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STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

29 HAZEN DRIVE, CONCORD, NH 03301-6503
603-271-4612 1-800-852-3345 Ext. 4612
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NH DIVISION OF Public Health Services
Improving health, preventing disease, reducing costs for all

Jeffrey A. Meyers
Commissioner

Marcella Jordan Bobinsky
Acting Director

June 15, 2016

Her Excellency, Governor Margaret Wood Hassan
and the Honorable Council
State House
Concord, New Hampshire 03301

REQUESTED ACTION

Authorize the Department of Health and Human Services to enter into an agreement with Harvey L. Levy, MD, (Vendor # 167308-B001), of 58 Greenlawn Avenue, Newton, MA 02459-6504 in an amount not to exceed $54,000 to provide physician consultant services on an individual, case-by-case, as needed basis to the New Hampshire Newborn Screening Program and the New Hampshire Medical Community, effective July 1, 2016 or upon the date of Governor and Council approval, whichever is later, through June 30, 2019. Funds are 100% Other Funds.

Funds are available in the following account for State Fiscal Year 2017, and are anticipated to be available in State Fiscal Years 2018 and 2019, upon the availability and continued appropriation of funds in the future operating budgets, with authority to adjust encumbrances between State Fiscal Years through the Budget Office if needed and justified, without further approval from the Governor and Executive Council.

05-95-90-902010-5240 HEALTH AND SOCIAL SERVICES, DEPT OF HEALTH AND HUMAN SERVICES, HHS: DIVISION OF PUBLIC HEALTH, BUREAU OF POPULATION HEALTH AND COMMUNITY SERVICES, NEWBORN SCREENING REVOLVING FUND

State Fiscal Year	Class/Account	Class Title	Job Number	Total Amount
2017	102-500731	Contracts for Program Services	90080013	$18,000
2018	102-500731	Contracts for Program Services	90080013	$18,000
2019	102-500731	Contracts for Program Services	90080013	$18,000
			Total	$54,000

EXPLANATION

The purpose of this request is to enter into an agreement for the provision of specialty physician consultant services, which will be utilized by the Department's Newborn Screening Program and the New Hampshire Medical Community on an individual, case-by-case, as-needed basis. Specialty physician consultation services are needed by the Department and the medical community when newborn screenings indicate clinically significant abnormal screening results that require specific and prompt medical action.

Newborn screening programs, statewide, screen newborns for potentially life threatening, complicated medical disorders through a blood test shortly after birth. These screening programs have become increasingly complex since the 1960's when screening for one disorder, Phenylketonuria (PKU), first began. Advancing science and technology in the 1990's has made it possible to screen for many more disorders using the same blood specimen. The nineteen (19) metabolic disorders that were added to the New Hampshire screening panel in 2007 and one (1) added in 2010 are relatively rare and often unfamiliar to the general physician. Because of this, specialty medical consultation is necessary to provide guidance, direction and support to the general physician in handling clinically significant abnormal screening results and in assuring that infants receive optimal care in a timely manner. In many cases, these infants appear healthy at birth, giving no indication that something is wrong.

To ensure positive health outcomes, conditions must be identified and appropriate medical treatment instituted as quickly as possible, before clinical symptoms become apparent. The need for this service remains critical in order to prevent unnecessary death and illness among the infants identified with these rare conditions. This service will require a yearly review in order to closely evaluate both the usage and the need for this specialty consultation.

The greatest need at present continues to be for metabolic specialty consultation because most of the conditions that are screened for are metabolic in nature. Medical sub-specialists experienced in the treatment of these rare metabolic conditions are few. Currently there is no pediatric metabolic specialist in state employ; therefore, the Department must contract with a medical specialist to provide guidance to New Hampshire's medical providers for the conditions identified through the state-screening panel.

This contract was competitively bid. A Request for Applications was available on the Department of Health and Human Services' website from April 11, 2016 through May 9, 2016. One application was received in response to the Request for Applications. The application was evaluated based on the criteria published in the Request for Applications by a team of individuals with program specific knowledge and expertise. Dr. Harvey L. Levy was selected. The bid summary is attached.

