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STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

29 HAZEN DRIVE, CONCORD, NH 03301-6503
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NH DIVISION OF Public Health Services
Improving health, preventing disease, reducing costs for all

Jeffrey A. Meyers
Commissioner

Marcella J. Bobinsky
Acting Director

August 12, 2016

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

REQUESTED ACTION

Authorize the Department of Health and Human Services, Division of Public Health Services to enter into **sole source** agreements with the vendors listed in the table below to provide analytical specialty laboratory testing services. No maximum service volume is guaranteed. The price limitation amongst all contracts is $250,000 for State Fiscal Year 2017, effective upon Governor and Executive Council approval, through June 30, 2017. 100% General Funds.

Vendor	Address	Vendor Number
* Health Research, Inc.	Riverview Center 150 Broadway, Suite 560 Menands, NY 12204-2719	TBD
HCA Health Services of New Hampshire, Inc., d/b/a Portsmouth Regional Hospital	330 Borthwick Ave #112 Portsmouth, NH 03801	TBD
Southern New Hampshire Medical Services	8 Prospect Street Nashua, NH 03061	TBD

Funds are available in the following accounts for State Fiscal Year 2017.

05-095-010-090-51700000 HEALTH AND SOCIAL SERVICES, DEPT OF HEALTH AND HUMAN SERVICES, HHS: DIVISION OF PUBLIC HEALTH, BUREAU OF INFECTIOUS DISEASE CONTROL, DISEASE CONTROL

Class	Title	Activity Code	Amount
547-500395	Disease Control Emergencies	90027022	$100,000
546-500390	Patient Care	90027022	$40,000
		Subtotal:	***$140,000***

05-095-010-090-52620000 HEALTH AND SOCIAL SERVICES, DEPT OF HEALTH AND HUMAN SERVICES, HHS: DIVISION OF PUBLIC HEALTH, BUREAU OF INFORMATICS

Class	Title	Activity Code	Amount
102-500731	Contracts for Program Services	90027022	$15,000
		Subtotal:	***$15,000***

05-95-010-090-79660000 HEALTH AND SOCIAL SERVICES, DEPT OF HEALTH AND HUMAN SERVICES, HHS: DIVISION OF PUBLIC HEALTH, PUBLIC HEALTH LABORATORY

Class	Title	Activity Code	Amount
102-500731	Contracts for Program Services	90027022	$95,000
		Subtotal:	***$95,000***
		Contracts Total:	**$250,000**

EXPLANATION

These agreements are **sole source** because HCA Health Services of New Hampshire, Inc., d/b/a Portsmouth Regional Hospital and Southern New Hampshire Medical Services have the controlled environments that are needed in order to conduct phlebotomy services without exposing blood samples to excessive plastics that could otherwise contaminate the testing process.

Health Research, Inc.(Wadsworth Center), has the technical expertise , instrumentation and capacity for high throughput testing of perfluorochemicals in human serum. The laboratory has sufficient capacity to analyze the large number of samples anticipated and report in a timely manner.

Portsmouth Regional Hospital and Southern New Hampshire Medical Services will be providing phlebotomy services to individuals in need of perfluorochemical testing, including preparing the specimens for testing. The specimens will be de-identified and delivered to the Department's Public Health Lab for processing and sent to Health Research, Inc. (Wadsworth Center) for high throughput testing.

The purpose of these agreements is to conduct analytical laboratory testing services to measure perfluorochemicals (PFC) in human serum collected as a result of potential exposure to PFC contaminated drinking water at the Pease Tradeport and in identified municipalities in New Hampshire. At this time, the Department has identified approximately six hundred (600) households as eligible for testing. Testing is being offered to individuals who live near homes with private water well contamination.

This package contains one (1) of the three (3) agreements for 'PFC Exposure Testing Services.' The Governor and Executive Council have approved the other two contracts at the July 13, 2016 meeting (Item #6D).

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 PFC exposure.

The Department identified two hospitals and one laboratory with the technical capability and combined capacity to assist in the testing and analysis of human serum. The two hospitals and one laboratory were contacted and contracts were negotiated.

These contracts contain language that reserves the Department's right to renew each of the contracts for up to two years subject to the continued availability of funds, satisfactory performance of services and approval by the Governor and Executive Council, should the Department continue to have a need for these specialized services.

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 and southern New Hampshire affected populations, which will result in affected community members not receiving their expected individual test results.

Area Served: Statewide

Source of Funds: 100% General

Respectfully submitted,

Marcella J. Bobinsky
Acting Director

Approved by:

Jeffrey A. Meyers
Commissioner

Subject: PFC Exposure Testing Services - Laboratory Assessments (SS-2017-DPHS-12-NY)

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 & Human Services		1.2 State Agency Address 129 Pleasant Street Concord, NH 03301	
1.3 Contractor Name Health Research, Inc.		1.4 Contractor Address Riverview Center 150 Broadway, Suite 560 Menands, NY 12204-2719	
1.5 Contractor Phone Number (518) 431-1265	1.6 Account Number 05-095-010-090-51700000 05-095-010-090-52620000 05-95-010-090-79660000	1.7 Completion Date June 30, 2017	1.8 Price Limitation $250,000
1.9 Contracting Officer for State Agency Eric D. Borrin, Director		1.10 State Agency Telephone Number	
1.11 Contractor Signature Cheryl A. Mattox		1.12 Name and Title of Contractor Signatory Cheryl A. Mattox, Executive Director	

1.13 Acknowledgement: State of NY, County of Albany

On August 8, 2016, 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 1.12.

1.13.1 Signature of Notary Public or Justice of the Peace
Marianne T. Castelot
[Seal]

Notary Public
State of New York
Marianne T. Castelot
My Appointment Expires on 5/17/19
Registration No. 01CA6024763

1.13.2 Name and Title of Notary or Justice of the Peace

1.14 State Agency Signature Marcella Bobinsky Date: 8/12/16	1.15 Name and Title of State Agency Signatory Marcella Bobinsky Acting Director

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: On: Megan A. Yarde - Attorney 8/17/16

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

Contractor Initials CAm
Date 5/5/16

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.

Contractor Initials CAM
Date 5/5/16

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 CAM
Date 5/6/16

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.

1.2. The Department agrees to not describe the High-Throughput method in any publication and appropriately acknowledge The Wadsworth Center, the New York State Department of Health, and its Investigators as the source of High-Throughput Method and Results in any scientific or scholarly publications resulting from work conducted by the Department or the Department's researcher with High-Throughput Method and Results. Separate approval for use of names of HRI, the Wadsworth Center, the New York State Department of Health, and its Investigators is not required for this type of acknowledgement.

2. Scope of Services

2.1. The Department shall enter test requests into the Wadsworth Center Clinical Laboratory Management System (CLIMS) via remote order entry function of the New York State Health Commerce system.

2.2. The Department shall send frozen serum specimens in shipments of 60 specimens or more, to the Wadsworth Center via express next day delivery, for receipt Tuesday-Thursday).

2.3. 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 Manual (SOPM).

2.4. The Contractor shall test samples labeled as 'PFC Panel' for the following analytes:

2.4.1. Perfluorobutane sulfonic acid (PFBuS).

2.4.2. Perfluorodecanoic acid (PFDeA).

2.4.3. Perfluorododecanoic acid (PFDoA).

2.4.4. Perfluoroheptanoic acid (PFHpA).

2.4.5. Perfluorohexane sulfonic acid (PFHxS).

2.4.6. Perfluorononanoic acid (PFNA).

2.4.7. Perfluorooctanoic acid (PFOA).

2.4.8. Perfluorooctane sulfonic acid (PFOS).

2.4.9. Perfluorooctane sulfonamide (PFOSA).

2.4.10. Perfluoroundecanoic acid (PFUA).

2.4.11. 2- (N-Methyl-perfluorooctane sulfonamido) acetic acid (Me-PFOSA-AcOH).

2.5. The Contractor shall test samples labeled as 'SNH' for the following analyte:

2.5.1. Perfluorooctanoic acid (PFOA).

2.5.2. Perfluorooctane sulfonic acid (PFOS).

2.6. The Contractor agrees to analyze up to 500 specimens per month. The Contractor may agree to test more than 500 specimens in a given month, but only after consultation and agreement.

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

2.7.1. Identification of appropriate detection limits.

2.7.2. Quality assurance measures practiced during testing.

2.8. The Contractor shall return the frozen specimens to the NH Public Health Laboratories, Analytical Chemistry Laboratory, 29 Hazen Drive Concord, NH 03301, at the conclusion of the project.

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 as follows:

3.2.1. Individual patient reports shall be available to the Department in PDF, identified by number.

3.2.2. Individual laboratory reports shall be posted on the NYS DOH HCS system, as they become available.

3.2.3. A summary of the test results shall be provided to the Department in an Excel spreadsheet at the conclusion of the project.

