federal Regulations.

b. "Business Associate" has the meaning given such term in section 160.103 of Title 45, Code of Federal Regulations.

c. "Covered Entity" has the meaning given such term in section 160.103 of Title 45, Code of Federal Regulations.

d. "Designated Record Set" shall have the same meaning as the term "designated record set" in 45 CFR Section 164.501.

e. "Data Aggregation" shall have the same meaning as the term "data aggregation" in 45 CFR Section 164.501.

f. "Health Care Operations" shall have the same meaning as the term "health care operations" in 45 CFR Section 164.501.

g. "HITECH Act" means the Health Information Technology for Economic and Clinical Health Act, TitleXIII, Subtitle D, Part 1 & 2 of the American Recovery and Reinvestment Act of 2009.

h. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 and the Standards for Privacy and Security of Individually Identifiable Health Information, 45 CFR Parts 160, 162 and 164 and amendments thereto.

i. "Individual" shall have the same meaning as the term "individual" in 45 CFR Section 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR Section 164.501(g).

j. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Parts 160 and 164, promulgated under HIPAA by the United States Department of Health and Human Services.

k. "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 CFR Section 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

l. "Required by Law" shall have the same meaning as the term "required by law" in 45 CFR Section 164.103.

m. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his/her designee.

n. "Security Rule" shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 CFR Part 164, Subpart C, and amendments thereto.

o. "Unsecured Protected Health Information" means protected health information that is not secured by a technology standard that renders protected health information unusable, unreadable, or indecipherable to unauthorized individuals and is developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

p. Other Definitions - All terms not otherwise defined herein shall have the meaning established under 45 C.F.R. Parts 160, 162 and 164, as amended from time to time, and the HITECH
Act.

(2) **Business Associate Use and Disclosure of Protected Health Information.**

a. Business Associate shall not use, disclose, maintain or transmit Protected Health Information (PHI) except as reasonably necessary to provide the services outlined under Exhibit A of the Agreement. Further, Business Associate, including but not limited to all its directors, officers, employees and agents, shall not use, disclose, maintain or transmit PHI in any manner that would constitute a violation of the Privacy and Security Rule.

b. Business Associate may use or disclose PHI:
   I. For the proper management and administration of the Business Associate;
   II. As required by law, pursuant to the terms set forth in paragraph d. below; or
   III. For data aggregation purposes for the health care operations of Covered Entity.

c. To the extent Business Associate is permitted under the Agreement to disclose PHI to a third party, Business Associate must obtain, prior to making any such disclosure, (i) reasonable assurances from the third party that such PHI will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party; and (ii) an agreement from such third party to notify Business Associate, in accordance with the HIPAA Privacy, Security, and Breach Notification Rules of any breaches of the confidentiality of the PHI, to the extent it has obtained knowledge of such breach.

d. The Business Associate shall not, unless such disclosure is reasonably necessary to provide services under Exhibit A of the Agreement, disclose any PHI in response to a request for disclosure on the basis that it is required by law, without first notifying Covered Entity so that Covered Entity has an opportunity to object to the disclosure and to seek appropriate relief. If Covered Entity objects to such disclosure, the Business

Associate shall refrain from disclosing the PHI until Covered Entity has exhausted all remedies.

e. If the Covered Entity notifies the Business Associate that Covered Entity has agreed to be bound by additional restrictions over and above those uses or disclosures or security safeguards of PHI pursuant to the Privacy and Security Rule, the Business Associate shall be bound by such additional restrictions and shall not disclose PHI in violation of such additional restrictions and shall abide by any additional security safeguards.

(3) Obligations and Activities of Business Associate.

a. The Business Associate shall notify the Covered Entity's Privacy Officer immediately after the Business Associate becomes aware of any use or disclosure of protected health information not provided for by the Agreement including breaches of unsecured protected health information and/or any security incident that may have an impact on the protected health information of the Covered Entity.

b. The Business Associate shall immediately perform a risk assessment when it becomes aware of any of the above situations. The risk assessment shall include, but not be limited to:

- The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification;
- The unauthorized person used the protected health information or to whom the disclosure was made;
- Whether the protected health information was actually acquired or viewed
- The extent to which the risk to the protected health information has been mitigated.

The Business Associate shall complete the risk assessment within 48 hours of the breach and immediately report the findings of the risk assessment in writing to the Covered Entity.

c. The Business Associate shall comply with all sections of the Privacy, Security, and Breach Notification Rule.

d. Business Associate shall make available all of its internal policies and procedures, books and records relating to the use and disclosure of PHI received from, or created or received by the Business Associate on behalf of Covered Entity to the Secretary for purposes of determining Covered Entity's compliance with HIPAA and the Privacy and Security Rule.

e. Business Associate shall require all of its business associates that receive, use or have access to PHI under the Agreement, to agree in writing to adhere to the same restrictions and conditions on the use and disclosure of PHI contained herein, including the duty to return or destroy the PHI as provided under Section 3 (l). The Covered Entity shall be considered a direct third party beneficiary of the Contractor's business associate agreements with Contractor's intended business associates, who will be receiving PHI

pursuant to this Agreement, with rights of enforcement and indemnification from such business associates who shall be governed by standard Paragraph #13 of the standard contract provisions (P-37) of this Agreement for the purpose of use and disclosure of protected health information.

f. Within five (5) business days of receipt of a written request from Covered Entity, Business Associate shall make available during normal business hours at its offices all records, books, agreements, policies and procedures relating to the use and disclosure of PHI to the Covered Entity, for purposes of enabling Covered Entity to determine Business Associate's compliance with the terms of the Agreement.

g. Within ten (10) business days of receiving a written request from Covered Entity, Business Associate shall provide access to PHI in a Designated Record Set to the Covered Entity, or as directed by Covered Entity, to an individual in order to meet the requirements under 45 CFR Section 164.524.

h. Within ten (10) business days of receiving a written request from Covered Entity for an amendment of PHI or a record about an individual contained in a Designated Record Set, the Business Associate shall make such PHI available to Covered Entity for amendment and incorporate any such amendment to enable Covered Entity to fulfill its obligations under 45 CFR Section 164.526.

i. Business Associate shall document such disclosures of PHI and information related to such disclosures as would be required for Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 CFR Section 164.528.

j. Within ten (10) business days of receiving a written request from Covered Entity for a request for an accounting of disclosures of PHI, Business Associate shall make available to Covered Entity such information as Covered Entity may require to fulfill its obligations to provide an accounting of disclosures with respect to PHI in accordance with 45 CFR Section 164.528.

k. In the event any individual requests access to, amendment of, or accounting of PHI directly from the Business Associate, the Business Associate shall within two (2) business days forward such request to Covered Entity. Covered Entity shall have the responsibility of responding to forwarded requests. However, if forwarding the individual's request to Covered Entity would cause Covered Entity or the Business Associate to violate HIPAA and the Privacy and Security Rule, the Business Associate shall instead respond to the individual's request as required by such law and notify Covered Entity of such response as soon as practicable.

l. Within ten (10) business days of termination of the Agreement, for any reason, the Business Associate shall return or destroy, as specified by Covered Entity, all PHI received from, or created or received by the Business Associate in connection with the Agreement, and shall not retain any copies or back-up tapes of such PHI. If return or destruction is not feasible, or the disposition of the PHI has been otherwise agreed to in the Agreement, Business Associate shall continue to extend the protections of the Agreement, to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business

Associate maintains such PHI. If Covered Entity, in its sole discretion, requires that the Business Associate destroy any or all PHI, the Business Associate shall certify to Covered Entity that the PHI has been destroyed.

(4) Obligations of Covered Entity

a. Covered Entity shall notify Business Associate of any changes or limitation(s) in its Notice of Privacy Practices provided to individuals in accordance with 45 CFR Section 164.520, to the extent that such change or limitation may affect Business Associate's use or disclosure of PHI.

b. Covered Entity shall promptly notify Business Associate of any changes in, or revocation of permission provided to Covered Entity by individuals whose PHI may be used or disclosed by Business Associate under this Agreement, pursuant to 45 CFR Section 164.506 or 45 CFR Section 164.508.

c. Covered entity shall promptly notify Business Associate of any restrictions on the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

(5) Termination for Cause

In addition to Paragraph 10 of the standard terms and conditions (P-37) of this Agreement the Covered Entity may immediately terminate the Agreement upon Covered Entity's knowledge of a breach by Business Associate of the Business Associate Agreement set forth herein as Exhibit I. The Covered Entity may either immediately terminate the Agreement or provide an opportunity for Business Associate to cure the alleged breach within a timeframe specified by Covered Entity. If Covered Entity determines that neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.

(6) Miscellaneous

a. Definitions and Regulatory References. All terms used, but not otherwise defined herein, shall have the same meaning as those terms in the Privacy and Security Rule, amended from time to time. A reference in the Agreement, as amended to include this Exhibit I, to a Section in the Privacy and Security Rule means the Section as in effect or as amended.

b. Amendment. Covered Entity and Business Associate agree to take such action as is necessary to amend the Agreement, from time to time as is necessary for Covered Entity to comply with the changes in the requirements of HIPAA, the Privacy and Security Rule, and applicable federal and state law.

c. Data Ownership. The Business Associate acknowledges that it has no ownership rights with respect to the PHI provided by or created on behalf of Covered Entity.

d. Interpretation. The parties agree that any ambiguity in the Agreement shall be resolved to permit Covered Entity to comply with HIPAA, the Privacy and Security Rule.

e. Segregation. If any term or condition of this Exhibit I or the application thereof to any person(s) or circumstance is held invalid, such invalidity shall not affect other terms or conditions which can be given effect without the invalid term or condition; to this end the terms and conditions of this Exhibit I are declared severable.

f. Survival. Provisions in this Exhibit I regarding the use and disclosure of PHI, return or destruction of PHI, extensions of the protections of the Agreement in section (3) I, the defense and indemnification provisions of section (3) e and Paragraph 13 of the standard terms and conditions (P-37), shall survive the termination of the Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Exhibit I.

NH DHHS	Public Health Institute
The State	Name of the Contractor
Signature of Authorized Representative	Signature of Authorized Representative
Brook R. Dupee	Joanna Jones
Name of Authorized Representative	Name of Authorized Representative
Bureau Chief	Director Bid/Proposal
Title of Authorized Representative	Title of Authorized Representative
11/19/15	10/28/15
Date	Date

CERTIFICATION REGARDING THE FEDERAL FUNDING ACCOUNTABILITY AND TRANSPARENCY ACT (FFATA) COMPLIANCE

The Federal Funding Accountability and Transparency Act (FFATA) requires prime awardees of individual Federal grants equal to or greater than $25,000 and awarded on or after October 1, 2010, to report on data related to executive compensation and associated first-tier sub-grants of $25,000 or more. If the initial award is below $25,000 but subsequent grant modifications result in a total award equal to or over $25,000, the award is subject to the FFATA reporting requirements, as of the date of the award.
In accordance with 2 CFR Part 170 (Reporting Subaward and Executive Compensation Information), the Department of Health and Human Services (DHHS) must report the following information for any subaward or contract award subject to the FFATA reporting requirements:

1. Name of entity
2. Amount of award
3. Funding agency
4. NAICS code for contracts / CFDA program number for grants
5. Program source
6. Award title descriptive of the purpose of the funding action
7. Location of the entity
8. Principle place of performance
9. Unique identifier of the entity (DUNS #)
10. Total compensation and names of the top five executives if:
    - 10.1. More than 80% of annual gross revenues are from the Federal government, and those revenues are greater than $25M annually and
    - 10.2. Compensation information is not already available through reporting to the SEC.

Prime grant recipients must submit FFATA required data by the end of the month, plus 30 days, in which the award or award amendment is made.
The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of The Federal Funding Accountability and Transparency Act, Public Law 109-282 and Public Law 110-252, and 2 CFR Part 170 (Reporting Subaward and Executive Compensation Information), and further agrees to have the Contractor's representative, as identified in Sections 1.11 and 1.12 of the General Provisions execute the following Certification:
The below named Contractor agrees to provide needed information as outlined above to the NH Department of Health and Human Services and to comply with all applicable provisions of the Federal Financial Accountability and Transparency Act.