As referenced in the Request for Application and in Exhibit C-1 of this contract, this competitively procured Agreement has the option to be extended for up to four (4) additional years, contingent upon satisfactory delivery of services, available funding, agreement of the parties and approval of the Governor and Executive Council.

Dr. Levy will be available by phone or pager Monday - Friday, 8:00 AM – 4:30 PM (EST), to provide consultation as needed, related to clinically significant abnormal newborn screening results. Additionally, Dr. Levy will participate in a periodic review of expanded screening, as requested, in conjunction with the staff of the Newborn Screening Program, the screening laboratory, and the Newborn Screening Advisory Committee as requested. Dr. Levy will also assist with the development and review of condition-specific standards and protocols to guide the daily operations of the New Hampshire Newborn Screening Program, as requested by the Department. Lastly, Dr. Levy will advise the New Hampshire Newborn Screening Program staff of medical developments that have relevance to newborn screening program operations as well as attend New Hampshire Newborn Screening Advisory Committee meetings, as needed.

Should the Governor and Executive Council not authorize this Request, the Department will not have access to specialty physician consultation services that are needed when newborn screenings indicate clinically significant abnormal results that require specific and prompt medical action. Lack of specialty services could result in infants not receiving the specialty care needed in time to prevent infant death.

Area served: Statewide.

Source of Funds is 100% Other Funds, Newborn Screening Revolving Fund.

In the event that the Federal Funds become no longer available, General Funds will not be requested to support this program.

Respectfully Submitted,

Marcella J. Bobinsky, MPH
Acting Director

Approved by:
Jeffrey A. Meyers
Commissioner

New Hampshire Department of Health and Human Services
Office of Business Operations
Contracts & Procurement Unit
Summary Scoring Sheet

Newborn Screening Program Physician Consultant
RFA Name

RFA-2017-DPHS-08-Newbo
RFA Number

Bidder Name	Pass/Fail	Maximum Points	Actual Points
1. Harvey L. Levy, M.D.		200	200
2. 0		200	0
3. 0		200	0
4. 0		200	0
5. 0		200	0
6. 0		200	0
7. 0		200	0

Reviewer Names

1. Linda Kincaid, Public Health Nurse Coord., DPHS
2. Audrey Knight, Public Health Nurse Consultant, DPHS
3. Anne Marie Mercuri, Public Health Nurse Consultant, DPHS
4.
5.
6.
7.
8.
9.

Subject: Newborn Screening Physician Consultant

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 New Hampshire Department of Health and Human Services		1.2 State Agency Address 29 Hazen Drive Concord, NH 03301-6504	
1.3 Contractor Name Harvey L. Levy, MD		1.4 Contractor Address 58 Greenlawn Avenue Newton, MA 02459-1714	
1.5 Contractor Phone Number (617) 355-6346	1.6 Account Number 05-95-90-902010-102-500731	1.7 Completion Date June 30, 2019	1.8 Price Limitation $54,000 ~~$52,000.00~~
1.9 Contracting Officer for State Agency Eric Borrin, Director of Contracts and Procurement		1.10 State Agency Telephone Number (603) 271-9558	
1.11 Contractor Signature		1.12 Name and Title of Contractor Signatory Harvey L. Levy, MD, Physician Consultant	

1.13 Acknowledgement: State of Massachusetts, County of Suffolk

On June 2 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

[Seal]

CYNTHIA E. OLDFIELD
Notary Public
Commonwealth of Massachusetts
My Commission Expires November 9, 2018

1.13.2 Name and Title of Notary or Justice of the Peace
Cynthia Oldfield

1.14 State Agency Signature Date: 6/24/16	1.15 Name and Title of State Agency Signatory Marilee Nihan Dep Commissioner
1.16 Approval by the N.H. Department of Administration, Division of Personnel *(if applicable)* By: Deputy Director, On: 6/27/16	
1.17 Approval by the Attorney General (Form, Substance and Execution) *(if applicable)* By: On: Megan A. Yusko Attorney 6/24/16	
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
Date 6/2/16

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 HR
Date 6/2/16

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 HPS
Date 6/2/16

SCOPE OF SERVICES

1. Provisions Applicable to all Services

1.1 The Contractor shall maintain a valid and unrestricted license to practice medicine in the United States, with specialty and clinical expertise to the management of clinically significant metabolic screening results, and be free from any mental or physical impairment or condition which would preclude the Contractor's ability to competently perform the essential functions or duties under this Agreement.