3.3. The Contractor shall retain test results for seven (7) years after the completion of testing and reporting.

NYS Department of Health - Wadsworth Center Biggs Laboratory – Division of Environmental Health Sciences Laboratory Response Network – Chemical Defense	Title: Perfluoroalkyl Substances (PFASs) Analysis in Serum by LC/MS/MS	
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Standard Operating Procedure Manual

Perfluoroalkyl Substances (PFASs) Analysis in Serum

by LC/MS/MS

Prepared by: Qian Wu **Date: 6/14/2016**

Approvals:

Section Assistant Director: _____ Date: _____

Division Director: _____ Date: _____

Record of Revisions (subsequent to initial approval)

Rev. #	Date	Responsible Person	Description of SOP Revision

Approval of Revisions and Annual Review

Rev. # or Annual Review	Director or Designee (Print Name)	Signature	Date

Employee Attestation to Training and Competency

Employee Name (Printed)	Original (Initial /Date)	Rev. #1 (Initial /Date)	Rev. #2 (Initial /Date)	Rev. #3 (Initial /Date)

Date: 6/15/16

Contractor Initials: CAW

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Contents

Date: 6/16/16

Contractor Initials: CAM

Date: 5/5/16

Contractor Initials: CAM

Purpose:

This method describes the procedure for extraction of Perfluoroalkyl Substances (PFASs) from serum. In this method PFASs and their labeled internal standard are extracted into an organic solvent. The target analytes are separated from sample extracts by HPLC and analyzed by tandem mass spectrometry (MS/MS) detector using multiple reaction monitoring (MRM).

SCOPE AND APPLICATION

This is a liquid chromatography/tandem mass spectrometry (LC/MS/MS) method for the determination of selected Perfluoroalkyl Substances (PFASs) in serum.
Accuracy and precision data have been generated in serum for the compounds listed in the supporting documents.

Analyte	Acronym	Chemical Abstract Services Registry Number (CASRN)
Perfluorobutanesulfonic acid	PFBS	375-73-5
Perfluorodecanoic acid	PFDA	335-76-2
Perfluorododecanoic acid	PFDoA	307-55-1
Perfluoroheptanoic acid	PFHpA	375-85-9
Perfluorohexanesulfonic acid	PFHxS	355-46-4
Perfluorohexanoic acid	PFHxA	307-24-4
Perfluorononanoic acid	PFNA	375-95-1
Perfluorooctanesulfonic acid	PFOS	1763-23-1
Perfluorooctanoic acid	PFOA	335-67-1
Perfluoroundecanoic acid	PFUnA	2058-94-8
N-methyl perfluorooctanesulfonamidoacetic acid	N-MeFOSAA	—

The Minimum Reporting Level (MRL) is the lowest analyte concentration that meets Data Quality Objectives (DQOs) that are developed based on the intended use of this method. The single laboratory lowest concentration MRL (LCMRL) is the lowest true concentration for which the future recovery is predicted to fall, with high confidence (99%), between 50 and 150% recovery.

Test Principle:

The serum samples are added into the Phree 96-Well Plate containing ^{13}C Labeled PFASs internal standards in acetonitrile. Occurs sample matrix protein precipitation followed by simultaneous extract filtration and phospholipids removal. Obtained extract containing target analytes and their internal standards after concentration step is applied for analysis via a liquid chromatography - tandem mass spectrometer (LC-MS/MS) equipped with electrospray ionization source.

Clinical Relevance:

Perfluoroalkyl Substances (PFASs) have been used since the 1950s in numerous commercial applications, including surfactants, lubricants, paper and textile coatings, polishes, food packaging, and fire-retarding foams. Some of these PFCSs, including perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA), persist in humans and the environment and have been detected worldwide in wildlife [1]. Exposure to PFASs in the general population is also widespread. In animals, exposure to PFASs is associated with adverse health effects albeit at serum concentrations orders of magnitude higher than the concentrations observed in the general population [2-5]. In May 2000, 3M, the sole manufacturer of PFOS in the United States and the principal manufacturer worldwide, announced that it was discontinuing its perfluorooctanesulfonyl fluoride chemistry, including the manufacture of PFOS. Although PFOA and its salts and precursors are still being manufactured by

others by a different process, reductions in their manufacturing emissions have been proposed [6-8]. The reductions in serum concentrations of several PFASs, including PFOS and PFOA, reported in humans and wildlife [9-11], are most likely related to such industrial production changes.

Specimens:

Patient Preparation: n/a.

Acceptable Specimens: Serum

Specimen Container: Serum (red top)

Specimen Volume:

- Preferred: 3 ml.
- Minimum: 500 uL.
- Analytic Volume: 50uL.

Specimen Stability:

- Not light sensitive to ambient room light.
- Ambient 10 days.*
- Refrigerated 14 days.**
- Frozen 11 months.**

** As per CDC publication* http://www.scopus.com/record/display.uri?eid=2-s2.0-84874252866&origin=inward&txGid=0

*** As per NMS Test summary.*

Rejection Criteria:

- Serum must be removed from red blood cells within 2 hrs.
- Improper handling, collection, and/or labeling.
- Moderately lipemic samples are acceptable, severely lipemic samples should be noted but analyzed.
- Moderately hemolyzed samples are acceptable, severely hemolyzed should be noted but analyzed.
- Collection materials/supplies that are not previously approved by collection protocol.

Specimen storage:

- Serum must be stored at -20C in securely locked storage facility.

Reagents:

Ammonium Acetate
$CH_3CO_2NH_4$; CAS # 631-61-8 (Sigma, Cat. #372331) ultrapure grade, or equivalent. Stable 10 years from open date at room temperature.

Acetonitrile
CH_3CN; CAS # 75-05-8 (Fisher, Cat. # A955-4) LC/MS grade, or equivalent. Stable 10 years from open date at room temperature. **FLAMMABLE**.

Methanol
CH3OH; CAS # 67-56-1 (Fisher, Cat. # A456-4,) LC/MS grade, or equivalent. Stable 10 years from open date at room temperature. **FLAMMABLE**.

Date: 5/5/16

Contractor Initials: CAM

Water

H_2O; CAS # 7732-15-5 (Fisher, Cat. # W6-4) LCMS grade, or equivalent. Stable 10 years from open date at room temperature.

Mobile Phase A: 0.1% ammonium acetate in water.

- Add 100mg of Ammonium Acetate to a 1L mobile phase bottle
- Add 1000ml of HPLC Water
- Mix WITHOUT using a magnetic stir bar
- Filter through a 0.2um filter prior to use

Mobile Phase B: methanol.

Note: *All mobile phase should be prepared in the fume hood using personal protective equipment (PPE) including but not limited to eye protection and appropriate chemical resistant gloves/apron.*

SAFETY CONSIDERATIONS

All safety considerations will be in accordance with Wadsworth-LOAC procedures and with the requirements of the Wadsworth Center Safety Manual. These requirements include:

Personnel protective equipment (PPE) consisting of lab coats, safety glasses, and latex gloves will be worn at all times when handling samples.
All personnel using such equipment must be aware of the hazards and must operate equipment according to the manufacturer's safety procedures.
Organic solvents are used for rinsing equipment, glassware cleaning, and in the extraction phase of the method. These solvents represent a potential hazard to personnel in the laboratory. Care must be taken to minimize exposure in accordance to institutional guidelines.

Disposal of wastes

Solvents and reagents should always be put to waste in an appropriate container clearly marked for waste products, and temporarily stored in a chemical fume hood. All disposable items that come in direct contact with the blood specimens are to be placed in biohazard autoclave bags that should be kept in appropriate containers. Wipe down all surfaces with a 10% sodium hypochlorite solution when work is finished. All non-disposable glassware that has contacted blood should be decontaminated with 10% sodium hypochlorite before further cleaning. All other glassware should be washed and recycled or disposed of in an appropriate manner.

Staff Training

Every staff member that will be performing this method will be trained by an experienced analyst. This training will include; observation of the experienced analyst performing the method, performing the method with supervision multiple times, demonstrating acceptable QC precision and accuracy.

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Equipment:

The procedure calls for a sample preparation utilizing Phree phospholipid removal 96 well plates, liquid handler and liquid chromatograph with a tandem mass spectrometer. A preventive maintenance log is kept for each system recording periodic checks, including a daily & weekly record of individual components comprising the system. The following equipment is used:

Analytical Systems and Components:

- Agilent 1290 UPLC system.
- Agilent 6460 triple quadrupole mass spectrometer.
- Nitrogen.

Extraction Equipment:

- Vortex.
- 200 uL pipetor.
- 50 uL pipetor.
- 1000 uL pipetor
- Repeat pipettor.
- Caliper Zephyr- Automated 96 well plate Solid Phase Extraction system
- Perkin-Elmer Janus liquid handler
- 20-300ul 12 channel pipettor
- Genevac Vacuum Evaporator

Disposable:

- 8E-S133-TGB Phree Phospholipid Removal 96-Well Plates, Phenomenex
- Nunc 96 Deep well 1.3mL plates p # 82-260251 or equivalent
- Thermo Fisher 350uL plates p # 12-565-216 or equivalent
- PCR Foil seal- plate cover p # AB0626, or equivalent
- Waters Acuity BEH C18 1.7 um 2.1x50mm UHPLC column p# 186002350
- Waters VanGuard Pre-Column BEH C18, 1.7um, 2.1 x 5mm p# 186003975

Operation & Maintenance:

- Refer to the Agilent Operator's Manuals for instructions on instrument operation.
- Refer to the daily and weekly LC-MS/MS maintenance policy for the Preventative Maintenance schedule.
- For instructions on liquid handler maintenance refer to the Janus Operator's Manuals.