Contractor Name:

10/28/15
Date

Name:
Title: Director

FORM A

As the Contractor identified in Section 1.3 of the General Provisions, I certify that the responses to the below listed questions are true and accurate.

1. The DUNS number for your entity is: 12866 3396

2. In your business or organization's preceding completed fiscal year, did your business or organization receive (1) 80 percent or more of your annual gross revenue in U.S. federal contracts, subcontracts, loans, grants, sub-grants, and/or cooperative agreements; and (2) $25,000,000 or more in annual gross revenues from U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements?

   X NO _____ YES

   If the answer to #2 above is NO, stop here

   If the answer to #2 above is YES, please answer the following:

3. Does the public have access to information about the compensation of the executives in your business or organization through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C.78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986?

   _____ NO _____ YES

   If the answer to #3 above is YES, stop here

   If the answer to #3 above is NO, please answer the following:

4. The names and compensation of the five most highly compensated officers in your business or organization are as follows:

   Name: _____ Amount: _____

   Name: _____ Amount: _____

   Name: _____ Amount: _____

   Name: _____ Amount: _____

   Name: _____ Amount: _____

Business Entity Detail

Data is updated to the California Business Search on Wednesday and Saturday mornings. Results reflect work processed through Tuesday, October 13, 2015. Please refer to Processing Times for the received dates of filings currently being processed. The data provided is not a complete or certified record of an entity.

Entity Name:	[redacted]
Entity Number:	C0464558
Date Filed:	[redacted]
Status:	ACTIVE
Jurisdiction:	[redacted]
Entity Address:	555 12TH STREET
Entity City, State, Zip:	[redacted]
Agent for Service of Process:	JAMES B, SIMPSON
Agent Address:	[redacted]
Agent City, State, Zip:	OAKLAND CA 94607

* Indicates the information is not contained in the California Secretary of State's database.

- If the status of the corporation is "Surrender," the agent for service of process is automatically revoked. Please refer to California Corporations Code section 2114 for information relating to service upon corporations that have surrendered.
- For information on checking or reserving a name, refer to Name Availability.
- For information on ordering certificates, copies of documents and/or status reports or to request a more extensive search, refer to Information Requests.
- For help with searching an entity name, refer to Search Tips.
- For descriptions of the various fields and status types, refer to Field Descriptions and Status Definitions.

State of California
Secretary of State

CERTIFICATE OF STATUS

ENTITY NAME:

PUBLIC HEALTH INSTITUTE

FILE NUMBER:	C0464558
FORMATION DATE:	01/20/1964
TYPE:	DOMESTIC NONPROFIT CORPORATION
JURISDICTION:	CALIFORNIA
STATUS:	ACTIVE (GOOD STANDING)

I, DEBRA BOWEN, Secretary of State of the State of California, hereby certify:

The records of this office indicate the entity is authorized to exercise all of its powers, rights and privileges in the State of California.

No information is available from this office regarding the financial condition, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of August 02, 2013.

Debra Bowen

DEBRA BOWEN
Secretary of State

California All-Purpose Certificate of Acknowledgment

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Alameda

s.s.

LISA K. STAUBER
COMM. #2103461
Notary Public - California
Alameda County
My Comm. Expires Mar. 16, 2019

On 10/28/15 before me, Lisa K. Stauber, Commission #2103461,
Name of Notary Public, Title

personally appeared Joanna Elise Gomes
Name of Signer (1)

Name of Signer (2)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature of Notary Public

Seal

OPTIONAL INFORMATION

Although the information in this section is not required by law, it could prevent fraudulent removal and reattachment of this acknowledgment to an unauthorized document and may prove useful to persons relying on the attached document

Description of Attached Document

The preceding Certificate of Acknowledgment is attached to a document titled/for the purpose of Agreement with State of New Hampshire, Account #05-95-90-902510-51700000

containing 10 pages, and dated 10/28/15.

The signer(s) capacity or authority is/are as:

- ☐ Individual(s)
- ☐ Attorney-in-fact
- ☐ Corporate Officer(s) _____
  Title(s)
- ☐ Guardian/Conservator
- ☐ Partner - Limited/General
- ☐ Trustee(s)
- ☐ Other: _____

representing: Public Health Institute
Name(s) of Person(s) Entity(ies) Signer is Representing

Additional Information

Method of Signer Identification

Proved to me on the basis of satisfactory evidence:

☒ form(s) of identification ☐ credible witness(es)

Notarial event is detailed in notary journal on:

Page # 3 Entry # 7

Notary contact: (707) 326-6457

Other

☐ Additional Signer ☒ Signer(s) Thumbprints(s)

☐ _____

California Jurat Certificate

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Alameda

S.S.

LISA K. STAUBER
COMM. #2103461
Notary Public - California
Alameda County
My Comm. Expires Mar. 16, 2019

Subscribed and sworn to (or affirmed) before me on this 28th day of October, Month

20 15, by James Barton Simpson and

Name of Signer (1)

_____, proved to me on the basis of

Name of Signer (2)

satisfactory evidence to be the person(s) who appeared before me.

_____
Signature of Notary Public

Lisa K. Stauber, Commission #2103461
For other required information (Notary Name, Commission No., etc.)

Seal

OPTIONAL INFORMATION

Although the information in this section is not required by law, it could prevent fraudulent removal and reattachment of this jurat to an unauthorized document and may prove useful to persons relying on the attached document.

Description of Attached Document

The certificate is attached to a document titled/for the purpose of

Public Health Institute Certificate of Secretary

Reproduction of Bylaws of the Public Health Institute are true and complete and Delegation of Authority to Sign documents is curreent and in full force.

containing 10 pages, and dated 10/28/15

Additional Information

Method of Affiant Identification

Proved to me on the basis of satisfactory evidence:
◉ form(s) of identification ○ credible witness(es)

Notarial event is detailed in notary journal on:

Page # 3 Entry # 6

Notary contact: (707) 326-6457

Other

☒ Affiant(s) Thumbprint(s) ☐ Describe: _____

PUBLIC HEALTH INSTITUTE

Public Health Institute
Certificate of Secretary

I, the undersigned, declare and certify as follows:

1. I am the duly appointed Deputy Secretary of the Public Health Institute, a California nonprofit public benefit corporation.

2. The attached reproduction of the Bylaws of the Public Health Institute dated December 8, 2008 is a true, correct and complete photocopy of a document in my possession.

3. The attached Delegation of Authority to Sign Documents dated April 15, 2009 is a true, correct and complete photocopy of a document in my possession.

4. The attached Bylaws of the Public Health Institute are current and in full force and effect as of the date of this affidavit.

5. The attached Delegation of Authority to Sign Documents is current and in full force and effect as of the date of this affidavit.

I declare under penalty of perjury under the laws of the State of California that the statements in the foregoing certificate are true and correct of my own knowledge and that this declaration was executed on October 28, 2015.

James B. Simpson,
General Counsel and Deputy Secretary

555 12th Street, 10th Floor
Oakland, CA 94760
Phone: 510-285-5500
Fax: 510-285-5501
Email: dssofaer@phi.org

PUBLIC HEALTH INSTITUTE

Memorandum

To: Mary A. Pittman, Dr.P.H., President & CEO

From: Donna Sofaer

Date: April 15, 2009

Re: Delegation of Authority to Sign PHI Documents

Under the authority delegated to the President and CEO by the Board of Directors, please sign below to delegate signature authority to the following individuals to sign all PHI proposals, contracts, grants, and related documentation.

Mary-Ellen Fortini, Manager, Bid & Proposal
Joanna Gomes, Manager, Bid & Proposal

I approve the above signature authorization:

Mary A. Pittman

Mary A. Pittman, Dr.P.H., President & CEO

cc: M. Fortini
J. Gomes

BYLAWS
OF
THE PUBLIC HEALTH INSTITUTE
A California Nonprofit Public Benefit Corporation

ARTICLE I: Principal Office

Section 1. The corporation's principal office is 555 12th Street, 10th Floor, Oakland, CA 94607-4046. The Board of Directors (herein called "Board") may change the principal office from one location to another and establish branch or subordinate offices.

ARTICLE II: Members

Section 1. The Corporation shall have no members.

ARTICLE III: Board of Directors

Section 1. General Corporate Powers

Subject to the provisions and limitations of the California Nonprofit Public Benefit Corporation Law and any other applicable laws, the Articles of Incorporation, and other sections of the Bylaws, the activities and affairs of the corporation shall be conducted and all corporate powers shall be exercised by or under the direction of the Board. The Board may delegate the management of the activities of the corporation to any person or persons, management company, or committee however composed, provided that the activities and affairs of the corporation shall be managed and all corporate powers shall be exercised under the ultimate direction of the Board.

Section 2. Number of Directors

The authorized numbers of directors shall consist of at least five (5) but no more than seventeen (17) directors until changed by amendment to the Bylaws. The exact number of directors shall be fixed within the foregoing limits by a resolution adopted by the Board.

Section 3. Selection and Term of Office of Directors

(a) The President and Chief Executive Officer shall be an ex officio voting member of the Board of Directors.

(b) All other directors shall be elected by two-thirds vote of the directors in office on the date of the election. Regular elections shall be held at a meeting duly called for that purpose each December, and special elections for vacant positions shall be held when needed.

(c) The terms of office of elected directors shall be two years commencing January 1 and ending December 31 of the following year, provided that the term of office of a director elected to a vacant position shall end when the term of office of their predecessor would have ended.

(d) A director shall be elected who is a principal investigator or project director of the corporation and who was nominated to serve as a director by the principal investigators and project directors.

(e) Elected directors shall serve no more than four successive terms of office. No former director shall be reelected for two full years after leaving office.

(f) A vacancy on the board shall exist upon: (i) the death or resignation of any director; (ii) a declaration by resolution adopted by the affirmative vote of two-thirds of the directors of a vacancy in the office of any director; (iii) the absence by any director from three (3) consecutive meetings of the board if said absences are without justification acceptable to the Board. Vacancies may be filled by a majority of the directors in office on the date of the election whether or not less than a quorum.

Section 4. Compensation of Directors

Directors may receive such compensation, if any, for their services as directors or officers, and such reimbursement of expenses, as the Board may determine by resolution to be just and reasonable as to the corporation at the time the resolution is adopted.

Section 5. Place of Meeting

Regular and special meetings of the Board shall be held at any place, within or without the state, that has been designated from time to time by resolution of the Board or by written consent of all members of the Board. In the absence of this designation the annual organization meeting and other regular and special meetings shall be held at the principal office of the corporation.

Section 6. Regular Meetings

Regular Meetings of the Board shall be held without call or notice on such dates and at such times as may be fixed by the Board.

Section 7. Special Meetings

Special Meetings of the Board for any purpose or purposes may be called at any time by the President and Chief Executive Officer or any two directors. Special meetings of the Board shall be held upon four (4) days' notice by first-class mail or forty-eight

(48) hours' notice given personally or by telephone, telegraph, telex, or other similar means of communication. Any such notice shall be addressed or delivered to each director at such director's address as it is shown upon the records of the corporation or as may have been given to the corporation by the director for purposes of notice or, if such address is not shown on such records or is not readily ascertainable, at the place in which the meetings of the directors are regularly held.

Section 8. Quorum

A majority of the authorized number of directors constitutes a quorum of the Board for the transaction of business, except that a majority of the directors present, whether or not a quorum is present, may adjourn any directors' meeting to another time and place. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board, unless a greater number is required by law, the Articles, or the Bylaws, except as provided in the next sentence. A meeting at which a quorum is initially present may continue to transact business notwithstanding the withdrawal of directors, if any such action taken is approved by at least a majority of the required quorum for such meeting.

Section 9. Participation in Meetings by Conference Telephone

Members of the Board may participate in a meeting through use of conference telephone or similar communications equipment, so long as all members participating in such meeting can hear one another.

Section 10. Waiver of Notice

Notice of a meeting need not be given to any director who signs a waiver of notice or a written consent to holding the meeting or an approval of the minutes thereof, whether before or after the meeting, or who attends the meeting without protesting, prior thereto or at its commencement, the lack of notice to such director. All such waivers, consents, and approvals shall be filed with the corporate records or made a part of the minutes of the meeting.

Section 11. Action Without Meeting

Any action required or permitted to be taken by the Board may be taken without a meeting if all members of the Board shall individually or collectively consent in writing to such action. Such consent or consents shall have the same effect as a unanimous vote of the Board and shall be filed with the minutes of the proceedings of the Board.