2. Scope of Work

2.1 The Contractor shall provide consultation services to the New Hampshire Newborn Screening Program, the Newborn Screening Program's screening laboratory, and New Hampshire medical community on the diagnosis and management of clinically significant screening results. Consultation services shall include, but not be limited to:

2.1.1. being available by phone or pager Monday - Friday, 8:00 AM – 4:30 PM (EST), to provide consultation as needed, related to clinically significant screening results;

2.1.2. assisting in the verification of medical consulting services delivered by completing a Department medical consultation encounter form for each consultation within thirty (30) days of the consultation encounter;

2.1.3. participating in a periodic review of expanded screening, as requested, in conjunction with the staff of the Newborn Screening Program, the screening laboratory, and the Newborn Screening Advisory Committee as requested;

2.1.4. assisting in the development and review of condition-specific standards and protocols to guide the daily operations of the New Hampshire Newborn Screening Program, as requested;

2.1.5. advising the New Hampshire Newborn Screening Program staff of medical developments that have relevance to newborn screening program operations as indicated; and

2.1.6. attending New Hampshire Newborn Screening Advisory Committee meetings, as needed.

Exhibit B

Method and Conditions Precedent to Payment

1. This Contract is funded by Other Funds.

2. The Department shall pay the Contractor an amount not to exceed the Price Limitation on Form P-37, Block 1.8, for the services provided by the Contractor pursuant to Exhibit A, Scope of Services.

3. Payment for services shall be for actual hours worked payable at a rate of $300.00 per hour, not to exceed 60 hours per year.

4. Payment for Services shall be made as follows:

   4.1 The Contractor shall submit monthly invoices for reimbursement of actual hours worked during the month.

   4.2 The Department shall make payment to the Contractor within thirty (30) days of receipt of each invoice for Contractor services provided pursuant to this Agreement.

   4.3 Invoices identified in Section 4.1 must be submitted to:

   Linda Kincaid, Public Health Nurse Coordinator
   Department of Health and Human Services
   Division of Public Health Services
   29 Hazen Drive
   Concord, NH 03301-6504
   Email: Linda.L.Kincaid@dhhs.nh.gov

5. Payments may be withheld pending receipt of required reports or documentation as identified in Exhibit A, Scope of Services.

6. A final payment request shall be submitted no later than sixty (60) days after the end of the contract. Failure to submit the invoice, and accompanying documentation, could result in non-payment.

7. Notwithstanding anything to the contrary herein, the Contractor agrees that funding under this Contract may be withheld, in whole or in part, in the event of noncompliance with any State or Federal law, rule, or regulation applicable to the services provided, or if the said services have not been completed in accordance with the terms and conditions of the 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's regulations, the Contractor shall retain medical records on each patient/recipient of services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DEPARTMENT: NH Department of Health and Human Services.

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

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

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

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

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

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

REVISIONS TO GENERAL PROVISIONS

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

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

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

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

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

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

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

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

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

4. Subparagraph 14.1.1 of the General Provisions, Insurance, of this contract is deleted and the following subparagraph is added:
   14.1.1 Medical Professional Liability in an amount of $5,000,000.00 each "Claim" and $10,000,000.00 annual aggregate each insured person, for all claims made and reported during the Policy Period.

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:

6/2/16
Date

Name: HARVEY LEVY
Title: MD

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:

6/2/16
Date

Name: Harvey Levy
Title: MD

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:

6/2/16
Date

Name: HARVEY LEVY
Title: MD

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:

6/2/16
Date

Name: HARVEY LEVY
Title: MD

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:

6/2/16
Date

Name: HARVEY LEVY
Title: MD

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.