Calibration:

Frequency:
A 6-point calibration curve is run each time a new plate is prepared. The standard concentrations are 100, 50, 25, 5, 1 and 0.5 ng/ml.

Acceptance Criteria:
In each 6-point calibration curve the coefficient of determination (R^2), must have a minimum value of 0.990 and recovers within 20% of value assigned when analyzed against calibration curve .By using a 6-point calibration curve, the technologist has the ability to remove one point to improve

and allow the linear regression to meet the calibration acceptance criteria. Removing 100 ng/ml calibrator will change reportable range to 0.5-50 ng/ml; Removing 0.5 ng/ml calibrator changes reportable range to 1-100 ng/ml.
PFOA assay reportable range is 0.5-100ng/ml. The reportable ranges for other PFASs are under laboratory validation. If 0.5 ng/ml calibrator will be removed, all samples within 0.5-1 ng/ml range in that batch have to be re-tested. If 100 ng/ml calibrator will be removed from the calibration curve, all samples within 50-100 ng/ml range have to be re-tested in that batch.

Acceptance Responsibility:
All staff that have been trained and signed off on the PFASs protocol have the ability to approve all calibration curves.

Documentation:
All calibration curves are documented using MassHunter software using the Calibration Curves template and saved on the LRN-C shared drive under Data Review/PFASs and the run ID.

Preparation:
A 6-point calibration curve is generated and analyzed in Analyst. The preparation protocol is described in "Sample Set-up".

Stock I Calibrator:
PFAS SRM (50 +/- 2.5 ug/mL in MeOH, available from Wellington Laboratories, Ontario, Canada).

Stock II Calibrator: 5 ug/mL PFAS Mixture

- Aspirate 1 ml of PFAS Stock 1 and place into a 10 mL Class A volumetric flask.
- Bring to volume with methanol. Mix well.
- Stable 1 year when stored at -20°C.

Working Calibrators:

PFAS-S1 0.5 ng/ml
- Transfer 2.5 ul of PFAS-Stock 2 to a 25 mL Class A volumetric flask.
- Bring to volume with calf serum or HSA matrix. Mix well.
- Stable at least 1 year when stored at -20°C and light protected.

PFAS-S2 1 ng/ml
- Transfer 5 ul of PFAS-Stock 2 to a 25 mL Class A volumetric flask.
- Bring to volume with calf serum or HSA matrix. Mix well.
- Stable at least 1 year when stored at -20°C and light protected

PFAS-S3 5 ng/ml
- Transfer 25 ul of PFAS-Stock 2 to a 25 mL Class A volumetric flask.
- Bring to volume with calf serum or HSA matrix. Mix well.
- Stable at least 1 year when stored at -20°C and light protected.

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PFAS-S4 25 ng/ml

- Transfer 12.5 ul of PFAS-Stock 1 to a 25 mL Class A volumetric flask.
- Bring to volume with calf serum or HSA matrix. Mix well.
- Stable at least 1 year when stored at -20°C and light protected.

PFAS-S5 50 ng/ml

- Transfer 25 ul of PFAS-Stock 1 to a 25 mL Class A volumetric flask.
- Bring to volume with calf serum or HSA matrix. Mix well.
- Stable at least 1 year when stored at -20°C and light protected.

PFAS-S6 100 ng/ml

- Transfer 50 ul of PFAS-Stock 1 to a 25 mL Class A volumetric flask.
- Bring to volume with calf serum or HSA matrix. Mix well.
- Stable at least 1 year when stored at -20°C and light protected.

Matrix Blank

- 100% calf serum or 5% HSA isotonic solution (9 g NaCl/L).

Internal standard (Isotopic-labeled) standard Solution A preparation. 4.545 ug/ml

- Aliquot 1 mL of 50 ug/mL $^{13}C_3$-PFBS, 50 ug/mL $^{18}O_2$-PFHxS, 50 ug/mL $^{13}C_8$-PFOS, 50 ug/mL $^{13}C_2$-PFHxA, 50 ug/mL $^{13}C_4$-PFHpA, 50 ug/mL $^{13}C_8$-PFOA, 50 ug/mL $^{13}C_5$-PFNA, 50 ug/mL $^{13}C_2$-PFDA, 50 ug/mL $^{13}C_2$-PFUnA, 50 ug/mL $^{13}C_2$-PFDoA, and 50 ug/mL d_3-N-MeFOSAA (Wellington Laboratories, Guelph, Ontario, Canada) into a 10 ml Class A Volumetric flask, make up to mark with Methanol.
- Vortex
- Transfer into a 4mL cryovials
- Stable 1 year when stored at -20°C.

Internal standard (Isotopic-labeled) standard Solution B preparation. 500 ng/ml

- Aliquot 1.1 mL of Internal Standard Stock A into a 10 ml Class A Volumetric flask, make up to mark with Methanol.
- Vortex
- Transfer into a 4mL cryovials
- Stable 1 year when stored at -20°C.

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Quality Control:

Establishing QC Range:
PFAS controls were prepared by spiking known amount of SRM material to blank calf serum. Target value was assigned by preparation.

Acceptable Limits:
The control values are calculated and reviewed in Analyst software. Control values that fall within 20% of anticipated target concentration are acceptable and require no further action. Concentration of PFASs in the negative blank control should be below the limit of quantitation for the method.

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Corrective Action:
Any controls exceeding acceptance criteria requires review and correction plan by supervisor

QC Review:
On a monthly basis the QC designee reviews the Levey-Jennings chart located on shared LRN-C drive for completeness and shifts/trends.

Proficiency Testing:
Proficiency testing or accuracy assessment will take place biannually. The specimen for the evaluation will be provided by the Arctic Monitoring and Assessment Programme (AMAP) or will prepared internally.

Control Preparation:
All controls are included in each batch of patient samples.

- QC_L: 5 ng/ml PFASs spiked in calf serum.
- Transfer 5 ul of PFAS SRM (50 +/- 2.5 ug/mL in MeOH, available from Wellington Laboratories, Ontario, Canada) using a 10 ul volumetric pipette to 50 mL volumetric flask. Mix, and bring to volume with calf serum.
- Dispense 3.0 mL to 4 mL cryovials.
- Stable 1 year when stored at -20°C.
- Stable 14 days after defrosting if stored at 2-8°C.

QC_M: 25 ng/ml PFAS spiked in blank calf serum.

- Transfer 25 ul of PFAS SRM (50 +/- 2.5 ug/mL in MeOH, available from Wellington Laboratories, Ontario, Canada) using a 50 ul volumetric pipette to 25 mL of calf serum in a 50 mL volumetric flask. Mix, and bring to volume with calf serum.
- Dispense 3.0 mL to 4 mL cryovials.
- Stable 1 year when stored at -20°C.
- Stable 14 days after defrosting if stored at 2-8°C.

QC_H: 50 ng/ml PFAS spiked in blank calf serum.

- Transfer 50 ul of PFAS SRM (50 +/- 2.5 ug/mL in MeOH, available from Wellington Laboratories, Ontario, Canada) using a 50 ul volumetric pipette to 25 mL of calf serum in a 50 mL volumetric flask. Mix, and bring to volume with calf serum.
- Dispense 3.0 mL to 4 mL cryovials.
- Stable 1 year when stored at -20°C.
- Stable 14 days after defrosting if stored at 2-8°C.

Assay Procedure:

Generate sample map:

Sample Set-up:
- Remove from freezer and thaw calibrators, controls and specimens.
- Ensure that all specimens are at room temperature with no ice crystals or serum protein clumps in them before proceeding with analysis.
- Ensure that all specimens are thoroughly mixed by inversion or vortexing.

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1. Aliquot 625 uL of internal standard Solution B into appropriately labeled 100 ml Class A volumetric flask and bring to volume with acetonitrile. Mix well.
2. Place Phree Sample preparation on Janus liquid handler deck
3. Place IS/acetonitrile into a reagent trough
4. Dispense 400 ul of IS/acetonitrile into each well of Phree plate.
5. Aliquot 50 ul of sample or calibrator and dispense into a center position of well.
6. Vortex Phree plate at 700 RPM for 2 minutes
7. Transfer plate to Caliper Zephyr- Automated 96 well plate Solid Phase Extraction system and place on vacuum manifold
8. Apply Vacuum at 5-10 inches Hg until filtrate is collected.
9. Add 100ul of HPLC grade water to each well
10. Dry plate using vacuum concentrator for 45 min
11. Transfer extracts to 350uL wellplate.
12. Seal a plate with a plate cover.
13. Inject 10 uL of each partially concentrated extract on a LC-MS/MS system using the conditions and parameters described in the procedure in *"Instrument Set-up".*

Dilutions:

- Samples may be run diluted or undiluted for first run based on project history.
- Patient sample exceeding ULOQ should be diluted based upon the results from the first extraction, if first run undiluted.
- The next consecutive sample after sample exceeding ULOQ should be considered for re-testing if carryover is suspected
- The diluted samples will then be analyzed with future batches.