Section 12. Rights of Inspection

Every director shall have the absolute right at any reasonable time to inspect and copy all books, records, and documents of every kind and to inspect the physical properties of the corporation.

Section 13. Committees

The Board may appoint one or more committees, each consisting of two or more directors, and delegate to such committees any of the authority of the Board except with respect to:

(g) The filling of vacancies on the Board or any committee;

(h) The amendment or repeal of Bylaws or the adoption of new Bylaws;

(i) The amendment or repeal of any resolution of the Board which by its express terms is not so amendable or repealable;

(j) The appointment of other committees of the Board or the members thereof;

(k) The approval of any self-dealing transaction, as such transactions are defined in Section 5233(a) of the California Nonprofit Public Benefit Corporation Law.

(l) Any such committee must be created, and the members thereof appointed, by resolution adopted by a majority of the authorized number of directors then in office, provided a quorum is present, and any such committee may be designated an Executive Committee or by such other names as the Board shall specify. The Board may appoint, in the same manner, alternate members of any committee who may replace any absent member at any meeting of the committee. The Board shall have the power to prescribe the manner in which proceedings of any such committee shall be conducted. In the absence of any such prescription, such committee shall have the power to prescribe the manner in which its proceedings shall be conducted. Unless the Board or such committee shall otherwise provide, the regular and special meetings and other actions of any such committee shall be governed by the provisions of this Article applicable to meetings and actions of the Board. Minutes shall be kept of each meeting of each committee.

Section 14. There is established a committee which shall be known as the Nominating Committee. The Chairman of the Board shall annually appoint three Board members to the Nominating Committee. The Nominating Committee shall consider and nominate to the full Board of Directors persons for election as directors and officers of the corporation.

Section 15 Audit Committee

There is established a committee which shall be known as the Audit Committee.

Subject to the supervision of the Board of Directors, the Audit Committee shall the following responsibilities:

(a) Recommend to the Board of Directors the retention and termination of an independent certified public accountant who shall audit the annual financial statements of the corporation in conformity with generally accepted auditing standards;

(b) Negotiate the independent auditor's compensation on behalf of the Board of Directors;

(c) Confer with the independent auditor to satisfy the members of the Audit Committee that the financial affairs of the corporation are in order;

(d) Review and determine whether to accept the independent audit;

(e) Assure that any nonaudit services performed by the independent auditor conform with the standards for auditor independence set forth in the latest revision of the Government Accounting Standards, issued by the Comptroller General of the United States (the Yellow Book) and any California Attorney General regulations prescribing standards for auditor independence in the performance of nonaudit services; and

(f) Approve performance of nonaudit services by the independent auditor.

(g) Oversee the compliance program established by the Board of Directors and report on compliance to the Board.

The Board of Directors shall appoint the members of the Audit Committee. The Audit Committee may include persons who are not members of the Board of Directors. The member or members of the Audit Committee shall not include any members of the staff of the corporation, including the President/Chief Executive Officer and the Chief Financial Officer. Members of the Executive-Finance Committee may serve on the Audit Committee, provided that they shall constitute less than one-half of the membership of the Audit Committee. The chair of the Audit Committee may not be a member of the Executive-Finance Committee. Members of the Audit Committee shall not receive any compensation from the corporation in excess of the compensation, if any, received by members of the Board of Directors for service on the Board and shall not have a material financial interest in any entity doing business with the corporation.

Section 16. Emeritus Board

The Board of Directors may designate former members of the Board of Directors to serve as emeritus members. The criteria for emeritus membership shall be long-term

service on the Board, exceptional leadership or special and extraordinary contributions to PHI's growth, development and mission. An emeritus member shall not be a member of the Board of Directors, but may be invited to attend meetings of the Board of Directors, participate in Board deliberations, sit on advisory committees to the Board of Directors, and perform other functions as the Board of Directors shall specify.

ARTICLE IV. OFFICERS

Section 1. Selection and Term of Office of Officers

The corporation shall have a Chairman of the Board, a Vice Chairman, a Chief Financial Officer (who shall be known as the Treasurer), and a Secretary. They shall be chosen by the Board each September for a term of office commencing January 1 of the following year and ending December 31. No person shall serve more than two consecutive terms in any one such office. The Chairman of the Board shall preside at meetings of the Board and have such other powers and duties as may be prescribed from time to time by the Board. The Board may appoint other officers, with such powers and duties as the Board may prescribe. Any number of offices may be held by the same person, but neither the Treasurer nor the Secretary may serve concurrently as Chairman. Officers other than the Chairman need not be members of the Board.

Section 2. Vacancies

A vacancy in any office because of death, resignation, removal, disqualification, or otherwise shall be filled by the Board.

Section 3. Chief Executive Officer

The corporation shall have a Chief Executive Officer who shall be known as the President and Chief Executive Officer. Subject to the control of the Board, the President and Chief Executive Officer shall have general supervision, direction, and control of the business and affairs of the corporation.

ARTICLE V: INDEMNIFICATION

Section 1. Right of Indemnity

To the fullest extent permitted by law, this corporation shall indemnify the directors, officers, employees, and other persons described in Section 5238(a) of the California Corporations Code, including persons formerly occupying any such position, against all expenses, judgments, fines, settlements, and other amounts actually and reasonably incurred by them in connection with any "proceeding," as that term is used in that Section, and including an action by or in the right of the corporation, by reason of the fact that the person is or was a person described in that Section. "Expenses," as used

in this bylaw, shall have the same meaning as in Section 5238(a) of the California Corporations Code.

Section 2. Approval of Indemnity

On written request to the board by any person seeking indemnification under Section 5238(b) or Section 5238(c) of the California Corporations Code, the board shall promptly determine under Section 5238(e) whether the applicable standard of conduct set forth in Section 5238(b) or Section 5238(c) has been met and, if so, the board shall authorize indemnification.

ARTICLE VI: AMENDMENTS

Section 1. These Bylaws may be repealed or amended or new Bylaws adopted at a meeting of the Board of Directors by the affirmative vote of two-thirds of the members of the Board of Directors.

Section 2. The most recent amendment of these Bylaws was December 8, 2008.

h:\jsimpson\forms\phi bylaws.doc

ACORD ™ CERTIFICATE OF LIABILITY INSURANCE

Date (MM/DD/YR): 10/15/2015

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Heffernan Insurance Brokers
1350 Carlback Avenue, Suite 200
Walnut Creek, CA 94596
CA License #0564249

CONTACT NAME:
PHONE (A/C,No,Ext): 925-934-8500 FAX (A/C,No): 925-934-8278
EMAIL ADDRESS:

INSURERS AFFORDING COVERAGE		NAIC #
INSURER A:	General Insurance Company of America	24732
INSURER B:	Berkshire Hathaway Homestate Ins. Co.	20044
INSURER C:	American States Insurance Company	19704
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Public Health Institute
555 12th Street, 10th Floor
Oakland, CA 94607-4046

COVERAGES: **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	GENERAL L IABILITY [X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L. AGGREGATE LIMIT APPLIES PER [ ] POLICY [ ] PROJECT [X] LOC			24CC26025670	01/01/15	01/01/16	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 3,000,000 $ 3,000,000
A	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] ALL OWNED AUTOS [ ] SCHEDULED AUTOS [X] HIRED AUTOS [X] NON-OWNED AUTOS			24CC26025670	01/01/15	01/01/16	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
C	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [X] RETENTION $ 10,000			01SU41100170	01/01/15	01/01/16	EACH OCCURRENCE AGGREGATE	$ 6,000,000 $ 6,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N *ANY PROPRIETOR/PARTNER/EXECUTIVE/ OFFICER/MEMBER EXCLUDED?* (Mandatory in N.H.) [ ] If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		PUWC602661	05/20/15	05/20/16	[X] WC STATU-TORY LIMITS [ ] OTHER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (Attach ACORD 101, Additional Remarks Schedule, if more space is required)
Re: As Per Contract or Agreement on File with Insured. Cancellation notice for the General Liability policy is attached, if required.

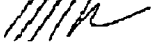
CERTIFICATE HOLDER

New Hampshire Department of Health
and Human Services
129 Pleasant Street
Concord, NH 03301-3857

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE



THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

CALIFORNIA CHANGES — CANCELLATION AND NONRENEWAL

This endorsement modifies insurance provided under the following:

BOILER AND MACHINERY COVERAGE PART
CAPITAL ASSETS PROGRAM (OUTPUT POLICY) COVERAGE PART
COMMERCIAL AUTOMOBILE COVERAGE PART
COMMERCIAL GENERAL LIABILITY COVERAGE PART
COMMERCIAL INLAND MARINE COVERAGE PART
COMMERCIAL PROPERTY COVERAGE PART
CRIME AND FIDELITY COVERAGE PART
EMPLOYMENT-RELATED PRACTICES LIABILITY COVERAGE PART
FARM COVERAGE PART
LIQUOR LIABILITY COVERAGE PART
POLLUTION LIABILITY COVERAGE PART
PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE PART
PROFESSIONAL LIABILITY COVERAGE PART

A. Paragraphs **2.** and **3.** of the Cancellation Common Policy Condition are replaced by the following:

2. All Policies In Effect For 60 Days Or Less

If this policy has been in effect for 60 days or less, and is not a renewal of a policy we have previously issued, we may cancel this policy by mailing or delivering to the first Named Insured at the mailing address shown in the policy and to the producer of record, advance written notice of cancellation, stating the reason for cancellation, at least:

a. 10 days before the effective date of cancellation if we cancel for:

(1) Nonpayment of premium; or

(2) Discovery of fraud by:

(a) Any insured or his or her representative in obtaining this insurance; or

(b) You or your representative in pursuing a claim under this policy.

b. 30 days before the effective date of cancellation if we cancel for any other reason.

3. All Policies In Effect For More Than 60 Days

a. If this policy has been in effect for more than 60 days, or is a renewal of a policy we issued, we may cancel this policy only upon the occurrence, after the effective date of the policy, of one or more of the following:

(1) Nonpayment of premium, including payment due on a prior policy we issued and due during the current policy term covering the same risks.

(2) Discovery of fraud or material misrepresentation by:

(a) Any insured or his or her representative in obtaining this insurance; or

(b) You or your representative in pursuing a claim under this policy.

(3) A judgment by a court or an administrative tribunal that you have violated a California or Federal law, having as one of its necessary elements an act which materially increases any of the risks insured against.

(4) Discovery of willful or grossly negligent acts or omissions, or of any violations of state laws or regulations establishing safety standards, by you or your representative, which materially increase any of the risks insured against.

(5) Failure by you or your representative to implement reasonable loss control requirements, agreed to by you as a condition of policy issuance, or which were conditions precedent to our use of a particular rate or rating plan, if that failure materially increases any of the risks insured against.

(6) A determination by the Commissioner of Insurance that the:

(a) Loss of, or changes in, our reinsurance covering all or part of the risk would threaten our financial integrity or solvency; or

(b) Continuation of the policy coverage would:

(i) Place us in violation of California law or the laws of the state where we are domiciled; or

(ii) Threaten our solvency.

(7) A change by you or your representative in the activities or property of the commercial or industrial enterprise, which results in a materially added, increased or changed risk, unless the added, increased or changed risk is included in the policy.

b. We will mail or deliver advance written notice of cancellation, stating the reason for cancellation, to the first Named Insured, at the mailing address shown in the policy, and to the producer of record, at least:

(1) 10 days before the effective date of cancellation if we cancel for nonpayment of premium or discovery of fraud; or

(2) 30 days before the effective date of cancellation if we cancel for any other reason listed in Paragraph **3.a.**

E. The following provision is added to the **Cancellation Common Policy Condition:**

7. Residential Property

This provision applies to coverage on real property which is used predominantly for residential purposes and consisting of not more than four dwelling units, and to coverage on tenants' household personal property in a residential unit, if such coverage is written under one of the following:

Commercial Property Coverage Part

Farm Coverage Part – Farm Property – Farm Dwellings, Appurtenant Structures And Household Personal Property Coverage Form

a. If such coverage has been in effect for 60 days or less, and is not a renewal of coverage we previously issued, we may cancel this coverage for any reason, except as provided in b. and c. below.

b. We may not cancel this policy solely because the first Named Insured has:

(1) Accepted an offer of earthquake coverage; or

(2) Cancelled or did not renew a policy issued by the California Earthquake Authority (CEA) that included an earthquake policy premium surcharge.