The State	Name of the Contractor
Marilee Nihan	
Signature of Authorized Representative	Signature of Authorized Representative
Marilee Nihan	HARVEY L. LEVY
Name of Authorized Representative	Name of Authorized Representative
Dep Commissioner	MD
Title of Authorized Representative	Title of Authorized Representative
6/24/16	6/2/16
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:

6/2/16
Date

Name: HARVEY LEVY
Title: MD

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: _____

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?

   ✓ 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: _____

CONTROLLED RISK INSURANCE COMPANY OF VERMONT INC. (A Risk Retention Group)
Burlington, Vermont

Confirmation of Coverage for Physicians, Dentists, and Podiatrists

CHILDREN'S MEDICAL CENTER CORPORATION

Date: 05/05/2016

HARVEY L. LEVY MD
CHILDREN'S HOSPITAL PEDIATRIC ASSOCIATES, INC.
300 LONGWOOD AVENUE
BOSTON, MA 02115

This confirms the existence of your insurance coverage as set forth below. Coverage is subject to all the terms, conditions and exclusions of the policy referenced below.

Medical Professional Liability: *	Limits of Liability:	
	$5,000,000.00	each "Claim"
	$10,000,000.00	annual aggregate each insured person, for all claims made and reported during the "Policy Period"
Policy Number:		
Policy Period:	1/1/2016 - 12/31/2016	

No person, organization or entity who is insured for liability for injury arising from a "Medical Incident" under any other policy of insurance issued by the "Company" shall be insured under the policy of insurance referenced above. No person, organization or entity is entitled to exceed the "each 'Claim'" or "annual aggregate" Limits of Liability during the "Policy Period" referenced above, regardless of the number of different capacities in which such person, organization or entity might qualify as an "Insured".

Coverage terminates as respects physicians, dentists, and podiatrists at the earlier of:

a) The date upon which the individual elects to cancel coverage; or

b) The date the individual is removed from the Schedule of Insured Physicians, Dentists, and Podiatrists maintained by the Risk Management Foundation.

* LIMITED CLAIMS MADE AND REPORTED POLICY WITH TAIL COVERAGE: This is a limited claims made and reported policy with tail coverage. Please review the policy carefully.

NOTICE

The policy pursuant to which this confirmation is provided is issued by the "Named Insured's" risk retention group. The "Named Insured's" risk retention group may not be subject to all the insurance laws and regulations of your State. State insurance insolvency funds are not available for the "Named Insured's" risk retention group.

Terms appearing in quotation marks in the Confirmation of Coverage shall have the same meaning as the definition of that term in the policy.

Any request for claim information should be directed to Risk Management Foundation, 1325 Boylston Street, Boston, Massachusetts, 02215, or underwritingapps@rmf.harvard.edu.

Controlled Risk Insurance Company of Vermont, Inc.
(A Risk Retention Group)

Duly Authorized Representative

PART I: GENERAL INFORMATION

Date Prepared: May 2016

HARVEY L. LEVY

Office Address: Children's Hospital Boston, 1 Autumn St., Rm 526-1, Boston, MA 02115

Home Address: 58 Greenlawn Ave, Newton, MA 02459

Email: Harvey.Levy@childrens.harvard.edu Fax: 617-730-4856

Place of Birth: Augusta, GA

EDUCATION

1956	No degree (early admission to medical school)	Emory University
1960	MD	Medical College of Georgia

POSTDOCTURAL TRAINING

1960-61	Intern	Pediatrics	Boston City Hospital
1961-62	Resident	Pediatric Pathology	Columbia-Presbyterian Medical Center
1964-65	Resident	Pediatrics	John Hopkins Hospital
1965-66	Chief Resident	Pediatrics	Boston City Hospital
1966-68	Clinical Research Fellow	Neurology	Massachusetts General Hospital

LICENSURE AND CERTIFICATION

1966	Massachusetts Physician, License # 29131
1966	American Board of Pediatrics, Certification
1968	American Academy of Pediatrics, Fellow
1982	American Board of Medical Genetics, Certification
1982	American Board of Medical Genetics, Certification in Biochemical Genetics
2004	American College of Medical Genetics, Fellow