1:10 dilution

- Add 900 mcL of 5% HSA solution to a 2.0 mL cryovial tube with a pipettor.
- Add 100 mcL of undiluted patient sample and vortex.
- Extract the sample following the protocol described above.

1:100 dilution

- Add 900 mcL of 5% HSA solution to a second 2.0 mL cryovial with a pipettor.
- Add 100 mcL of the 1:10 diluted patient sample and vortex.
- Extract the sample following the protocol described above.

1:1000 dilution

- Add 900 mcL of or 5% HSA solution to a third 2.0 mL cryovial with a pipettor.
- Add 100 mcL of the 1:100 diluted patient sample and vortex.
- Extract the sample following the protocol described above.

Other dilutions can be made as necessary, all dilutions will be made in 5% HSA solution. In a case of repeated/replicated analysis, analytical values obtained from undiluted samples (if they are met acceptance criteria) will be reported. If repeated/replicated samples are met acceptance criteria, however have different clinical interpretation, these samples have to be re-tested.

Mass Spectrometry Conditions

Mass spectrometric analyses are conducted on the Agilent 6460 tandem mass spectrometer in the Jet Stream negative ion spray mode. The source parameters are listed in table below.

Parameters	Value
Gas Temp (°C)	260

Gas Flow (L/min)	8
Nebulizer (psi)	25
SheathGasHeater	350
SheathGasFlow	10
Capillary (V)	4000
ESI	Negative

The precursor ions and product ions for the target analytes are listed in table below.

Analyte	Precursor Ion	Product Ion
PFBS	299	80
PFHxS	399	80
PFOS	499	80
PFHxA	313	269
PFHpA	363	319
PFOA	413	369
PFNA	463	419
PFDA	513	469
PFUnA	563	519
PFDoA	613	569
N-MeFOSAA	570	419
$^{13}C_3$-PFBS	302	80
$^{18}O_2$-PFHxS	403	84
$^{13}C_8$-PFOS	507	80
$^{13}C_2$-PFHxA	315	270
$^{13}C_4$-PFHpA	367	322
$^{13}C_8$-PFOA	421	376
$^{13}C_5$-PFNA	468	423
$^{13}C_2$-PFDA	515	470
$^{13}C_2$-PFUnA	565	520
$^{13}C_2$-PFDoA	615	570
d_3-N-MeFOSAA	573	419

HPLC configuration

Establish UPLC operating parameters that optimize resolution and peak shape. UPLC system components, as well as the mobile phase constituents, contain many of the method analytes in this method. Thus, these PFASs will build up on the head of the UPLC column during mobile phase equilibration. To minimize the background PFAS peaks and to keep background levels constant, the time the UPLC column sits at initial conditions must be kept constant and as short as possible (while ensuring reproducible retention times). In addition, prior to daily use, flush the UPLC system with 100% methanol for at least 10 min before initiating a sequence. The mobile phase of UPLC in this method is described in sections above. The table below shows the gradient program for the mobile phase.

Time	A	B	Flow
0 min	90 %	10 %	0.3 mL/min
0.5 min	90 %	10 %	0.3 mL/min
1.0 min	25 %	75 %	0.3 mL/min
4.0 min	0 %	100 %	0.3 mL/min
4.5 min	0 %	100 %	0.3 mL/min
4.8 min	90 %	10 %	0.3 mL/min

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6.0 min	90 %	10 %	0.3 mL/min

Instrument Set-up:

1. Assign Batch Name using experiment day in the nomenclature of NYYMMDDX, where X is A-Z
2. Select Acquisition method PFAS.
3. Select Quantitation Method PFCS.
4. Make sure that Acquisition Method and Quantitation Method are entered correctly.
5. Open autosampler door and make sure your sample tray has been placed in the proper rack.
6. Click the "Submit" button to submit the whole batch, or any portion of the batch you wish to analyze.
7. Submitted batch appears in queue manager; verify that Acquisition Method and Quantitation Method methods are listed correctly.

Interpretation of results

All raw data files are quantified using the quantitation software package in MassHunter. The data processing results are saved in a quantitation file. This file contains a graphic depiction of the retention time window and the area integrated for the analyte and the internal standard for each sample. The file shows the calibration curve used and its R-value. Follow MassHunter manual for peak integrations.

Calculations:

- Calculations are made using isotopic-labeled PFAS as the internal standard.
- A weighted 1/x, linear six-point standard curve is derived and stored by MassHunter.
- All calculations are performed by the MassHunter software.
- All dilutions must have the dilution factor entered into the quantitation table

Chromatogram Review:

- All chromatograms should be reviewed for appropriate/consistent retention time by an operator and supervisor. The expected retention time is based on the previous day's internal standard check that is recorded in the instrument's logbook. The retention time should not fall outside of the allowable window as set in MassHunter software.
- Additionally, all chromatograms must be reviewed for significant peak fronting, tailing, splitting, and/or band widening. If any of these characteristics are present to a significant degree the chromatogram should be rejected.
- Open a calibration pane and a peak review pane. Review the integration of the target, qualifier and internal standard peaks and manually correct the integration as necessary. (Note: all manual integrations must be performed following LOAC-011-03SOP: Manual Integration, and approved by the supervisor.
- Qualifier to Quantifier ratio shall not exceed 30%

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At the end of each analytical run blank water will be run using an instrument method that employs buffer free solvents. Needle seats, precolumns, LC filters and analytical columns will be changed as needed. The curtain plate and LC source will be removed and cleaned as needed. The electrode will be replaced when reduced sensitivity is detected. Clogged lines will be cleared or replaced. A service engineer will be called in to fix any problem beyond the analyst's training and experience. A full service contract is in effect on the Agilent 6460. Any maintenance performed will be recorded in the instrument logbook.

Reporting/Interpreting Results:

Analytical Measurement Range (AMR):

- The AMR is the range the method can measure directly on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process.
- The AMR is 0.5-100 ng/ml
- The AMR is validated with each acceptable calibration.

Clinically Reportable Range (CRR):

- The CRR is the range that a method can measure allowing for specimen dilution, concentration, or pretreatment.
- Samples with a value greater than the upper standard are diluted with blank human albumin isotonic solution, extracted and run.
- The greatest dilution that can be performed is 1:1000. Results greater than the CRR are reported as >1 X 10^5 ng/ml

LIS Reporting:

Result	***Report***
Below 0.5 ugl/L	Report as <0.5 ug/L
Between 0.5 and 100 ug/L	Report 3 significant figures
Above 100 ug/L	• Repeat at appropriate dilution using 100% blank human serum or 5% HSA. • Multiply result by dilution factor.

- In a case that 0.5 ng/ml calibrator was removed from a calibration curve, specimen value below 1 ng/ml will be reported as <1 ng/ml.
- In a case that 100 ng/ml calibrator was removed from a calibration curve, all samples with above 50 ng/ml values should be appropriately diluted and re-tested

Results reporting

All results are reported to the HCN through CLIMS system. Currently, the results are imported into CLIMS by the analyst, using the most recent instructions from Wadsworth Center after supervisor approval. The results are then checked by the analyst and sent to the supervisor for another check and data approval. After supervisor approval the results will be released, and reports created.

Date: 5/18/16

Contractor Initials: CA

References

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Date: 5/10/16

Contractor Initials: CAM

Method and Conditions Precedent to Payment

1 This agreement is funded with 100% general funds.

2 This Agreement is one (1) of three (3) agreements that will complete PFC Exposure Testing Services for the Department. No maximum or minimum service volume is guaranteed. Accordingly, the price limitation among all Agreements is identified in Form P-37, General Provisions, Block 1.8, Price Limitation.

3 The Department shall reimburse the Contractor for actual services provided in accordance with the following all-inclusive rates:

3.1 $125.00 per PFOA/PFOS sample tested as described in Exhibit A, Scope of Services

3.2 $150.00 per PFC panel completed, as described in Exhibit A, Scope of Services.

4 Payment for said services shall be made as follows:

4.1 The Contractor shall submit monthly invoices for services provided in the previous month no later than the 10th day of the month for services specified in Exhibit A, Scope of Services at the rate specified in Paragraph 3, above, which shall include:

4.1.1 The total number of PFOA/PFOS samples tested in the previous month.

4.1.2 The total number of PFC panels conducted in the previous month.

4.2 The Contractor shall submit monthly invoices to:

Financial Manager
129 Pleasant Street
Concord, NH 03301

E-mail: dphscontractbilling@dhhs.state.nh.us

4.3 Payment shall be made by the Department subsequent to the approval of submitted invoices, if sufficient funds are available, within 30 days of receiving invoices.

5 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.

6 Notwithstanding anything to the contrary herein, the Contractor agrees that payment under this agreement may be withheld, in whole or in part, in the event of noncompliance with any Federal or State law, rule or regulation applicable to the services provided, or if the said services have not been satisfactorily completed in accordance with the terms and conditions of this Agreement.