However, we shall cancel this policy if the first Named Insured has accepted a new or renewal policy issued by the CEA that includes an earthquake policy premium surcharge but fails to pay the earthquake policy premium surcharge authorized by the CEA.

c. We may not cancel such coverage solely because corrosive soil conditions exist on the premises. This Restriction **(c.)** applies only if coverage is subject to one of the following, which exclude loss or damage caused by or resulting from corrosive soil conditions:

(1) Capital Assets Program Coverage Form (Output Policy);

(2) Commercial Property Coverage Part – Causes Of Loss – Special Form; or

(3) Farm Coverage Part – Causes Of Loss Form – Farm Property, Paragraph D. Covered Causes Of Loss – Special.

C. The following is added and supersedes any provisions to the contrary:

NONRENEWAL

1. Subject to the provisions of Paragraphs **C.2.** and **C.3.** below, if we elect not to renew this policy, we will mail or deliver written notice stating the reason for nonrenewal to the first Named Insured shown in the Declarations and to the producer of record, at least 60 days, but not more than 120 days, before the expiration or anniversary date.

   We will mail or deliver our notice to the first Named Insured, and to the producer of record, at the mailing address shown in the policy.

2. **Residential Property**

   This provision applies to coverage on real property used predominantly for residential purposes and consisting of not more than four dwelling units, and to coverage on tenants' household property contained in a residential unit, if such coverage is written under one of the following:

   Capital Assets Program (Output Policy) Coverage Part

   Commercial Property Coverage Part

   Farm Coverage Part – Farm Property – Farm Dwellings, Appurtenant Structures And Household Personal Property Coverage Form

   a. We may elect not to renew such coverage for any reason, except as provided in **b.**, **c.** and **d.** below:

   b. We will not refuse to renew such coverage solely because the first Named Insured has accepted an offer of earthquake coverage.

      However, the following applies only to insurers who are associate participating insurers as established by Cal. Ins. Code Section 10089.16. We may elect not to renew such coverage after the first Named Insured has accepted an offer of earthquake coverage, if one or more of the following reasons applies:

      (1) The nonrenewal is based on sound underwriting principles that relate to the coverages provided by this policy and that are consistent with the approved rating plan and related documents filed with the Department of Insurance as required by existing law;

      (2) The Commissioner of Insurance finds that the exposure to potential losses will threaten our solvency or place us in a hazardous condition. A hazardous condition includes, but is not limited to, a condition in which we make claims payments for losses resulting from an earthquake that occurred within the preceding two years and that required a reduction in policyholder surplus of at least 25% for payment of those claims; or

      (3) We have:

         (a) Lost or experienced a substantial reduction in the availability or scope of reinsurance coverage; or

         (b) Experienced a substantial increase in the premium charged for reinsurance coverage of our residential property insurance policies; and

      the Commissioner has approved a plan for the nonrenewals that is fair and equitable, and that is responsive to the changes in our reinsurance position.

   c. We will not refuse to renew such coverage solely because the first Named Insured has cancelled or did not renew a policy, issued by the California Earthquake Authority that included an earthquake policy premium surcharge.

   d. We will not refuse to renew such coverage solely because corrosive soil conditions exist on the premises. This Restriction **(d.)** applies only if coverage is subject to one of the following, which exclude loss or damage caused by or resulting from corrosive soil conditions:

      (1) Capital Assets Program Coverage Form (Output Policy)

(2) Commercial Property Coverage Part — Causes Of Loss — Special Form; or

(3) Farm Coverage Part Causes Of Loss Form — Farm Property, Paragraph **D.** Covered Causes Of Loss — Special.

3. We are not required to send notice of nonrenewal in the following situations:

   a. If the transfer or renewal of a policy, without any changes in terms, conditions, or rates, is between us and a member of our insurance group.

   b. If the policy has been extended for 90 days or less, provided that notice has been given in accordance with Paragraph **C.1.**

   c. If you have obtained replacement coverage, or if the first Named Insured has agreed, in writing, within 60 days of the termination of the policy, to obtain that coverage.

   d. If the policy is for a period of no more than 60 days and you are notified at the time of issuance that it will not be renewed.

   e. If the first Named Insured requests a change in the terms or conditions or risks covered by the policy within 60 days of the end of the policy period.

   f. If we have made a written offer to the first Named Insured, in accordance with the timeframes shown in Paragraph **C.1.**, to renew the policy under changed terms or conditions or at an increased premium rate, when the increase exceeds 25%.

PUBLIC HEALTH INSTITUTE®

Mission

PHI generates and promotes research, leadership and partnerships to build capacity for strong public health policy, programs, systems and practices.

Values

Health is a fundamental human right. Just societies ensure equitable health outcomes for everyone.

Vision

Healthy communities where individuals reach their highest potential.

Principles

- Accountability
- Leadership and creativity in individuals and institutions
- Cross-sector thinking
- Innovation
- Evidence-based public health

Goals

- Strengthen public health engagement and leadership
- Advance sustainable global health solutions
- Strengthen public health systems, services and research
- Advance policy to improve social determinants of health
- Diversify and strengthen funding base to ensure long-term impact
- Deliver operational excellence to PHI programs

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AUDIT REPORT

FINANCIAL AND FEDERAL AWARD COMPLIANCE EXAMINATION

FOR THE YEAR ENDED DECEMBER 31, 2014

PUBLIC HEALTH INSTITUTE

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FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2014 AND 2013

PUBLIC HEALTH INSTITUTE

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GELMAN, ROSENBERG
& FREEDMAN
CERTIFIED PUBLIC ACCOUNTANTS

INDEPENDENT AUDITOR'S REPORT

To the Board of Directors
Public Health Institute
Oakland, California

Report on the Financial Statements

We have audited the accompanying financial statements of the Public Health Institute (the Institute), which comprise the statements of financial position as of December 31, 2014 and 2013, and the related statements of activities and changes in net assets and cash flows for the years then ended, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

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Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Institute as of December 31, 2014 and 2013, and the changes in its net assets and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Other Matter

Our audits were conducted for the purpose of forming an opinion on the financial statements as a whole. The Schedule of Expenditures of Federal Awards on pages I-(15 - 18), as required by Office of Management and Budget Circular A-133, *Audits of States, Local Governments, and Non-Profit Organizations*, is presented for purposes of additional analysis and is not a required part of the financial statements. Such information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the financial statements. The information has been subjected to the auditing procedures applied in the audit of the financial statements and certain additional procedures, including comparing and reconciling such information directly to the underlying accounting and other records used to prepare the financial statements or to the financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the information is fairly stated, in all material respects, in relation to the financial statements as a whole.

Other Reporting Required by Government Auditing Standards

In accordance with *Government Auditing Standards*, we have also issued our report dated June 2, 2015 on our consideration of the Institute's internal control over financial reporting and on our tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements and other matters. The purpose of that report is to describe the scope of our testing of internal control over financial reporting and compliance and the results of that testing, and not to provide an opinion on internal control over financial reporting or on compliance. That report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the Institute's internal control over financial reporting and compliance.

Gelman Rosenberg & Freedman

June 2, 2015

PUBLIC HEALTH INSTITUTE

STATEMENTS OF FINANCIAL POSITION
AS OF DECEMBER 31, 2014 AND 2013

ASSETS

	2014	2013
CURRENT ASSETS		
Cash and cash equivalents	$ 10,991,904	$ 5,389,645
Grants and contracts receivable, net of allowance for doubtful accounts of $75,000 in 2014 and 2013 (Note 2)	15,663,139	24,114,020
Prepaid expenses	1,205,458	1,016,490
Other assets	247,355	63,160
Total current assets	28,107,856	30,583,315
FURNITURE, EQUIPMENT AND COMPUTER SOFTWARE		
Furniture, equipment and computer software, net of accumulated depreciation and amortization of $538,075 and $472,903 for 2014 and 2013, respectively (Note 3)	829,214	195,715
TOTAL ASSETS	**$ 28,937,070**	**$ 30,779,030**

LIABILITIES AND NET ASSETS

CURRENT LIABILITIES		
Accounts payable	$ 3,531,448	$ 6,890,459
Accrued salaries and related leave	7,075,784	6,875,680
Other accrued liabilities	-	19,920
Contract advances	4,200,274	4,198,731
Total current liabilities	14,807,506	17,984,790
NET ASSETS		
Unrestricted:		
Undesignated	5,538,218	4,708,019
Designated (Note 4)	940,728	1,028,537
Total unrestricted	6,478,946	5,736,556
Temporarily restricted (Note 5)	7,650,618	7,057,684
Total net assets	14,129,564	12,794,240
TOTAL LIABILITIES AND NET ASSETS	**$ 28,937,070**	**$ 30,779,030**

See accompanying notes to financial statements.

PUBLIC HEALTH INSTITUTE

STATEMENTS OF ACTIVITIES AND CHANGES IN NET ASSETS
FOR THE YEARS ENDED DECEMBER 31, 2014 AND 2013

	2014			2013		
	Unrestricted	Temporarily Restricted	Total	Unrestricted	Temporarily Restricted	Total
SUPPORT AND REVENUE						
Grants and contracts (Notes 2 and 9)	$ 91,436,749	$ 14,036,326	$ 105,473,075	$ 100,990,139	$ 12,990,706	$ 113,980,845
Contributions	1,447,166	-	1,447,166	-	-	-
Other revenue (Note 7)	172,009	-	172,009	239,729	-	239,729
Net assets released from donor restrictions	13,443,392	(13,443,392)	-	13,791,810	(13,791,810)	-
Total support and revenue	106,499,316	592,934	107,092,250	115,021,678	(801,104)	114,220,574
EXPENSES						
Direct expenses:						
Salaries, wages and benefits (Note 8)	55,640,785	-	55,640,785	56,915,924	-	56,915,924
Professional services	6,550,777	-	6,550,777	5,364,551	-	5,364,551
Travel	5,823,108	-	5,823,108	5,542,479	-	5,542,479
Occupancy (Note 7)	3,482,140	-	3,482,140	3,306,041	-	3,306,041
Supplies	935,192	-	935,192	2,459,795	-	2,459,795
Training and professional development	2,227,396	-	2,227,396	1,756,153	-	1,756,153
Publications and printing	1,244,032	-	1,244,032	3,871,023	-	3,871,023
Temporary help	236,309	-	236,309	333,588	-	333,588
Communications	995,978	-	995,978	978,780	-	978,780
Postage and delivery	460,600	-	460,600	530,376	-	530,376
Subcontracts and grants	13,771,579	-	13,771,579	18,029,554	-	18,029,554
Other	511,507	-	511,507	852,676	-	852,676
Total direct expenses	91,879,403	-	91,879,403	99,940,940	-	99,940,940
Indirect expenses:						
Allocated	13,781,552	-	13,781,552	14,155,784	-	14,155,784
Unallocated	95,971	-	95,971	73,317	-	73,317
Total indirect expenses	13,877,523	-	13,877,523	14,229,101	-	14,229,101
Total expenses	105,756,926	-	105,756,926	114,170,041	-	114,170,041
Changes in net assets	742,390	592,934	1,335,324	851,637	(801,104)	50,533
Net assets at beginning of year	5,736,556	7,057,684	12,794,240	4,884,919	7,858,788	12,743,707
NET ASSETS AT END OF YEAR	**$ 6,478,946**	**$ 7,650,618**	**$ 14,129,564**	**$ 5,736,556**	**$ 7,057,684**	**$ 12,794,240**

See accompanying notes to financial statements.