ACADEMIC APPOINTMENTS

1968-69	Instructor in Neurology	Harvard Medical School
1969-70	Instructor in Neurology at the Massachusetts General Hospital	Harvard Medical School
1970-76	Assistant Professor of Neurology at the Massachusetts General Hospital	Harvard Medical School
1976-86	Associate Professor of Neurology at the Massachusetts General Hospital	Harvard Medical School
1986-94	Associate Professor of Neurology	Harvard Medical School
1991-97	Adjunct Professor of Nutrition	University of Illinois, Chicago
1995-04	Associate Professor of Pediatrics	Harvard Medical School
2004-	Professor of Pediatrics	Harvard Medical School

HOSPITAL AND AFFILIATED INSTITUTION APPOINTMENTS

1962-64	General Medical Officer, USNR	Subic Bay, Philippines
1968-80	Assistant in Neurology	Massachusetts General Hospital
1978-83	Assistant Pediatrician	Massachusetts General Hospital

1980-92	Assistant Neurologist	Massachusetts General Hospital
1983-86	Associate Pediatrician	Massachusetts General Hospital
1987-	Pediatrician	Massachusetts General Hospital
1978-	Senior Associate in Medicine	Boston Children's Hospital
1978-88	Director, IEM-PKU Program	Boston Children's Hospital
1981-	Director, Maternal PKU Program*	Boston Children's Hospital
1985-	Core Investigator and Member of Executive Committee, Mental Retardation Research Program	Boston Children's Hospital
2008-	Senior Physician in Medicine	Boston Children's Hospital

STATE LABORATORY INSTITUTE APPOINTMENTS

1968-71	Assistant Director, Massachusetts Metabolic Disorders Program
1972-76	Director, Massachusetts Metabolic Disorders Program
1976-97	Chief of Biochemical Genetics, New England Newborn Screening Program

OTHER PROFESSIONAL POSITIONS AND MAJOR VISITING APPOINTMENTS

1971-80	Associate, Center for Human Genetics	Harvard Medical School
1968-90	Consultant in Metabolic Disorders	Eunice Kennedy Shriver Center for Research in Mental Retardation, Waltham, MA
1991-95	Visiting Director, Midwest Maternal PKU Center	University of Illinois, Chicago
1981	Associate in Health Sciences	Foundation for Blood Research, Scarborough, ME
1984-96	Associate Staff	Tufts-New England Medical Center

HOSPITAL SERVICE RESPONSIBILITIES

1970-90	Attending in Genetics	Massachusetts General Hospital
1978-	Attending in Metabolism/Genetics	Boston Children's Hospital
2013-	Consultant, Neonatology	Beth-Israel Deaconess Medical Center

MAJOR ADMINISTRATIVE RESPONSIBILITIES

1978-88	Director, IEM-PKU Program	Boston Children's Hospital
1981-	Director, Maternal PKU Program	Boston Children's Hospital
1972-76	Director, Massachusetts Metabolic Disorders Program	State Laboratory Institute

MAJOR COMMITTEE ASSIGNMENTS

AFFILIATED INSTITUTION

1996-2000	Hospital Based Faculty Research Council	Boston Children's Hospital
1990-94	Advisory Board, Brain Tissue Center	McLean Hospital
2006-	GCRC (CTSU) Protocol Review Subcommittee	Boston Children's Hospital
2006-	GCRC (CTSU) Scientific Advisory Committee	Boston Children's Hospital

LOCAL

1971-72	Committee of Fetus and Newborn	Massachusetts Chapter, American Academy of Pediatrics
1979-82	Task Force on Screening, Chairman	Commonwealth of Massachusetts
1978-97	Advisory Committee for Genetic Services	Commonwealth of Massachusetts

1997-98	Newborn Screening Advisory Committee	Commonwealth of Massachusetts
2006-2008	Standing Committee on Promotions, Reappointments, and Appointments	Harvard Medical School
2009-	Admissions Committee	Harvard Medical School Training Program in Medical Genetics