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 30 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 Division reserves the right to renew the Contract for up to two additional 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:

5/8/16
Date

Cheryl A. Mattox
Name:
Title:

Cheryl A. Mattox
Executive Director, HRI

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:

8/8/16
Date

Cheryl A. Mattox
Name:
Title: **Cheryl A. Mattox**
Executive Director, HRI

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 (l)(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:

5/8/16
Date

Cheryl A. Mattox
Name:
Title:

Cheryl A. Mattox
Executive Director, HRI

Contractor Initials CAM
Date 5/8/16

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:

8/8/16
Date

Cheryl A. Mattox
Name:
Title: Cheryl A. Mattox
Executive Director, HRI

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:

8/8/16
Date

Cheryl A. Mattox
Name:
Title:
Cheryl A. Mattox
Executive Director, HRI

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.

Dept of Health & Human Services	Health Research, Inc.
The State	Name of the Contractor
Marcella Bobinsky	Cheryl A. Mattox
Signature of Authorized Representative	Signature of Authorized Representative
Marcella Bobinsky	Cheryl A. Mattox
Name of Authorized Representative	Name of Authorized Representative
Acting Director	Executive Director
Title of Authorized Representative	Title of Authorized Representative
8/12/16	8/8/16
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:

5/8/16
Date

Cheryl A. Mattox
Name:
Title:

Cheryl A. Mattox
Executive Director, HRI

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: 153695478

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: _____

CERTIFICATE OF VOTE

I, ___Mary Hefner_____, do hereby certify that:
(Name of the elected Officer of the Agency; cannot be contract signatory)

1. I am a duly elected Officer of _____Health Research, Inc._____.
(Agency Name)

2. The following is a true copy of the resolution duly adopted at a meeting of the Board of Directors of

the Agency duly held on ___07/07/15_____:
(Date)

RESOLVED: That the ___Executive Director_____
(Title of Contract Signatory)

is hereby authorized on behalf of this Agency to enter into the said contract with the State and to execute any and all documents, agreements and other instruments, and any amendments, revisions, or modifications thereto, as he/she may deem necessary, desirable or appropriate.

3. The forgoing resolutions have not been amended or revoked, and remain in full force and effect as of

the ___8__ day of __August_____, 2016.
(Date Contract Signed)

4. __Cheryl A. Mattox_____ is the duly elected __Executive Director_____
(Name of Contract Signatory) (Title of Contract Signatory)

of the Agency.

Mary Hefner
(Signature of the Elected Officer)

STATE OF NEW YORK

County of Albany

The forgoing instrument was acknowledged before me this 11th day of August, 2016

By Mary Hefner.
(Name of Elected Officer of the Agency)

Jane Harding
(Notary Public/Justice of the Peace)

(NOTARY SEAL)

Commission Expires: _____.

JANE HARDING
Notary Public, State of New York
Reg. No. 4827655
Residing in Saratoga County
Commission Expires December 31, 2017

Client#: 19911 HEALTRES

ACORD™ CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 8/18/2016

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 may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Amsure - a Division of ATCFSI 12 Computer Drive West PO Box 15044 Albany, NY 12212-5044	PHONE (A/C, No, Ext): 518 458-1800	FAX (A/C, No): 518 458-8390
	E-MAIL ADDRESS:	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Federal Insurance Company	20281
INSURED Health Research Inc. Riverview Center 150 Broadway, Suite 560 Menands, NY 12204	INSURER B : Chubb National Insurance Co.	10052
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

THIS IS TO CERTIFY THAT THE 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	X COMMERCIAL GENERAL LIABILITY			35394900	04/01/2016	04/01/2017	EACH OCCURRENCE	$10,000,000
	X CLAIMS-MADE ☐ OCCUR			*Note: Products-			DAMAGE TO RENTED PREMISES (Ea occurrence)	$10,000,000
	X BI/PD Ded:$25,000			Compl Ops Under			MED EXP (Any one person)	$10,000
				Policy #74993037			PERSONAL & ADV INJURY	$10,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$10,000,000
	☐ POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$10,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY			73507418	04/01/2016	04/01/2017	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	☐ ALL OWNED AUTOS ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS X NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			71704556	04/01/2016	04/01/2017	X PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A					E.L. EACH ACCIDENT	$500,000
	(Mandatory in NH)						E.L. DISEASE - EA EMPLOYEE	$500,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - POLICY LIMIT	$500,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: PFC Exposure Testing Services-Laboratory Assessments

CERTIFICATE HOLDER

State of New Hampshire
Dept of Health & Human Services
129 Pleasant Street
Concord, NH 03301

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

Mary Alouse (m)

JMH

HEALTH RESEARCH
INCORPORATED

Board of Directors
4/1/2016 – 3/31/2017

Board President
Dr. Howard A. Zucker
Commissioner
NYS Department of Health
ESP Corning Tower
Albany, NY 12237

Board Vice President
Sally Dreslin
Executive Deputy Commissioner
NYS Department of Health
ESP Corning Tower
Albany, NY 12237

Board Secretary/Treasurer
Marybeth Hefner
Director, Fiscal Management Group
NYS Department of Health
ESP Corning Tower
Albany, NY 12237

Board Director
Magdalena Ramirez
Vice President of Membership Services
American Medical Rehabilitation Providers Assoc.
257 Clinton Street, Apt 18N
New York, NY 10002

Board Director
Dr. Kunle Odunsi
Deputy Director
Roswell Park Cancer Institute Corporation
Elm and Carlton Streets
Buffalo, NY 14263

Board Director
Michael B. Sexton, Esq.
Chief Operations Officer and General Counsel
Roswell Park Cancer Institute Corporation
Elm and Carlton Streets
Buffalo, NY 14263

Board Director
Candace Johnson
President and CEO
Roswell Park Cancer Institute Corporation
Elm and Carlton Streets
Buffalo, NY 14263

Board Director
David Hernandez
Director, Health Facility Management Group
NYS Department of Health
ESP Corning Tower
Albany, NY 12237

Board Director
Tim Reynolds
Chief Financial Officer
Rehabilitation Support Services
5172 Western Turnpike
Altamont, NY 12009

Internal Revenue Service

District
Director

Department of the Treasury

P.O. Box 1680, GPO Brooklyn, N.Y. 11202

Date 24 JUL 1986

Person to Contact:
Mrs. E. Casa
Contact Telephone Number:
(718) 780-6622

Re: EIN#: 14-1402155

Health Research, Inc.
Corporate Division
1315 Empire State Plaza
Mayor Erastus Corning 2nd Tower
Albany, NY 12237
ATTN: Lee J. VanDeCarr
Secretary/Treasurer

Dear Sir or Madam:

Reference is made to your request for verification of the tax exempt status of Health Research, Inc.

A determination or ruling letter issued to an organization granting exemption under the Internal Revenue Code of 1954 or under a prior or subsequent Revenue Act remains in effect until exempt status has been terminated, revoked or modified.

Our records indicate that exemption was granted as shown below.

Sincerely yours,

Raymond Silvas
for

Leonard Gass
District Disclosure Officer

Name of Organization: Health Research, Inc.

Date of Exemption Letter: March, 1955

Exemption granted pursuant to 1954 Code section 501(c)(3) or its predecessor Code Section.

Foundation Classification (If Applicable): Not a private foundation as you are an organization described in section 509(a)(1) of the Internal Revenue Code.

U. S. TREASURY DEPARTMENT
WASHINGTON 25

OFFICE OF
COMMISSIONER OF INTERNAL REVENUE

ADDRESS REPLY TO
COMMISSIONER OF INTERNAL REVENUE
WASHINGTON 25, D.C.
AND REFER TO

T:R:PEO:E
WLH

MAR 30 1955

RECEIVED
APR 1 1955
DEPUTY COMMISSIONER

Health Research, Inc.
c/o Dr. Hollis S. Ingraham, Vice-President
39 Columbia Street
Albany, New York

Gentlemen:

It is the opinion of this office, based upon the evidence presented, that you are exempt from Federal income tax as an organization described in section 501(c)(3) of the Internal Revenue Code of 1954, as it is shown that you are organized and operated exclusively for scientific purposes.

Accordingly, you are not required to file income tax returns unless you change the character of your organization, the purposes for which you were organized, or your method of operation. Any such changes should be reported immediately to the District Director of Internal Revenue for your district in order that their effect upon your exempt status may be determined.

You are required, however, to file an information return, Form 990A, annually, with the District Director of Internal Revenue for your district so long as this exemption remains in effect. This form may be obtained from the District Director and is required to be filed on or before the fifteenth day of the fifth month following the close of your annual accounting period.

Contributions made to you are deductible by the donors in computing their taxable income in the manner and to the extent provided by section 170 of the 1954 Code (and, where applicable, by sections 23(o)(2) and (q)(2) of the 1939 Code).