PUBLIC HEALTH INSTITUTE

STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2014 AND 2013

	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES		
Changes in net assets	$ 1,335,324	$ 50,533
Adjustments to reconcile changes in net assets to net cash provided (used) by operating activities:		
Depreciation and amortization	65,172	62,390
(Increase) decrease in:		
Grants and contracts receivable	8,450,881	(7,250,288)
Prepaid expenses	(188,968)	(54,741)
Other assets	(184,195)	30,645
Increase (decrease) in:		
Accounts payable	(3,359,011)	2,952,942
Accrued salaries and related leave	200,104	103,150
Other accrued liabilities	(19,920)	123
Contract advances	1,543	370,790
Net cash provided (used) by operating activities	6,300,930	(3,734,456)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of furniture, equipment and computer software	(698,671)	(31,406)
Net cash used by investing activities	(698,671)	(31,406)
Net increase (decrease) in cash and cash equivalents	5,602,259	(3,765,862)
Cash and cash equivalents at beginning of year	5,389,645	9,155,507
CASH AND CASH EQUIVALENTS AT END OF YEAR	**$ 10,991,904**	**$ 5,389,645**

See accompanying notes to financial statements.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND GENERAL INFORMATION

Organization -

The Public Health Institute (the Institute) is an independent, not-for-profit organization dedicated to promoting health, well-being and quality of life for people throughout California, across the nation and around the world. As one of the largest and most comprehensive public health organizations in the nation, the Institute is at the forefront of research and innovation to improve the efficacy of public health statewide, nationally and globally.

The Institute's mission is to generate and promote research, leadership and partnerships to build capacity for strong public health policy, programs, systems and practices. The Institute believes that health is a fundamental human right and just societies ensure equitable health outcomes for everyone. The Institute is guided by the following key principles:

- Accountability
- Leadership and creativity in individuals and institutions
- Cross-sector thinking
- Diverse partnerships throughout the world
- Innovation
- Evidence-based public health

The Institute has adopted a five-year strategic framework for fiscal years 2010 through 2014. Following are the strategic framework's six overarching goals:

- Strengthen public health engagement and leadership
- Advance sustainable global health solutions
- Strengthen public health systems, services and research
- Advance policy to improve social determinants of health
- Diversify and strengthen funding base to ensure long-term impact
- Deliver operational excellence to the Institute's programs

Basis of presentation -

The accompanying financial statements are presented on the accrual basis of accounting, and in accordance with FASB ASC 958, *Not-for-Profit Entities*.

Cash and cash equivalents -

The Institute considers all cash and other highly liquid investments with initial maturities of three months or less when purchased to be cash equivalents.

Bank deposit accounts are insured by the Federal Deposit Insurance Corporation ("FDIC") up to a limit of $250,000. At times during the year, the Institute maintains cash balances in excess of the FDIC insurance limits. Management believes the risk in these situations to be minimal.

Furniture, equipment and computer software -

Furniture, equipment and computer software in excess of $5,000 are capitalized and stated at cost if purchased, or at fair value if donated.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND GENERAL INFORMATION (Continued)

Furniture, equipment and computer software (continued) -

Furniture, equipment and computer software are depreciated/amortized on a straight-line basis over the estimated useful lives of the related assets, generally five to seven years. The cost of maintenance and repairs is recorded as expenses are incurred.

Compensated absences -

The Institute's current policy is to allow employees to accrue up to a maximum of 640 hours of paid time off. As of December 31, 2014 and 2013, the liability for accrued compensated absences aggregated $6,497,655 and $6,337,941, respectively, and is included in accrued salaries and related leave in the accompanying Statements of Financial Position.

Net asset classification -

The net assets are reported in three self-balancing groups as follows:

- **Unrestricted net assets** include unrestricted revenue and contributions received without donor-imposed restrictions. These net assets are available for the operation of the Institute and include both internally designated (Note 4) and undesignated resources.

- **Temporarily restricted net assets** include revenue and contributions subject to donor-imposed stipulations that will be met by the actions of the Institute and/or the passage of time. When a restriction expires, temporarily restricted net assets are reclassified to unrestricted net assets and reported in the Statements of Activities and Changes in Net Assets as net assets released from restrictions.

- **Permanently restricted net assets** represent funds restricted by the donor to be maintained in-perpetuity by the Institute. There were no permanently restricted net assets as of December 31, 2014 and 2013.

Grants and contracts -

Grants are recognized as temporarily restricted when deemed to be a purpose or time restricted contribution. Temporarily restricted grants received in excess of qualifying direct and indirect expenses incurred are shown as temporarily restricted net assets in the accompanying financial statements.

Contracts are recorded as unrestricted revenue as reimbursable costs are incurred or on a percentage of completion method (if a fixed price agreement). Contract funding received in advance of incurring the related expenses is recorded as a contract advance.

The Institute receives funding under grants and contracts from the U.S. Government for direct and indirect program costs. This funding is subject to contractual restrictions, which must be met through incurring qualifying expenses for particular programs. Accordingly, such grants are considered to be exchange transactions and are recorded as unrestricted income to the extent that related direct and indirect expenses are incurred in compliance with the criteria stipulated in the grant agreements.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND GENERAL INFORMATION (Continued)

Grants and contracts (continued) -

Grants and contracts receivable represents amounts due from funding organizations for reimbursable expenses incurred in accordance with the related agreements. Grants and contracts receivable approximate fair value.

The allowance for doubtful accounts is determined based upon an annual review of account balances, including the age of the balance and the historical experience with the funder.

Income taxes -

The Institute is exempt from Federal income taxes under Section 501(c)(3) of the Internal Revenue Code and from state income and franchise taxes under Section 23701d of the California Revenue and Taxation Code, except to the extent of unrelated business taxable income as defined under Internal Revenue Code Sections 511 through 515. A provision for income taxes has not been recorded in the accompanying financial statements. The Institute is not a private foundation.

Uncertain tax positions -

For the years ended December 31, 2014 and 2013, the Institute has documented its consideration of FASB ASC 740-10, *Income Taxes*, that provides guidance for reporting uncertainty in income taxes and has determined that no material uncertain tax positions qualify for either recognition or disclosure in the financial statements.

The Federal Form 990, *Return of Organization Exempt from Income Tax*, is subject to examination by the Internal Revenue Service, generally for three years after it is filed.

Use of estimates -

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Accordingly, actual results could differ from those estimates.

Functional allocation of expenses -

The costs of providing the various programs and other activities have been summarized on a functional basis in the Statements of Activities and Changes in Net Assets. Accordingly, certain costs have been allocated among the programs and supporting services benefited.

2. CONCENTRATION OF REVENUE AND RECEIVABLES

Approximately 76% and 76% of the Institute's total support and revenue for the years ended December 31, 2014 and 2013, respectively, was derived from various agencies of the U.S. Government; approximately 30% and 29% of the Institute's total support and revenue for the years ended December 31, 2014 and 2013, respectively, was received under a single cooperative agreement from the United States Agency for International Development.

2. CONCENTRATION OF REVENUE AND RECEIVABLES (Continued)

Approximately 17% and 47% of grants and contracts receivable for the years ended December 31, 2014 and 2013, respectively, was due under contracts with the State of California Department of Public Health.

The Institute has no reason to believe that the relationship with these agencies will be discontinued in the foreseeable future. However, any interruption of these relationships (i.e., the failure to renew grant agreements or withholding of funds) may adversely affect the Institute's ability to finance ongoing operations.

3. FURNITURE, EQUIPMENT AND COMPUTER SOFTWARE

Furniture, equipment and computer software consisted of the following at December 31, 2014 and 2013:

	2014	2013
Furniture and equipment	$ 153,275	$ 135,996
Computer software	1,214,014	532,622
Total furniture, equipment and computer software	1,367,289	668,618
Less: Accumulated depreciation and amortization	(538,075)	(472,903)
NET FURNITURE, EQUIPMENT AND COMPUTER SOFTWARE	**$ 829,214**	**$ 195,715**

Total depreciation and amortization expense for the years ended December 31, 2014 and 2013 was $65,172 and $62,390, respectively.

4. DESIGNATED NET ASSETS

As of December 31, 2014 and 2013, net assets have been designated for the following purposes:

	2014	2013
Adeline Hackett Innovations Initiative	$ -	$ 6,498
Program Designated Funds	940,728	1,022,039
TOTAL DESIGNATED NET ASSETS	**$ 940,728**	**$ 1,028,537**

5. TEMPORARILY RESTRICTED NET ASSETS

As of December 31, 2014 and 2013 temporarily restricted net assets consisted of funds set aside for specific programs, as stipulated by the following donors providing the restricted support:

	2014	2013
The California Endowment	$ 1,342,583	$ 2,146,942
The Kresge Foundation	1,394,860	900,572
The Bill and Melinda Gates Foundation	529,118	1,636,570
David and Lucile Packard Foundation	492,625	253,035
The Health Trust	476,611	-
The Nike Foundation	435,967	-
Robert Wood Johnson Foundation	411,848	239,163
California Healthcare Foundation	402,878	273,337
Kaiser Permanente	309,944	87,626
CNET	284,351	-
The Summit Foundation	280,291	129,471
The Flight Attendant Medical Research Institute	183,373	183,952
The United Nations Foundation	161,297	126,418
Springcreek Foundation	153,763	-
NoVo Foundation	116,882	166,017
CRGC Core Support	109,644	107,050
Westwind Foundation	100,549	-
The California Wellness Foundation	94,252	-
Ford Foundation	37,242	237,810
Other	332,540	569,721
TOTAL TEMPORARILY RESTRICTED NET ASSETS	**$ 7,650,618**	**$ 7,057,684**

6. LINE OF CREDIT

In December 2012, the Institute opened a revolving bank line of credit for $4,000,000 that has the option to renew annually, and currently is set to expire in February 1, 2016. Amounts borrowed under this agreement bear interest equal to LIBOR Daily Floating rate plus 2% (2.25% and 2.10% at December 31, 2014 and 2013, respectively). The line is secured by the cash and accounts receivable of the Institute. As of December 31, 2014 and 2013, there were no outstanding borrowings on the line of credit.

Additionally, the line of credit agreement contains various covenants, which requires the Institute to maintain certain financial ratios and submit various financial reports throughout its fiscal year. As of the date of the report, the Institute was in compliance with the reporting covenants.

7. LEASE COMMITMENTS

The Institute leases office space under several agreements, expiring in various years through 2022. The Institute generally attempts to include a clause in its lease agreements which enables the lease to be terminated should support from a funding agency be terminated.

7. LEASE COMMITMENTS (Continued)

Future minimum lease payments under operating leases with remaining terms in excess of one year as of December 31, 2014 are as follows:

Year Ending December 31,	
2015	$ 4,569,424
2016	2,769,489
2017	1,741,791
2018	1,103,805
2019	1,115,598
Thereafter	2,311,026
	$ 13,611,133

The following is a summary of rent expense under all operating leases during the years ended December 31, 2014 and 2013:

	2014	2013
Rental expense	$ 4,499,359	$ 4,657,943
Less: Sublease rentals	(19,210)	(340,368)
NET RENTAL EXPENSE	**$ 4,480,149**	**$ 4,317,575**

Rent expense, included in direct occupancy expense in the accompanying Statements of Activities and Changes in Net Assets for the years ended December 31, 2014 and 2013, totaled $3,158,484 and $2,943,460, respectively. During the same periods, $1,321,665 and $1,374,115, respectively, was included in allocated indirect expenses. Sublease revenue for the years ended December 31, 2014 and 2013 was $19,210 and $340,368, respectively, and has been presented as a reduction of rent expense in the accompanying Statements of Activities and Changes in Net Assets. As of December 31, 2014, the Institute did not have any active sub-leasing arrangements.

8. TAX SHELTERED ANNUITY PLAN

In lieu of a standard retirement plan, the Institute offers participation in a tax sheltered annuity plan. Employees who work a minimum of 20 hours per week, after six full months of employment, are eligible to participate. The Institute contributes 10% of gross wages to the tax sheltered annuity plan. An employee's minimum contribution is $25 per month. The maximum combined contributions are determined by limits set under Federal law.

During the years ended December 31, 2014 and 2013, the Institute contributed $4,341,017 and $4,332,703, respectively, to the tax sheltered annuity plan. The aforementioned contributions are fully vested and are administered by TIAA/CREF.

9. CONTINGENCY

The Institute receives assistance from various agencies of the United States Government; such awards are subject to audit under the provisions of OMB Circular A-133. The ultimate determination of amounts received under United States Government awards is based upon the allowance of costs reported to and accepted by the United States Government as a result of the audits. Audits in accordance with the provisions of OMB Circular A-133 have been completed for all required fiscal years through 2014. Until such audits have been accepted by the United States Government, there exists a contingency to refund any amount received in excess of allowable costs. Management is of the opinion that no material liability will result from such audits.