REGIONAL

1978-88	Screening Committee, Chair	New England Regional Genetics Group
1985-88	Newborn Screening Committee, Chairman	New England Regional Genetics Group
1999-	New England Consortium of Metabolic Programs, Co-Chair	New England Regional Genetics Group
1994-2001	Advisor and Oversight Committee Member	Quebec Neuroblastoma Screening Program
2003-	Massachusetts Representative	New England Regional Genetics Group

NATIONAL

1968-	NIH ad hoc review committees	NIH
1971-73	Amniocentesis Registry	NICHD, NIH
1976-78	Subcommittee on Amino Acid Modified Diets	FDA/Amer Acad of Pediatrics
1979-81	Chemistry and Hematology Committee	Amer Public Health Assoc
1984-85	Task Force on Dietary Management of Metabolic Disorders, Committee on Nutrition, Chairperson	FDA/Amer Acad of Pediatrics
1985-86	Task Force on Clinical Evaluation of Products for Metabolic Disorders, Committee on Nutrition, Chairperson	FDA/Amer Acad of Pediatrics
1986-88	Advisory Panel on Technology and Child Health and Developmental Abnormalities	Office of Technology Assessment, U.S. Congress ASSOC
1989-90	Task Force on Protein Hydrolysate Formulas, Committee on Nutrition, Chairperson	FDA/Amer Acad of Pediatrics
1993-	Scientific Advisory Board	Metabolic Information Network
1999	Newborn Screening Task Force	MCH/HRSA/Amer Acad of Pediatrics
2000	Planning Committee, NIH Consensus Statement: Phenylketonuria (PKU): Screening and Management	NIH
2002	Advisory Board on Neonatal Screening for Inborn Errors of Metabolism Using Tandem Mass Spectrometry	California Health Resources and Service Administration
2002	Scientific Committee, National Meeting on Tandem Mass Spectrometry for Newborn Screening	HRSA, MCH Research
2003-	Workgroup on Diagnosis and Follow-up in Expanded Newborn Screening, Chair	American College of Medical Genetics
2004-	PKU Advisory Board, Co-Chairperson	BioMarin Pharmaceutical, Inc.
2004-06	Committee on Direct to Consumer Marketing of Genetic Tests	National Human Genome Research Institute/NIH
2005 -	Advisory Committee for the National Coordinating Center for the Genetics and NBS Regional Collaboratives	American College of Medical Genetics
2006-	Workgroup on Newborn Screening and Follow-Up, Chair 2006-14	American College of Medical Genetics
2009	Committee on Long-Term Follow-up of Newborn Screening	Southeast Regional Genetics Group

2009-	Standing Committee, Newborn Screening Translational Research Network, Chair 2009-12, co-chair 2012-13	American College of Medical Genetics
2011-	Scientific Advisory Board	National PKU Alliance
2014-	Scientific Advisor	Codexis, Inc.
2016-	Clinical Advisory Board	Synlogics, Inc.

INTERNATIONAL

2005-	International Scientific Advisory Committee	The Israel Center for Newborn Screening

PROFESSIONAL SOCIETIES

1966-	American Academy of Pediatrics	Member
1967-80	Massachusetts Medical Society	Member
1968-	Society of Pediatric Research	Member, Emeritus
1984-	American Pediatric Society	Member
1976-	American Society for Human Genetics	Member
1977-	Society for Inherited Metabolic Disorders	
	1978-83	Director-at-Large
	1979	Program Chairman
	1983-84	President
	1984-86	Board of Directors
1980-	Society for the Study of Inborn Errors of Metabolism	Member
1986-	International Society for Neonatal Screening	Member

COMMUNITY SERVICE RELATED TO PROFESSIONAL WORK

1968-75	Medical Research Committee	Mass Assoc for Retarded Citizens
1991-	Advisory Board	New England Connection for PKU and Allied Metabolic Disorders
1994-	Advisory Board	Scott Foster Memorial Fund for MSUD
1995-2000	Scientific Review Committee	Mass Chapter, March of Dimes