Bequests, legacies, devises or transfers to or for your use are deductible in computing the value of the taxable estate of a decedent for Federal estate tax purposes in the manner and to the extent provided by sections 2055 and 2106 of the 1954 Code (and, where applicable, by sections 812(d) and 861(a)(3) of the 1939 Code). Gifts of property to or for your use are deductible in computing taxable gifts for Federal gift tax purposes in the manner and to the extent provided by section 2522 of the 1954 Code (and, where applicable, by sections 1004(a)(2)(B) and 1004(b)(2) and (3) of the 1939 Code).

In the event you have not filed a waiver of exemption certificate in accordance with the applicable provisions of the Federal Insurance Contributions Act, no liability is incurred by you for the taxes imposed under such Act. Tax liability is not incurred by you under the Federal Unemployment Tax Act. Any question relating to the filing of a waiver of exemption certificate should be taken up with your District Director of Internal Revenue.

Your attention is called to the provisions of section 501(c)(3) of the Internal Revenue Code of 1954 under which your exemption will be revoked if any substantial part of your activities consists of carrying on propaganda, or otherwise attempting, to influence legislation, or if you participate in, or intervene in (including the publishing or distributing of statements), any political campaign on behalf of any candidate for public office.

The District Director of Internal Revenue, is being advised of this action.

Very truly yours,

P Henry Needham

Chief, Pensions and
Exempt Organizations Branch

HEALTH RESEARCH, INC.

Financial Statements as of
March 31, 2016 and 2015
Together with
Independent Auditor's Report

Bonadio & Co., LLP
Certified Public Accountants

Bonadio & Co., LLP
Certified Public Accountants

INDEPENDENT AUDITOR'S REPORT

June 28, 2016

To the Board of Directors of
Health Research, Inc.:

Report on the Financial Statements
We have audited the accompanying financial statements of Health Research, Inc. (a New York nonprofit organization) which comprise the statements of financial position as of March 31, 2016 and 2015, and the related statements of activities, 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. Those standards require that we plan and perform the audit 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.

6 Wembley Court
Albany, New York 12205
p (518) 464-4080
f (518) 464-4087

www.bonadio.com

(Continued)

Opinion
In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Health Research, Inc. as of March 31, 2016 and 2015, 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.

Bonadio & Co., LLP

HEALTH RESEARCH, INC.

STATEMENTS OF FINANCIAL POSITION
MARCH 31, 2016 AND 2015

	2016	2015
ASSETS		
Cash and cash equivalents	$ 169,787,792	$ 187,010,486
Investments (note 3)	327,614,366	212,797,223
Expense reimbursements due from sponsors (note 10)	47,938,868	45,573,884
Accrued interest receivable	821,304	416,726
Prepaid expenses	349,354	347,982
Property and equipment, net (note 4)	539,964	655,859
Agency fund (note 5)	53,280,324	52,954,652
	$ 600,331,972	$ 499,756,812
LIABILITIES AND NET ASSETS		
Accounts payable	$ 32,019,101	$ 24,923,597
Accrued payroll and related liabilities	17,732,376	12,692,596
Estimated liability for compensated absences	9,019,877	8,816,541
Restricted advances and deferred revenue	409,525,359	324,628,244
Agency fund (note 5)	53,280,324	52,954,652
Total liabilities	521,577,037	424,015,630
UNRESTRICTED NET ASSETS	78,754,935	75,741,182
Total liabilities and net assets	$ 600,331,972	$ 499,756,812

The accompanying notes are an integral part of these statements.

HEALTH RESEARCH, INC.

STATEMENTS OF ACTIVITIES
FOR THE YEARS ENDED MARCH 31, 2016 AND 2015

	2016	2015
REVENUE:		
Grants and contracts (note 10)	$ 668,635,452	$ 672,154,203
Contract fees and technology transfer revenue earned (note 8)	2,443,125	3,805,273
Investment (loss) income (note 3)	(282,385)	1,920,389
Total revenue	670,796,192	677,879,865
EXPENSES:		
Direct research, prevention and treatment costs	634,762,470	635,508,940
Indirect costs charged (note 2)	33,019,969	32,849,372
Total expenses	667,782,439	668,358,312
Excess of revenue over expenses	3,013,753	9,521,553
CHANGE IN POSTRETIREMENT OBLIGATIONS OTHER THAN NET PERIODIC POSTRETIREMENT BENEFIT COST (note 6)	-	13,059,065
CHANGE IN NET ASSETS	3,013,753	22,580,618
UNRESTRICTED NET ASSETS - beginning of year	75,741,182	53,160,564
UNRESTRICTED NET ASSETS - end of year	$ 78,754,935	$ 75,741,182

The accompanying notes are an integral part of these statements.

HEALTH RESEARCH, INC.

STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED MARCH 31, 2016 AND 2015

	2016	2015
CASH FLOW FROM OPERATING ACTIVITIES:		
Change in net assets	$ 3,013,753	$ 22,580,618
Adjustments to reconcile change in net assets to net cash flow from operating activities:		
Depreciation and amortization	313,864	450,950
Realized and unrealized losses (gains) on investments	2,010,816	(542,597)
Changes in:		
Expense reimbursements due from sponsors	(2,364,984)	22,310,914
Accrued interest receivable	(404,578)	680,924
Prepaid expenses	(1,372)	(24,539)
Accounts payable	7,095,504	(5,357,081)
Accrued expenses and other liabilities	5,039,780	466,516
Estimated liability for compensated absences	203,336	(41,288)
Restricted advances and deferred revenue	84,897,115	50,503,990
Accrued postretirement benefit obligation	-	(102,038,802)
Net cash flow from operating activities	99,803,234	(11,010,395)
CASH FLOW FROM INVESTING ACTIVITIES:		
Purchases of investments	(430,070,403)	(335,695,644)
Sales of investments	313,242,444	396,662,987
Purchases of property and equipment	(197,969)	(7,770)
Net cash flow from investing activities	(117,025,928)	60,959,573
CHANGE IN CASH AND CASH EQUIVALENTS	(17,222,694)	49,949,178
CASH AND CASH EQUIVALENTS - beginning of year	187,010,486	137,061,308
CASH AND CASH EQUIVALENTS - end of year	$ 169,787,792	$ 187,010,486

The accompanying notes are an integral part of these statements.

1. DESCRIPTION OF THE ORGANIZATION

Health Research, Inc. (the Corporation) is a nonprofit organization chartered under the laws of New York State in 1953 primarily to apply for, secure and administer gifts or grants in furtherance of the research, prevention, and treatment of diseases and conditions by the New York State Department of Health (NYS DOH), the Roswell Park Cancer Institute Corporation (RPCIC) (a public benefit corporation) and other health related entities. The Corporation has divisions in Buffalo (Roswell Division) and Albany (Albany Division), New York which administer projects conducted at the RPCIC, the NYS DOH and other health related entities, primarily financed by private and governmental contracts, grants, and donations. The Corporation has an agreement with NYS DOH and RPCIC which defines the operating relationship, administrative authority, facilities use and financial guidelines. The Corporation is included in the financial statements of the State of New York as a component unit for financial reporting purposes.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Accounting

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The most significant areas which are affected by the use of estimates include the expense reimbursements and deferred revenue from sponsors. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents include cash held in bank demand deposit and money market accounts. The Corporation's cash balances may at times exceed federally insured limits. The Corporation has not experienced any losses in these accounts and believes it is not exposed to any significant risk with respect to cash.

Investments

All investments are stated at fair value. Investments are exposed to various risks such as interest rate, market and credit risks. Due to the level of risk associated with certain investments, it is at least reasonably possible that changes in the values of investments will occur in the near term and that such changes could materially affect the amounts reported in the accompanying financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Investments (Continued)
Investments are held in the Corporation's name, as described in Note 3. Investment income, including interest and dividend income and realized and unrealized gains and losses on the Corporation's unrestricted assets, is recognized in the statements of activities.

Expense Reimbursements Due From Sponsors
Expense reimbursements due from sponsors consist of primarily grants and contract payments due from the federal government. Management evaluates the collectability of the amounts due on a periodic basis and has determined that an allowance for uncollectible receivables is not necessary at March 31, 2016 and 2015.

Property and Equipment
Property and equipment is stated at cost less accumulated depreciation. Depreciation and amortization are computed utilizing the straight-line method over the estimated useful lives of the assets or lease term for leasehold improvements, ranging from 5 to 10 years.

The Corporation capitalizes property and equipment purchased with non-sponsored funds in excess of $5,000 and a useful life greater than one year. Generally, equipment purchased using sponsored funds is directly charged as an expense to the respective grant or contract and not capitalized.

Agency Fund
As more fully described in Note 5, the Corporation administers an agency fund on behalf of the Office of the Attorney General, New York State Department of Law (OAG), pursuant to an Assurance Discontinuance Agreement signed on December 22, 2010. Interest income earned on money market accounts of the Agency Fund are recognized in the statements of financial position as an increase to the Agency Fund liability.

Estimated Liabilities for Compensated Absences
Employees are granted vacation leave and other compensated absences at varying amounts. In the event of termination or upon retirement, employees are entitled to payment for their accumulated vacation and compensated absences. Estimated vacation leave and other compensated absences has been recognized in the financial statements based on the present rates of pay.