10. SUBSEQUENT EVENTS

In preparing these financial statements, the Institute has evaluated events and transactions for potential recognition or disclosure through June 2, 2015, the date the financial statements were issued.

SUPPLEMENTAL INFORMATION

PUBLIC HEALTH INSTITUTE

SCHEDULE OF EXPENDITURES OF FEDERAL AWARDS
FOR THE YEAR ENDED DECEMBER 31, 2014

Federal Granting Agency/ Name of Program	Pass-Through Entity	CFDA Number	Grant/Contract Number	Expenditures
Research and Development Cluster:				
U.S. Department of Justice (US DOJ):				
National Institute of Justice Research, Evaluation, and Development Project Grants	-	16.560	2011-MU-MU-0023	$ 256,941
Environmental Protection Agency (EPA):				
Science to Achieve Results (STAR) Research Program	U.C. San Francisco	66.509	7954SC	294
U.S. Department of Education (US DOE):				
National Institute on Disability and Rehabilitation Research	-	84.133A	H133A110024	1,048,556
National Institute on Disability and Rehabilitation Research	University of New Hampshire	84.133B	14-043	115,308
National Institute on Disability and Rehabilitation Research	Institute for Rehabilitation	84.133A	ADA.PHI-3-13	91,095
National Institute on Disability and Rehabilitation Research	Transcen, Inc.	84.133A	None	6,147
National Institute on Disability and Rehabilitation Research	U.C. San Francisco	84.133B	5811SC	4,330
Subtotal CFDA #84.133				**1,265,436**
Special Education Technology and Media Services for Individuals with Disabilities	FHI Development 360, LLC	84.327	3057	5,722
Subtotal - US DOE Programs				**1,271,158**
Department of Health and Human Services (DHHS):				
Environmental Public Health and Emergency Response	Centers for Disease Control and Prevention	93.070	2U38EH000953-04	367,564
Environmental Health	National Institutes of Health	93.113	1R01ES022722-01A1	450,783
Environmental Health	National Institutes of Health	93.113	1U01ES019471-04	409,070
Environmental Health	University of California - Davis	93.113	201300414-01	105,329
Environmental Health	U.C. San Francisco	93.113	7923SC	294
Environmental Health	U.C. San Francisco	93.113	8049SC	147
Subtotal CFDA #93.113				**965,623**
Health Program for Toxic Substances and Disease Registry	McKing Consulting Corporation	93.161	4560	99,791
Disabilities Prevention	Centers for Disease Control and Prevention	93.184	1U50DD001008-01	347,225
Mental Health Research Grants	Brown University	93.242	00000487 PO# P275877	76,371
Mental Health Research Grants	Temple University	93.242	360762-PHI	52,014
Subtotal CFDA #93.242				**128,385**
Substance Abuse and Mental Health Services Projects of Regional and National Significance	National Institutes of Health	93.243	1U79SP017379-01	325,432
Substance Abuse and Mental Health Services Projects of Regional and National Significance	National Institutes of Health	93.243	1U79SP015000-01	3,234
Subtotal CFDA #93.243				**328,666**
Occupational Safety and Health Programs	Centers for Disease Control and Prevention	93.262	5 U60 OH008468-04	1,071,374
Alcohol Research Programs	National Institutes of Health	93.273	2P50AA005595-31	1,419,867
Alcohol Research Programs	National Institutes of Health	93.273	1R01AA021742-01	651,717
Alcohol Research Programs	National Institutes of Health	93.273	1 R21 AA018365-01	502,256
Alcohol Research Programs	National Institutes of Health	93.273	1R01AA020328-01A1	489,422
Alcohol Research Programs	National Institutes of Health	93.273	1R01AA018119-02	277,816
Alcohol Research Programs	National Institutes of Health	93.273	1R01AA017954-02	248,215
Alcohol Research Programs	National Institutes of Health	93.273	1R01AA022668-01	172,669
Alcohol Research Programs	National Institutes of Health	93.273	1R01AA020474-01	149,796
Alcohol Research Programs	National Institutes of Health	93.273	1R01AA022791-01	124,007
Alcohol Research Programs	National Institutes of Health	93.273	1R01AA022857-01A1	88,569
Alcohol Research Programs	National Institutes of Health	93.273	2R01AA013750-08A1	86,023
Alcohol Research Programs	Board of Regents of the University of California	93.273	0350GRA729	31,103
Alcohol Research Programs	National Institutes of Health	93.273	1R01AA021448-01A1	29,606
Alcohol Research Programs	National Institutes of Health	93.273	1R34AA022697-01A1	17,061
Alcohol Research Programs	National Institutes of Health	93.273	1R03AA019791-01A1	2,722
Subtotal CFDA #93.273				**4,290,849**
Drug Abuse and Addiction Research Programs	National Institutes of Health	93.279	1R01DA034973-01A1	671,420
Drug Abuse and Addiction Research Programs	National Institutes of Health	93.279	1 R01 DA024714-01A1	164,256
Drug Abuse and Addiction Research Programs	National Institutes of Health	93.279	1R21DA033869-01A1	135,175
Drug Abuse and Addiction Research Programs	National Institutes of Health	93.279	1R03DA034961-01A1	70,711
Drug Abuse and Addiction Research Programs	National Institutes of Health	93.279	1R01DA036606-01A1	29,176
Drug Abuse and Addiction Research Programs	U.C. San Francisco	93.279	7281SC	28,144
Drug Abuse and Addiction Research Programs	National Institutes of Health	93.279	1R03DA035175-01A1	12,663
Subtotal CFDA #93.279				**1,111,545**
Cancer Cause and Prevention research	Northeastern University	93.393	500117 P1001942	4,694
Cancer Detection and Diagnosis Research	University of Southern California	93.394	47354313	9,997
Cancer Detection and Diagnosis Research	University of Southern California	93.394	44873956	4,919
Subtotal CFDA #93.394				**14,916**

PUBLIC HEALTH INSTITUTE

SCHEDULE OF EXPENDITURES OF FEDERAL AWARDS
FOR THE YEAR ENDED DECEMBER 31, 2014

Federal Granting Agency/ Name of Program	Pass-Through Entity	CFDA Number	Grant/Contract Number	Expenditures
Research and Development Cluster (Continued):				
Department of Health and Human Services (DHHS) (continued):				
Cancer Treatment Research	The Children's Hospital	93.395	9500080215-02C	$ 3,639,674
Cancer Treatment Research	University of Florida	93.395	UFDSP00010187	3,169,046
Cancer Treatment Research	The Children's Hospital	93.395	9400200000	909,184
Cancer Treatment Research	The Children's Hospital	93.395	FP17458_SUB01_01	273,964
Cancer Treatment Research	University of Florida	93.395	UFDSP00010389	92,346
Cancer Treatment Research	The Children's Hospital	93.395	9500090215-05	68,688
Cancer Treatment Research	University Southern California	93.395	45555513	24,772
Cancer Treatment Research	The Children's Hospital	93.395	9500080215-S5	11,302
Cancer Treatment Research	The Childrens Hospital	93.395	9500020513	864,573
Cancer Treatment Research	University of Nebraska	93.395	34-5410-2003-002	639,133
Cancer Treatment Research	The Childrens Hospital	93.395	9500060715-02C	1,083,761
Cancer Treatment Research	The Childrens Hospital	93.395	9500020513	357,531
Subtotal CFDA #93.395				**11,133,974**
Cardiovascular Diseases Research	University of Utah	93.837	10028784-01	77,256
Arthritis, Musculoskeletal and Skin Diseases Research	Georgetown University	93.846	U01AR057971-01	27,656
Allergy, Immunology and Transplantation Research	U.C. San Francisco	93.855	7406SC	19,173
Center for Research for Mothers and Children	Columbia University	93.865	GG004992	60,594
Center for Research for Mothers and Children	Stanford University	93.865	60520239-107774	56,640
Subtotal CFDA #93.865				**117,234**
International Research and Research Training	National Institutes of Health	93.989	R01TW009295	311,399
Childrens Health and Development Studies	National Cancer Institute	N/A	HHSN261201300014I	3,170,630
Childrens Health and Development Studies	National Institutes of Health	N/A	HHSN275201100020C	338,736
Subtotal CFDA Unknown				**3,509,366**
Subtotal - DHHS Programs				**23,926,690**
Total Research and Development Cluster				**25,455,083**
Other Programs:				
U.S. Agency for International Development (USAID):				
USAID Foreign Assistance for Programs Overseas	-	98.001	AID-OAA-A-11-00025	31,582,441
USAID Foreign Assistance for Programs Overseas	Program for Appropriate Technology in Health	98.001	AID.1659-05454-SUB	410,988
USAID Foreign Assistance for Programs Overseas	-	98.001	GPO-A-00-06-00005-00	(235,348)
Subtotal - CFDA 98.001				**31,758,081**
Department of Agriculture (USDA):				
State Administrative Matching Grants for the Supplemental Nutrition Assistance Program	Department of Public Health	10.561	08-85554	12,640,728
State Administrative Matching Grants for the Supplemental Nutrition Assistance Program	Department of Public Health	10.561	14-10306	1,082,804
State Administrative Matching Grants for the Supplemental Nutrition Assistance Program	Department of Public Health	10.561	13-20938	308,620
State Administrative Matching Grants for the Supplemental Nutrition Assistance Program	Department of Public Health	10.561	13-20936	271,371
State Administrative Matching Grants for the Supplemental Nutrition Assistance Program	County of Fresno	10.561	13-721	266,208
State Administrative Matching Grants for the Supplemental Nutrition Assistance Program	Department of Public Health	10.561	08-85554	76,457
State Administrative Matching Grants for the Supplemental Nutrition Assistance Program	Department of Public Health	10.561	08-85554	5,298
State Administrative Matching Grants for the Supplemental Nutrition Assistance Program	Department of Public Health	10.561	08-85554	660
Subtotal CFDA #10.561				**14,652,146**
Department of Housing and Urban Development (HUD):				
Sustainable Communities Regional Planning Grant Program	Metropolitan Transportation Commission	14.703	None	46,365
Environmental Protection Agency (EPA):				
Surveys, Studies, Research, Investigations, Demonstrations and Special Purpose Activities Relating to the Clean Air Act	-	66.034	83575801	34,266
Department of Health and Human Services (DHHS):				
Telehealth Programs	Health Resources and Services Administration	93.211	G22RH24746-01-00	302,550
Community Transformation Grants and National Dissemination and Support for Community Transformation Grants	National Institutes of Health	93.531	1U58DP003677-01	5,068,213
Community Transformation Grants and National Dissemination and Support for Community Transformation Grants	American Public Health Association	93.531	1U58DP003757-01	2,591
Subtotal CFDA #93.531				**5,070,804**