EDITORIAL BOARDS

1992-96	Co-Editor-in-Chief	Screening
1976-	Ad Hoc Reviewer	N Engl J Med
1978-	Ad Hoc Reviewer	J Pediatr
1978-	Ad Hoc Reviewer	Pediatrics
1983-	Ad Hoc Reviewer	J Inherit Metab Dis
1986-	Ad Hoc Reviewer	J Clin Invest
1984-	Ad Hoc Reviewer	Am J Hum Genet
2000-	Ad Hoc Reviewer	Genetics in Medicine
1997-	Ad Hoc Reviewer	J Chromatog
1999-	Ad Hoc Reviewer	J Med Screening
1997-	Ad Hoc Reviewer	Mol Genet Metab
1993-	Ad Hoc Reviewer	Am J Med Genet
1994-	Ad Hoc Reviewer	Clin Chem
1997-	Ad Hoc Reviewer	Human Genet

1993-	Ad Hoc Reviewer	JAMA
1997-	Ad Hoc Reviewer	J Pediatr Gastroenterol Nutr
2002-	Ad Hoc Reviewer	Human Mutation
2015 -	Editorial Board	International Journal of Neonatal Screening (IJNS)
2016-	Editorial Board	J Pediatr Biochem (JPB)

AWARDS AND HONORS

1972	Alfred L. Frechette Award for Public Health, Massachusetts Department of Public Health
1996	Robert Guthrie Award for Advances in Biochemical and Molecular Genetics, American Association for Mental Retardation
1997	Robert Guthrie Award in World-Wide Recognition of Outstanding Contributions to Newborn Screening, International Society for Neonatal Screening
2003	Allen Crocker Award, New England Regional Genetics Group
2012	Asbjørn Følling Award, European Society for Phenylketonuria
2013	Distinguished Alumnus Award, Medical College of Georgia
2014	PKU "Hero" Award, National PKU Alliance
2015	Harland Sanders Award for Lifetime Achievement in Genetics, March of Dimes

PART II: RESEARCH, TEACHING, AND CLINICAL CONTRIBUTIONS

A. NARRATIVE REPORT

My career as a physician-scientist has involved three areas of biochemical genetics - neonatal screening, the teratogenic effects of maternal inborn errors of metabolism, and investigation of several specific inborn errors.

During my metabolic training under Mary Efron and Hugo Moser at the MGH I learned about neonatal screening and the possibility this offered in preventing mental retardation and other neurologic disability. I also soon discovered that much was still unknown about the medical and biochemical implications of the disorders identified by neonatal screening and that this lack of knowledge had tragic consequences. Consequently, after completing my fellowship I joined the Massachusetts (later New England) Newborn Screening Program at the State Laboratory Institute while continuing my research at the MGH, subsequently at both the MGH and Children's Hospital and, since 1990, exclusively at Children's Hospital. It was this unique situation that enabled me to establish a medical and scientific foundation to newborn screening. This included studies establishing the importance of newborn screening in preventing the mental retardation of phenylketonuria (21), of the reliability of screening in specimens collected within the first day of life (63, 111, 166), of the relationship between the newborn screening findings and biochemical and clinical phenotypes in phenylketonuria (28, 84, 96) and galactosemia (47, 51, 52, 53, 66, 120, 129, 155; review 17), establishing histidinemia as

essentially a non-disease not relevant to newborn screening (42, 71, 72) and examinations of other screened inborn errors.

Most recently I initiated and led the successful effort in Massachusetts to expand newborn screening. This involved calling the attention of the Department of Public Health to the importance of expansion and the methodologies that can be used in screening which, in turn, led to the development of the state Newborn Screening Advisory Committee on which I served as a member. I now lead this effort nationally. I believe I am considered one of the foremost advocates for expanded newborn screening nationally and internationally. I am now leading a long-term study of outcome in expanded newborn screening (182, 187, 193).