Restricted Advances and Deferred Revenue
Restricted advances consist of contracts and grants received in advance of related expenses. Deferred revenue represents unexpended proceeds received by the Corporation, primarily including amounts for the AIDS Drug Assistance Program. These restricted advances and deferred revenue amounts are recorded as revenue when applicable expenses are incurred by the Corporation.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Financial Reporting

The Corporation reports its activities and the related net assets using three net asset categories: unrestricted, temporarily restricted and permanently restricted.

Unrestricted net assets include resources that are available for the support of the Corporation's operating activities.

Temporarily restricted net assets include resources that have been donated to the Corporation subject to purpose or time restrictions as defined by the donor.

Permanently restricted net assets include resources that have been restricted by donors to be maintained by the Corporation in perpetuity. Generally, the Corporation is permitted to use all income and gains derived from these assets.

As of March 31, 2016 and 2015, management has determined that there are no temporarily or permanently restricted net assets.

Revenue Recognition

Substantially all of the Corporation's revenue is derived from restricted contracts, grants, and donations. Revenue is recognized when expenses relative to the contracts, grants, and donations are incurred. Restricted grants and contracts revenue whose restrictions are met in the same year are included in grants and contracts revenue in the statement of activities.

Indirect Costs

Grants and contracts generally provide for reimbursement of indirect costs through the use of an indirect cost rate agreed upon between the sponsor and the Corporation. The Corporation's standard rate is negotiated with the Federal Department of Health and Human Services (DHHS), which includes both Corporation and NYS DOH indirect costs, or, in the case of the Roswell Division, the RPCIC costs. Many nonfederal sponsors, and some federal grant programs, limit the amount of indirect cost reimbursement to less than the actual approved rate.

Joint Indirect Cost Rate

In general, personal services and facilities provided by NYS DOH or RPCIC, applicable to certain contract and grant research, are included as a component of the joint indirect cost rates allowable by certain contracting and granting agencies. Therefore, certain allowable costs relative to the personal services and facilities provided by NYS DOH or RPCIC are included in the Corporation's indirect costs charged and recovered. The Corporation recovers indirect costs through the use of an indirect cost rate agreed upon between the sponsor and the Corporation in its billing process and are used to support agency operations.

On an annual basis, the joint indirect cost rates are approved by DHHS based upon the submission of a joint indirect cost proposal for the Corporation and NYS DOH, and for the Corporation and RPCIC. Any adjustment to these fixed rates based on final costs or audit is normally reflected on a prospective basis, either as an increase or reduction in the subsequent year's rates.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Fair Value Measurement – Definition and Hierarchy
The Corporation uses various valuation techniques in determining fair value. A hierarchy for inputs used in measuring fair value has been established that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Corporation. Unobservable inputs are inputs that reflect the Corporation's assumptions about the assumptions market participants would use in pricing the asset or liability, developed based on the best information available in the circumstances.

The hierarchy is broken down into three levels based on the reliability of inputs as follows:

- Level 1 - Valuations based on quoted prices in active markets for identical assets or liabilities that the Corporation has the ability to access. Valuation adjustments are not applied to Level 1 instruments. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment. Fair value is determined using the market approach using relevant market data.

- Level 2 - Valuations based on quoted prices in markets that are not active or for which all significant inputs are observable, directly or indirectly.

- Level 3 - Valuations based on inputs that are unobservable and significant to the overall fair value measurement. The Corporation currently has no assets or liabilities that are measured using Level 3 inputs.

The availability of observable inputs can vary and is affected by a wide variety of factors. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Corporation in determining fair value is greatest for instruments categorized in Level 3. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for disclosure purposes the level in the fair value hierarchy within which the fair value measurement in its entirety falls is determined based on the lowest level input that is significant to the fair value measurement in its entirety.

Income Taxes
The Corporation is a nonprofit organization exempt from income taxes under Section 501(c)(3) of the Internal Revenue Code. The Corporation has also been classified by the Internal Revenue Service as an entity that is not a private foundation.

3. INVESTMENTS

In accordance with its investment policy, the Corporation invests in fixed income and equity securities and maintains deposits with financial institutions and obligations of, or which are guaranteed by the United States government. These investments are held by the Corporation's agents in the Corporation's name.

3. INVESTMENTS (Continued)

Investments consisted of the following at March 31, 2016:

Description	Division		Total
	Roswell	Albany	
Fixed income securities:			
United States government bonds and notes	$ 1,987,028	$ 261,038,867	$ 263,025,895
Asset backed securities	1,584,166	5,995,628	7,579,794
Corporate bonds	2,052,931	6,958,848	9,011,779
Mortgage backed securities	1,524,448	5,486,943	7,011,391
Collateralized mortgage obligations	124,363	460,941	585,304
Municipal bonds	452,689	1,407,470	1,860,159
Floating rate notes	353,316	1,279,536	1,632,852
Mutual Funds	7,574,675	27,600,365	35,175,040
Equity securities	370,664	1,361,488	1,732,152
	$ 16,024,280	$ 311,590,086	$ 327,614,366

Investments consisted of the following at March 31, 2015:

Description	Division		Total
	Roswell	Albany	
Fixed income securities:			
United States government bonds and notes	$ 1,700,938	$ 144,921,457	$ 146,622,395
Asset backed securities	1,635,890	5,932,103	7,567,993
Corporate bonds	1,990,014	7,216,237	9,206,251
Mortgage backed securities	1,608,588	5,833,100	7,441,688
Collateralized mortgage obligations	172,418	625,227	797,645
Municipal bonds	189,583	687,470	877,053
Floating rate notes	498,489	1,807,632	2,306,121
Mutual Funds	7,907,657	28,402,797	36,310,454
Equity securities	332,760	1,334,863	1,667,623
	$ 16,036,337	$ 196,760,886	$ 212,797,223

Equity securities are valued based on quoted market prices in active markets (Level 1 measurement).

Fixed income securities are valued based on quoted market prices in active markets (Level 1 measurement). When quoted market prices are not available, fair values are based on quoted market prices of comparable instruments (Level 2 measurement). When necessary, the Corporation utilizes matrix pricing from a third party pricing vendor to determine fair value pricing (Level 2 measurement). Matrix prices are based on quoted prices for securities with similar coupons, ratings, and maturities, rather than on specific bids and offers for the designated security.

The following presents the Corporation's investments at March 31, 2016 and 2015 that are measured at fair value on a recurring basis. Investments are classified in their entirety based on the lowest level of input that is significant to the fair value measurements. The Corporation's investments are redeemable subject to one day's notice.

3. INVESTMENTS (Continued)

The following investments are measured at fair value on a recurring basis at March 31, 2016:

Description	Level 1 Inputs	Level 2 Inputs	Total
Fixed investment securities:			
United States government bonds and notes	$ 259,276,438	$ 3,749,457	$ 263,025,895
Asset backed securities	-	7,579,794	7,579,794
Corporate bonds	-	9,011,779	9,011,779
Mortgage backed securities	-	7,011,391	7,011,391
Collateralized mortgage obligations	-	585,304	585,304
Municipal bonds	-	1,860,160	1,860,160
Floating rate notes	-	1,632,852	1,632,852
Equities securities:			
Domestic equities	1,732,152	-	1,732,152
Mutual funds:			
Fixed Income Mutual Funds	-	3,582,850	3,582,850
Domestic Equity Mutual Funds	1,857,034	-	1,857,034
International Equity Funds	6,779,919	-	6,779,919
State Street Global Advisors	-	7,899,860	7,899,860
Colchester Global Bond Fund	-	7,626,741	7,626,741
Western Asset Management Company	-	7,428,635	7,428,635
	$ 269,645,543	$ 57,968,823	$ 327,614,366

The following investments are measured at fair value on a recurring basis at March 31, 2015:

Description	Level 1 Inputs	Level 2 Inputs	Total
Fixed investment securities:			
United States government bonds and notes	$ 142,256,607	$ 4,365,789	$ 146,622,396
Asset backed securities	-	7,567,993	7,567,993
Corporate bonds	-	9,206,251	9,206,251
Mortgage backed securities	-	7,441,688	7,441,688
Collateralized mortgage obligations	-	797,645	797,645
Municipal bonds	-	877,053	877,053
Floating rate notes	-	2,306,121	2,306,121
Equities securities:			
Domestic equities	1,667,622	-	1,667,622
Mutual Funds			
Fixed Income Mutual Funds	-	3,735,388	3,735,388
Domestic Equity Mutual Funds	1,999,840	-	1,999,840
International Equity Funds	7,806,562	-	7,806,562
State Street Global Advisors	-	7,830,553	7,830,553
Colchester Global Bond Fund	-	7,362,756	7,362,756
Western Asset Management Company	-	7,575,355	7,575,355
	$ 153,730,631	$ 59,066,592	$ 212,797,223

3. INVESTMENTS (Continued)

The Corporation has no investments that are valued using Level 3 inputs as of March 31, 2016 and 2015. There were no significant transfers into or out of Level 1 and Level 2 for the years ended March 31, 2016 and 2015.