PUBLIC HEALTH INSTITUTE

SCHEDULE OF EXPENDITURES OF FEDERAL AWARDS
FOR THE YEAR ENDED DECEMBER 31, 2014

Federal Granting Agency/ Name of Program	Pass-Through Entity	CFDA Number	Grant/Contract Number	Expenditures
Other Programs (Continued):				
Department of Health and Human Services (DHHS) (continued):				
Special Projects of National Significance	Health Resources and Services Administration	93.928	1 H97HA24970-01-00	$ 441,549
Block Grants for Prevention and Treatment of Substance Abuse	Sacramento County	93.959	7206000-14-085	120,164
Department of Health and Human Services (DHHS) - Centers for Disease Control:				
Applied Leadership for Community Health Improvement	Centers for Disease Control and Prevention	93.055	1U38OT000106-01	1,115,800
Applied Leadership for Community Health Improvement	Centers for Disease Control and Prevention	93.055	3U380T000106-02W1	28,478
Subtotal CFDA #93.055				**1,144,278**
Disabilities Prevention	University of Alabama at Birmingham	93.184	000433099-008	61,085
Centers for Disease Control and Prevention Investigations and Technical Assistance	National Network of Public Health Institutes	93.283	C196	652,665
Centers for Disease Control and Prevention Investigations and Technical Assistance	Department of Public Health	93.283	1U58DP001488-01	119,000
Centers for Disease Control and Prevention Investigations and Technical Assistance	Department of Public Health	93.283	12-10251	74,274
Centers for Disease Control and Prevention Investigations and Technical Assistance	Department of Public Health	93.283	12-10247	58,207
Centers for Disease Control and Prevention Investigations and Technical Assistance	Department of Public Health	93.283	12-10249	33,219
Centers for Disease Control and Prevention Investigations and Technical Assistance	Department of Public Health	93.283	12-10246	29,572
Centers for Disease Control and Prevention Investigations and Technical Assistance	Department of Public Health	93.283	12-10250	20,267
Centers for Disease Control and Prevention Investigations and Technical Assistance	Department of Public Health	93.283	12-10248	16,233
Centers for Disease Control and Prevention Investigations and Technical Assistance	National Network of Public Health Institutes	93.283	C673	16,227
Centers for Disease Control and Prevention Investigations and Technical Assistance	National Network of Public Health Institutes	93.283	C217	(13,999)
Subtotal CFDA #93.283				**1,005,665**
National Public Health Improvement Imitative	National Network of Public Health Institutes	93.292	C769	2,848
Affordable Care Act - Building Epidemiology, Laboratory, and Health Information Systems Capacity	Public Health Foundation Enterprises	93.521	0235.015.930	691
Building Capacity of the Public Health System to Improve Population Health through National, Non-Profit Organizations - Financed in part by 2013 Prevention and Public Health Funds	National Network of Public Health Institutes	93.524	C663	298,925
Building Capacity of the Public Health System to Improve Population Health through National, Non-Profit Organizations - Financed in part by 2013 Prevention and Public Health Funds	National Network of Public Health Institutes	93.524	C522	76,731
Building Capacity of the Public Health System to Improve Population Health through National, Non-Profit Organizations - Financed in part by 2013 Prevention and Public Health Funds	Association of State and Territorial Health Officials	93.524	74-10041	228,858
Subtotal CFDA #93.524				**604,514**
Affordable Care Act - National Environmental Public Health Tracking Program	National Institutes of Health	93.538	IU38EH000953-01	668,196
Racial and Ethnic Approaches to Community Health Program financed solely by 2012 Public Prevention and Health Funds	National REACH Coalition	93.738	2012 Reach	29,922
Racial and Ethnic Approaches to Community Health Program financed solely by 2012 Public Prevention and Health Funds	Centers for Disease Control and Prevention	93.738	1U58DP005859-01	349
Subtotal CFDA #93.738				**30,271**
HIV Prevention Activities _ Health Department Based	Public Health Foundation Enterprises	93.940	None	114,487
Preventive Health and Health Services Block Grant	Department of Public Health	93.991	08-85554	98,842
No CFDA #, No Title Available	Centers for Disease Control and Prevention	N/A	200-2013-M-56428	14,381
No CFDA #, No Title Available	Centers for Disease Control and Prevention	N/A	200-2013-M-57376	7,516
Subtotal CFDA Unknown				**21,897**
TOTAL EXPENDITURES OF FEDERAL AWARDS				**$ 81,633,782**

PUBLIC HEALTH INSTITUTE

SCHEDULE OF EXPENDITURES OF FEDERAL AWARDS FOR THE YEAR ENDED DECEMBER 31, 2014

Notes to Schedule:

A The accompanying Schedule of Expenditures of Federal Awards (the Schedule) includes the Federal grant activity of the Institute under programs of the Federal government for the year ended December 31, 2014. The information in the Schedule is presented in accordance with the requirements of the Office of Management and Budget (OMB) Circular A-133, *Audits of States, Local Governments, and Non-Profit Organizations*. Because the Schedule presents only a selected portion of the operations of the Institute, it is not intended to and does not present the financial position, changes in net assets or cash flows of the Institute.

B Expenditures reported on the Schedule are reported on the accrual basis of accounting. Such expenditures are recognized following the cost principles contained in OMB Circular A-122, *Cost Principles for Non-Profit Organizations*, wherein certain types of expenditures are not allowable or are limited as to reimbursement. Negative amounts shown on the Schedule represent adjustments or credits made in the normal course of business to amounts reported as expenditures in prior years. Pass-through entity identifying numbers are presented where available.

C Of the Federal expenditures presented in the Schedule, the Institute provided Federal awards to subrecipients as follows:

Program Name	CFDA Number	Amount Provided
Community Transformation Grants and National Dissemination and Support for Community Transformation Grants	93.531	$ 3,679,792
State Administrative Matching Grants for the Supplemental Nutrition Assistance Program	10.561	$ 3,310,898
Research and Development Cluster	Various	$ 2,541,651
USAID Foreign Assistance for Programs Overseas	98.001	$ 1,286,573
Centers for Disease Control and Prevention Investigations and Technical Assistance	93.283	$ 214,584
Racial and Ethnic Approaches to Community Health Program Financed Solely by 2012 Public Prevention and Health Funds	93.738	$ 20,697
Surveys, Studies, Research, Investigations, Demonstrations and Special Purpose Activities Relating to the Clean Air Act	66.034	$ 16,666
Sustainable Communities Regional Planning Grant Program	14.703	$ 11,848
Special Projects of National Significance	93.928	$ 1,658

PUBLIC HEALTH INSTITUTE

SCHEDULE OF FINDINGS AND QUESTIONED COSTS
FOR THE YEAR ENDED DECEMBER 31, 2014

Section I - Summary of Auditor's Results

Financial Statements

1). Type of auditor's report issued: **Unmodified**

2). Internal control over financial reporting:

- Material weakness(es) identified? ☐ Yes ☒ No
- Significant deficiency(ies) identified that are not considered to be material weakness(es)? ☐ Yes ☒ None Reported

3). Noncompliance material to financial statements noted? ☐ Yes ☒ No

Federal Awards

4). Internal control over major programs:

- Material weakness(es) identified? ☐ Yes ☒ No
- Significant deficiency(ies) identified that are not considered to be material weakness(es)? ☐ Yes ☒ None Reported

5). Type of auditor's report issued on compliance for major programs: **Unmodified**

6). Any audit findings disclosed that are required to be reported in accordance with Section 510(a) of Circular A-133? ☐ Yes ☒ No

7). Identification of major programs:

Federal Program Title	CFDA	Expenditures
Research and Development Cluster	Various	$ 25,455,083
United States Agency for International Development: Foreign Assistance for Programs Overseas	98.001	$ 31,758,081
United States Department of Agriculture: State Administrative Matching Grants for the Supplemental Nutrition Assistance Program	10.561	$ 14,652,146

8). Dollar threshold used to distinguish between Type A and Type B programs: **$2,449,013**

9). Auditee qualified as a low-risk auditee? ☒ Yes ☐ No

PUBLIC HEALTH INSTITUTE

SCHEDULE OF FINDINGS AND QUESTIONED COSTS
FOR THE YEAR ENDED DECEMBER 31, 2014

Section II - Financial Statement Findings

There were no reportable findings.

Section III - Federal Award Findings and Questioned Costs (Circular A-133, Section .510)

There were no reportable findings.

Section IV - Prior Year Findings

There were no prior year audit findings.

GELMAN, ROSENBERG
& FREEDMAN
CERTIFIED PUBLIC ACCOUNTANTS

REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING AND ON COMPLIANCE AND OTHER MATTERS BASED ON AN AUDIT OF FINANCIAL STATEMENTS PERFORMED IN ACCORDANCE WITH GOVERNMENT AUDITING STANDARDS

Independent Auditor's Report

To the Board of Directors
Public Health Institute
Oakland, California

We have audited, in accordance with the auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards* issued by the Comptroller General of the United States, the financial statements of the Public Health Institute (the Institute) as of and for the year ended December 31, 2014, and the related notes to the financial statements, which collectively comprise the Institute's basic financial statements, and have issued our report thereon dated June 2, 2015.

Internal Control Over Financial Reporting

In planning and performing our audit of the financial statements, we considered the Institute's internal control over financial reporting (internal control) to determine the audit procedures that are appropriate in the circumstances, for the purpose of expressing our opinions on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of the Institute's internal control. Accordingly, we do not express an opinion on the effectiveness of the Institute's internal control.

A *deficiency in internal control* exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis. A *material weakness* is a deficiency, or a combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the Institute's financial statements will not be prevented, or detected and corrected on a timely basis. A *significant deficiency* is a deficiency, or a combination of deficiencies, in internal control that is less severe than a material weakness, yet important enough to merit attention by those charged with governance.

Our consideration of internal control was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control that might be material weaknesses or significant deficiencies and therefore, material weaknesses or significant deficiencies may exist that were not identified. Given these limitations, during our audit we did not identify any deficiencies in internal control that we consider to be material weaknesses. However, material weaknesses may exist that have not been identified.

Compliance and Other Matters

As part of obtaining reasonable assurance about whether the Institute's financial statements are free from material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements, noncompliance with which could have a direct and material effect on the determination of financial statement amounts. However, providing an opinion on compliance with those provisions was not an objective of our audit, and accordingly, we do not express such an opinion. The results of our tests disclosed no instances of noncompliance or other matters that are required to be reported under *Government Auditing Standards*.

Purpose of this Report

The purpose of this report is solely to describe the scope of our testing of internal control and compliance and the result of that testing, and not to provide an opinion on the effectiveness of the entity's internal control or on compliance. This report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the entity's internal control and compliance. Accordingly, this communication is not suitable for any other purpose.

Gelman Rosenberg & Freedman

June 2, 2015

GELMAN, ROSENBERG
& FREEDMAN
CERTIFIED PUBLIC ACCOUNTANTS

REPORT ON COMPLIANCE FOR EACH MAJOR FEDERAL PROGRAM AND REPORT ON INTERNAL CONTROL OVER COMPLIANCE REQUIRED BY OMB CIRCULAR A-133

Independent Auditor's Report

To the Board of Directors
Public Health Institute
Oakland, California

Report on Compliance for Each Major Federal Program

We have audited the Public Health Institute's (the Institute) compliance with the types of compliance requirements described in the *OMB Circular A-133 Compliance Supplement* that could have a direct and material effect on each of the Institute's major federal programs for the year ended December 31, 2014. The Institute's major federal programs are identified in the summary of auditor's results section of the accompanying Schedule of Findings and Questioned Costs.

Management's Responsibility

Management is responsible for compliance with the requirements of laws, regulations, contracts and grants applicable to its federal programs.

Auditor's Responsibility

Our responsibility is to express an opinion on compliance for each of the Institute's major federal programs based on our audit of the types of compliance requirements referred to above. We conducted our audit of compliance in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and OMB Circular A-133, *Audits of States, Local Governments, and Non-Profit Organizations*. Those standards and OMB Circular A-133 require that we plan and perform the audit to obtain reasonable assurance about whether noncompliance with the types of compliance requirements referred to above that could have a direct and material effect on a major federal program occurred. An audit includes examining, on a test basis, evidence about the Institute's compliance with those requirements and performing such other procedures as we considered necessary in the circumstances.

We believe that our audit provides a reasonable basis for our opinion on compliance for each major federal program. However, our audit does not provide a legal determination of the Institute's compliance.

Opinion on Each Major Federal Program

In our opinion, the Institute complied, in all material respects, with the types of compliance requirements referred to above that could have a direct and material effect on each of its major federal programs for the year ended December 31, 2014.

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Report on Internal Control Over Compliance

Management of the Institute is responsible for establishing and maintaining effective internal control over compliance with the types of compliance requirements referred to above. In planning and performing our audit of compliance, we considered the Institute's internal control over compliance with the types of requirements that could have a direct and material effect on each major federal program to determine the auditing procedures that are appropriate in the circumstances for the purpose of expressing an opinion on compliance for each major federal program and to test and report on internal control over compliance in accordance with OMB Circular A-133, but not for the purpose of expressing an opinion on the effectiveness of internal control over compliance. Accordingly, we do not express an opinion on the effectiveness of the Institute's internal control over compliance.

A *deficiency in internal control over compliance* exists when the design or operation of a control over compliance does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, noncompliance with a type of compliance requirement of a federal program on a timely basis. A *material weakness in internal control over compliance* is a deficiency, or combination of deficiencies, in internal control over compliance, such that there is a reasonable possibility that material noncompliance with a type of compliance requirement of a federal program will not be prevented, or detected and corrected, on a timely basis. A *significant deficiency in internal control over compliance* is a deficiency, or a combination of deficiencies, in internal control over compliance with a type of compliance requirement of a federal program that is less severe than a material weakness in internal control over compliance, yet important enough to merit attention by those charged with governance.