Net investment income (loss) is comprised of the following as of March 31, 2016:

Description	Division		Total
	Roswell	Albany	
Interest and dividend income, net of fees of $296,777	$ 285,087	$ 1,443,344	$ 1,728,431
Net unrealized losses	(428,195)	(981,560)	(1,409,755)
Net realized losses	(120,797)	(480,264)	(601,061)
	$ (263,905)	$ (18,480)	$ (282,385)

Net investment income is comprised of the following as of March 31, 2015:

Description	Division		Total
	Roswell	Albany	
Interest and dividend income, net of fees of $245,624	$ 417,445	$ 960,347	$ 1,377,792
Net unrealized losses	(3,754,475)	(5,911,987)	(9,666,462)
Net realized gains	3,913,297	6,295,762	10,209,059
	$ 576,267	$ 1,344,122	$ 1,920,389

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following as of March 31, 2016:

Description	Division		Total
	Roswell	Albany	
Buildings and improvements	$ 253,147	$ 4,445,740	$ 4,698,887
Furnitures, fixtures, and equipment (includes software)	439,594	479,258	918,852
	692,741	4,924,998	5,617,739
Less accumulated depreciation and amortization	420,140	4,657,635	5,077,775
	$ 272,601	$ 267,363	$ 539,964

4. PROPERTY AND EQUIPMENT (Continued)

Property and equipment consisted of the following as of March 31, 2015:

Description	Division		Total
	Roswell	Albany	
Buildings and improvements	$ 253,147	$ 4,445,740	$ 4,698,887
Furnitures, fixtures, and equipment (includes software)	441,616	318,858	760,474
	694,763	4,764,598	5,459,361
Less accumulated depreciation and amortization	455,673	4,347,829	4,803,502
	$ 239,090	$ 416,769	$ 655,859

Depreciation and amortization expense for the years ended March 31, 2016 and 2015 was $313,864 and $450,950 respectively.

5. AGENCY FUND

Pursuant to an Assurance of Discontinuance Agreement (AOD), the Office of the Attorney General, New York State Department of Law (OAG) required certain health insurers to fund the establishment and operation of new independent databases for determining fair and accurate reimbursement rates for out-of-network health services. In addition, the AOD requires the development of a website available to the public which discloses out-of-network reimbursement information that will educate consumers on the true cost of health care services and the reimbursement rate system.

As part of the AOD, FAIR Health, Inc. (FAIR Health), a New York Not-for-Profit Corporation was formed to create, maintain, operate and own the independent databases and website. FAIR Health entered into a Database and Website Agreement with Syracuse University to design, establish and maintain the new databases and website, under the oversight of an independent Contract Monitor.

On December 22, 2010, OAG entered into a Funding Administration Agreement with the Corporation to continue the administration of the funds collected to support the AOD activities contemplated through the establishment of FAIR Health and the provisions of the Database and Website Agreement. In connection with the Funding Administration Agreement, the Corporation accepted an assignment from the OAG, the responsibilities of the OAG under the Database and Website Agreement with FAIR Health.

Accordingly, OAG transferred to the Corporation approximately $56.0 million, which is reflected in the statements of financial position as an Agency Fund. The Corporation is entitled to a fixed annual fee of $75,000 to cover its costs and expenses in administering the remaining funds collected under the AOD beginning April 2011. The funds are held by a bank in money market cash accounts.

As of January 28, 2014, a second amendment was signed ending the contract between the Corporation and FAIR Health as the original terms of the agreement had been fulfilled and FAIR Health demonstrated its financial self-sufficiency. The Corporation will continue to administer the use of the remaining funds, in keeping with the purpose of AOD.

6. EMPLOYEE BENEFIT PLANS

Pension Benefits

The Corporation participates in the New York State and Local Employees' Retirement System (System), a defined benefit cost sharing, multiple-employer pension plan. The System is noncontributory except for employees with less than 10 years of service who joined the System after July 27, 1976 who are required by law to contribute 3% of their salary. In addition, employees entering the System after January 1, 2010 are required to contribute 3% of their salary for the duration of their employment. Employees entering the System after April 1, 2012 are required to contribute, for the duration of their employment, between 3% and 6% based on the value of their annual compensation. As set forth in the New York State Retirement and Social Security Law (NYSRSSL), the Comptroller of the State of New York (Comptroller) serves as sole trustee and administrative head of the System. The Comptroller shall adopt and may amend rules and regulations for the administration and transaction of the business of the System and for the custody and control of its funds, and the Comptroller shall certify annually the rates expressed as proportions of payroll of members, which shall be used in computing the contributions required to be made by employers. The rates billed by the Comptroller for the years ended March 31, 2016 and 2015 approximated 18.8% and 20.3% respectively.

The required pension contribution for plan years ended March 31, 2016 and 2015 consisted of the Corporation's contributions of $17,136,395 and $18,696,449, respectively, and employees' contributions of $1,467,252 and $1,442,713, respectively. Actuarial and plan asset data relating to employees of the Corporation is not available. The System issues a publicly available financial report which may be obtained by writing to the New York State and Local Retirement System, 110 State Street, Albany, NY 12236.

Postretirement Benefits

In addition to pension benefits, the Corporation provides postretirement health insurance benefits through the Health Research, Inc. Postretirement Health Benefits Trust (the Trust). Effective August 1, 2014, the Plan was changed to eliminate the Corporation's defined benefit obligation and replacing it with a defined contribution structure. This curtailment resulted in a one-time gain of approximately $13,000,000, which was recognized in the statement of activities for the year ended March 31, 2015 (changes other than net periodic pension costs).

The Trust was created to provide reimbursements for health insurance premiums, and qualifying medical expenses not covered by health insurance. Participants are eligible to participate in the Trust if they are a Class 1, Class 2 or Class 3 retiree, as defined by the Plan document. Employees become eligible for postretirement benefits upon retirement from the Corporation. Generally, eligibility begins at age 55 with 15 years of service. Prior to August 1, 2014, employees who had unused sick bank hours at retirement in excess of fifty days, had the option to convert those hours to a lifetime credit against the retiree contribution of health benefits.

The Corporation contributes annually to the Trust, in accordance with the contribution schedule included in the Plan document. During the years ended March 31, 2016 and 2015, the Corporation contributed approximately $2,200,000 and $1,300,000, respectively, to the Plan for the benefit of participants.

7. CONTRACT AND GRANT AWARDS

At March 31, 2016 and 2015, the unexpended portion of contract and grant awards available to be used in subsequent years totaled $308,072,598 (Roswell Division - $67,326,350 and Albany Division - $240,746,248) and $265,964,417 (Roswell Division - $64,578,384 and Albany Division - $201,386,033), respectively.

8. TECHNOLOGY TRANSFER

The Corporation serves as Technology Transfer administrator for the NYS DOH and RPCIC. If NYS DOH or the RPCIC assigns or sells any inventions developed by their employees to the Corporation, the Corporation assumes the responsibility for filing of patent applications and marketing the invention, usually in the form of royalty bearing licenses to companies which develop, produce, and sell products based upon the invention.

As of March 31, 2016 and 2015, the Corporation has a total of 128 and 115 inventions under administration, has obtained 87 and 105 U.S. patents, and 107 and 112 inventions have been licensed, respectively. During the years ended March 31, 2016 and 2015, the Corporation's expenses relating to these patents and inventions were $406,275 and $536,616 and the related income totaled $2,275,461 and $3,570,082, respectively.

9. OPERATING LEASES

Rent expense for the years ended March 31, 2016 and 2015 was approximately $3,006,000 and $2,958,000 per year, respectively. A summary of the Corporation's future minimum lease obligations is as follows:

Years Ending March 31,	
2017	$ 2,977,142
2018	2,978,162
2019	2,989,382
2020	1,557,675
2021	417,813
Thereafter	804,543
	$ 11,724,717

10. COMMITMENTS AND CONTINGENCIES

Significant Concentration

The majority of the Corporation's funding is received directly from DHHS. For the years ended March 31, 2016 and 2015, approximately 48% and 43%, respectively, of total revenue relates to contracts and grants from DHHS. Included in expense reimbursements due from sponsors at March 31, 2016 and 2015 is $24,886,179 and $25,773,450, respectively, due from DHHS.

Substantially all Federal contracts and grants are subject to financial and compliance audits by the grantor agencies of the Federal government. Disallowances, if any, as a result of these audits may become liabilities of the Corporation. Management believes that no material disallowances will result from audits by the grantor agencies.

10. COMMITMENTS AND CONTINGENCIES (Continued)

Collective Bargaining Agreement

Approximately 73% of the Corporation's employees are covered by a collective bargaining agreement. The labor contract, with the Civil Service Employee Association – Private Sector, covers a four-year period ended March 31, 2019. The agreement covers all Corporation employees, except persons in positions established under training grants or contracts, or training components of other grants or contacts; variable hour employees; and personnel in positons which are designated as Management/Confidential services employees.

11. SUBSEQUENT EVENTS

Subsequent events have been evaluated through June 28, 2016, which is the date the financial statements were available to be issued.