Our consideration of internal control over compliance was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control over compliance that might be material weaknesses or significant deficiencies and therefore, material weaknesses or significant deficiencies may exist that were not identified. We did not identify any deficiencies in internal control over compliance that we consider to be material weaknesses. However, material weaknesses may exist that have not been identified.

The purpose of this report on internal control over compliance is solely to describe the scope of our testing of internal control over compliance and the results of that testing based on the requirements of OMB Circular A-133. Accordingly, this report is not suitable for any other purpose.

Gelman Rosenberg & Freedman

June 2, 2015

PUBLIC HEALTH INSTITUTE

2015 BOARD OF DIRECTORS

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Park, June-Soo	Research Scientist, Environmental Chemistry Branch
eRA COMMONS USER NAME	CA Dept. of Toxic Substances Control, Cal/EPA

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Jeonnam National University, Korea	B.S.	1991	Oceanography
Texas A&M University	M.S.	1995	Oceanography (Chemistry Div.)
Texas A&M University	Ph.D.	2000	Oceanography (Chemistry Div.)

A. Personal Statement.

The goal of the proposed research is to identify POP metabolites in maternal and fetal tissues and to assess the related health outcomes. Our laboratory's role is to measure environmental endocrine disruptors from archived sera collected 50+ years ago. As a co-investigator or a lead scientist in many public health related investigations, I led a research group in many areas including method development for the chemical analyses, management of a large number of serum samples from each investigation, and applied the extreme caution and organizational skills required with sample inventory and chemical analysis that were usually limited to small sample volume (~ 1 mL), and handling with clean techniques. Many chemical measurement methods I developed have been successfully used to measure persistent organic pollutants in public health studies: "Automobile Exhaust and Human Health Effects" (HEI funded); "Slovakia PCB Exposure and Child Health Development Study (2003-2005)" (NIH); "Organochlorines in California Human Serum and Thyroid Effects" (NIH); "Hydroxylated PCB Metabolites in California Serum and Thyroid Effects " (NIH), "and "California Human Serum Organochlorines and Breast Density Study" (NIH); the California Environemntal Contaminants Biomonitoring Program (CDC). Related scientific publications are provided here and starting to appear. Thus, my expertise, leadership and motivation demonstrated in previous public health related studies will successfully carry out the similar proposed study in collaborating with epidemiologists, toxicologists, chemists, and stakeholders. I look forward to joining Dr. Woodruff in the search for *in utero* exposures of POP metabolites that influence developmental health outcomes.

B. Positions and Honors.

Positions and Employment

2000-2002	Research Associate, Department of Civil and Environmental Engineering, University of Wisconsin–Madison, Madison, WI
2003-2005	Project Scientist (SRA IV), Department of Public Health Sciences and Department of Environmental Toxicology, University of California, Davis, CA
2006-2011	Research Scientist, Environmental Chemistry Laboratory, Department of Toxic Substances Control, California Environmental Protection Agency, Berkeley, CA
11/2011-	Human & Environment Monitoring Section Chief (Research Scientist Supervisor), Environmental Chemistry Laboratory, Department of Toxic Substances Control, California Environmental Protection Agency, Berkeley, CA

Other Experience and Professional Memberships

1998-2000	National Estuary Program
2000-2002	American Association of Aerosol Research (AAAR)
2000-2002	American Geophysical Union (AGU)
2002-	American Chemical Society (ACS)
2005-	Dioxin. International Symposium on Halogenated Environmental Organic Pollutants and Persistent Organic Pollutants (POPs)
2006-	Society of Environmental Toxicology and Chemistry (SETAC)

C. Selected peer-reviewed publications (in chronological order, from over 45)

(Publications selected from peer-reviewed publications)

1. Rogers, E, Petreas, M, **Park J-S**, Zhao GM, Charles MJ. 2005. Evaluation of four capillary columns for the analysis of organochlorine pesticides, polychlorinated biphenyls, and polybrominated diphenyl ethers in human serum for epidemiologic studies, *Journal of Chromatography B.* 813(1-2): 269-285. **PMID:** 15556543
2. **Park J-S**, Linderholm L, Charles MJ, Athanasiadou M, Petrik J, Kocan A, Drobna B, Trnovec T, Bergman Å, Hertz-Picciotto I. 2007. Polychlorinated biphenyls and their hydroxylated metabolites (OH-PCBs) in pregnant women from Eastern Slovakia. *Environmental Health Perspectives.* 115(1): 20-27. **PMID:** 17366814
3. Linderholm L, **Park J-S**, Kocan A, Trnovec T, Athanasiadou M, Bergman Å, Hertz-Picciotto I. 2007. Maternal and cord serum exposure to PCB and DDE methyl sulfone metabolites in eastern Slovakia. *Chemosphere.* 69(3): 403-410. **PMID:** 17574648
4. **Park J-S**, Bergman Å, Linderholm L, Athanasiadou M, Kocan A, Petrik J, Drobna B, Trnovec T, Charles MJ, Hertz-Picciotto I. 2008. Placental Transfer of Polychlorinated Biphenyls, Their Hydroxylated Metabolites and Pentachlorophenol in Pregnant Women from Eastern Slovakia. *Chemosphere.* 70(9): 1676-1684. **PMID:** 17764717
5. **Park J-S**, Petreas M, Cohn BA, Cirillo PM, Factor-Litvak P. 2009. Hydroxylated PCB metabolites (OH-PCBs) in archived serum from 1950-60's California mothers. *Environmental International.* 35:937-942. **PMID:** 19439357
6. Park HY, **Park J-S**, Sovcikova, E, Kocan A, Trnovec T, Hertz-Picciotto I. 2009. Exposure to hydroxylated PCBs in the prenatal period and subsequent neurodevelopment in eastern Slovakia. *Environmental Health Perspectives.* 117(10): 1600-1606. **PMID:** 20019912
7. **Park J-S**, Holden A, Chu V, Kim M, Rhee A, Patel P, Yating S, Linthicum J, Walton BJ, McKeown K, Jewell NP, Hooper K. 2009. Time-trends and congener profiles of PBDEs and PCBs in California peregrine falcons (*Falco peregrinus*). *Environmental Science and Technology.* 43(23): 8744-8751. **PMID:** 19943641
8. Newsome SD, **Park J-S**, Henry RW, Holden A, Chu V, Fogel ML, Linthicum J, Hooper K. 2010. Polybrominated diphenyl ether (PBDE) levels in peregrine falcon (*Falco peregrinus*) eggs from California correlate with diet and human population density. *Environmental Science and Technology.* 44:5248–5255. **PMID:** 20540532
9. **Park J-S**, Fong A, Chu V, Linthicum J, Hooper K. 2011. Prey Species as possible sources of PBDE exposures for peregrine falcons (Falco peregrinus) Nesting in Major California Cities. *Archives of Environmental Contamination and Toxicology.* 60(3):518-523. **PMID:** 20514482
10. Cohn BA, Cirillo P, Sholtz, Ferrara, **Park J-S**, Schwingl P. 2011. Polychlorinated Biphenyl (PCB) exposure in mothers and time to pregnancy in daughters 30 years later. *Reproductive Toxicology.* 31:290–296. **PMID:** 21296657
11. Sholtz, RI, McLaughlin KR, Cirillo PM, Petreas M, **Park J-S**, Wolff MS, Factor-Litvak P, Eskenazi B, Krigbaum N, Cohn BA. 2011. Assaying Organochlorines in archived serum for a large, long-term cohort: Implications of combining assay results from multiple laboratories over time. *Environ International.* 37(4):709-14. **PMID:** 21333355
12. **Park J-S**, She J, Holden A, Sharp M, Gephart R, Souders-Mason G, Zhang V, Chow J, Leslie B, Hooper K. 2011. High postnatal exposures to polybrominated diphenyl ethers (PBDEs) and polychlorinated biphenyls (PCBs) via breast milk in California: Does BDE-209 transfer to breast milk? *Environmental Science and Technology.* 45(10):4579-85. **PMID:** 21495631

13. Zota AR, **Park J-S,** Wang Y, Petreas M, Zoeller RT, Woodruff TJ. 2011. Polybrominated diphenyl ethers (PBDEs), hydroxylated PBDEs, and thyroid hormones in second trimester pregnant women in California. *Environmental Science and Technology.* 45(18):7896-905. **PMID:** 21830753
14. Wang M, **Park J-S,** Petreas M. 2011. Temporal changes in the levels of perfluorinated compounds in California women serum over the past 50 Years. *Environmental Science and Technology.* 45(17):7510-6. **PMID:** 21732675
15. Harwani S, Henry RW, Rhee A, Patel P, Petreas M, Hooper K, **Park J-S.** 2010. Legacy and Contemporary Persistent Organic Pollutants in Pelagic North Pacific Albatrosses. *Environmental Toxicology and Chemistry.* 30(11):2562-9. **PMID:** 21898564

D. Research Support

Ongoing Research Support

NP979442010 June-Soo Park, PI
U.S. Environmental Protection Agency 4/21/2006-8/31/2012
Body Burdens in California Communities
A study examing the levels of organohalogen contaminants (e.g., PBDEs, PCBs) in women of child-bearing age in California, and their potential sources and exposure pathways
Role: Princial-Investigator

NP979442010 June-Soo Park, PI
NIEHS Center for Environmental Genetics Director's Discretionary Fund at the University of Cincinnati
4/01/2011-05/01/2012
PBDEs and OH-BDE metabolites in Cincinati population
A study examing the levels of PBDEs and OH-PBDEs in mother and cord blood serums in Cincinati.
Role: Princial-Investigator

Prenatal Organochlorine Exposure and Male Reproduction Pam Factor-Litvac, PI
National Institutes of Health 07/01/10 – 06/30/12
Examines associations between prenatal exposures to one class of endocrine disruptors, the organochlorine compounds, and testicular and endocrine function in adult men including semen quality, fertility potential, current hormone concentrations and time to pregnancy.
Role: Co-Investigator

16ZB-8501 Peggy Reynolds, PI
California Breast Cancer Research Program 2010-2014
Persistent Organic Pollutants and Breast Cancer Risk: Chemicals Old and New.
A study of body burden levels of legacy and newly introduced persistent organic pollutants and breast cancer in the California Teachers
Role: Co-Investigator

Barbara Cohn (PI)
Breast Cancer Research Program 01/02/09 – 01/01/2014
Environmental Causes of Breast Cancer across Three Generations
The major goals of this project are to test the hypothesis that *in utero* exposure to environmental chemicals increases the risk of breast cancer, and to initiate active follow-up of CHDS daughters and granddaughters.
Role: Co-Investigator

U01 ES019471-01 (NIEHS, NCI) Mary Beth Terry & Barbara Cohn (PIs)
Breast Cancer Research and Environment Program (BCERP) 9/30/10 – 4/30/15
PEDIGREE: Prenatal Environmental Determinants of InterGenerational Risk
This is a unique study of human exposure to organochlorines during two critical windows of exposure for the breast: 1) pregnancy which places the breast at risk for carcinogenesis in the mother and 2) the prenatal period when breast differentiation places the breast at risk for carcinogenesis in the daughter.
Role: Co-Investigator

R01 ES010026 (NIH) Zoeller, T (PI)
PCB Disruption of Thyroid Hormone Action during Development 7/1/10 – 6/30/12
This is a highly transdisciplinary collaboration to test the hypothesis that specific PCB metabolites – produced in human fetal liver – can interfere with thyroid hormone signaling. This is extremely important given that every American is contaminated not only with PCBs but with a number of chemicals known to interact directly with the thyroid hormone receptor. In addition, these studies will characterize the relationship between maternal PCB levels and fetal liver burden.

OVERLAP:

There is no scientific or budgetary overlap.

CONTRACTOR NAME

Key Personnel

Name	Job Title	Salary	% Paid from this Contract	Amount Paid from this Contract
Wendy Duong	Research Associate-I	$18.03 / Hour	100%	TBD
New PHI staff (To be hired)	Research Associate-II	$18.03 / Hour	100%	TBD
Erika Houtz	Research Scientist (non-PHI staff)		0	In Kind
Miaomiao Wang	Research Scientist (non-PHI staff)		0	In kind