Outside of newborn screening, I have contributed to an understanding in several areas of amino acid and carbohydrate disorders. One of my most notable achievements in establishing the heterogeneity of homocystinuria by the first description of homocystinuria occurring in other than the classical cystathionine β-synthase deficiency. This description was of the cobalamin (B_{12}) metabolic disorder now known as cblC defect (13, 16). Beyond expanding our understanding of homocystinuria, our studies led to our present understanding of vitamin-related cofactors in the etiology of metabolic disorders. Among the additional disorders in which I have contributed are phenylketonuria (60, 84, 94, 98, 108, 110, 115, 149, 184), galactosemia (48, 49, 70, 89, 130, 150), histidinemia (14, 22, 24) and methylmalonic acidemia (85, 93, 114).

I consider myself to be a moving force in an understanding of the teratogenic implications of maternal inborn errors. My study in 1980, which compiled and examined virtually all of the information available about maternal phenylketonuria (PKU), brought this very troubling teratogenic complication of pregnancy in phenylketonuria (PKU) to the attention of the metabolic community (59). The data from

this study has been the hallmark for a comprehensive understanding of maternal PKU and for examining the results of studies of treatment designed to prevent the teratogenesis. I organized and led the first comprehensive study of maternal PKU, the New England Maternal PKU Project (97) and, subsequently, was one of the organizers of the international Maternal PKU Collaborative Study (MPKUCS). I served as Associate Director of the MPKUCS and PI of its Northeast Contributing Center for the 18 years of the study. My studies in maternal PKU have had a major impact on treatment and prevention of teratogenic effects. These studies have been reported in numerous articles (65, 69, 77, 78, 107, 122, 126, 133, 135, 140, 147, 148). From my experience in maternal PKU I have recognized the importance of examining the effects of pregnancy in other inborn errors (91, 186, 191, 198).

At Children's Hospital I expanded what was primarily a PKU Clinic into a large and comprehensive clinical and clinical research program for inborn errors of metabolism. My recognition in the early 1980's of the vital role of molecular genetics in these metabolic disorders led me to redirect the primary affiliation of the program from the Developmental Evaluation Clinic to the Genetic Service, where it remains today. Within this program I have taught and continue to teach a generation of fellows, house officers and medical students through lectures, informal sessions, and individual

mentoring. Since 1988, my involvement is full-time at Children's Hospital where I see patients with biochemical genetic disorders and conduct clinical research.

In my current research I continue to lead an effort to examine the benefits and outcomes of expanded newborn screening using the technology of tandem mass spectrometry. I am also continuing to examine the teratogenic potential of the array of maternal inborn errors of metabolism and have expanded my interests into studies aimed at developing an innovative therapy for PKU.

B. FUNDING INFORMATION

1968-80	Children's Bureau	PI	Newborn Urine Screening for Inborn Errors of Metabolism
1977-94	NINCDS, NS RO1 NS05096	Investigator	New Amino Acid Disorders in Cerebral Disease
1981-84	HRSA/MCHB	PI	New England Maternal PKU Project
1984-2002	NICHD Contract No1-HD-2-3149	PI	Effects of Maternal Phenylketonuria (PKU) on Pregnancy Outcome
1989-93	ILSI	PI	Fetal Effects and Offspring Outcome in Maternal Mild Hyperphenylalaninemia
1989-	NIGMS	Faculty Member	HMS Training Grant for Genetics
1998-2000	Scientific Hospital Supplies	PI	Assessment of the Phenylalanine-Free Formula Phlexy-10
1999	New England Regional Genetics Group	Investigator	New England Consortium of Metabolic Programs Group
1999-2002	HRSA/MCHB Project 5H46 MC 00158-02	PI	Expanded Newborn Screening for Metabolic Disorders: Model Program for the Integration of Health Services
1999	Mead Johnson	PI	Clinical Experience with 3360-B in the Dietary Management of Phenylketonuria
2000-06	NIH (ELSI) R01 HG02085	Co-Investigator	Expanded Newborn Screening for Metabolic Disorders
2000-03	MCH Research MCHB 2R40 MC 00162-02	Co-Investigator	The Maternal PKU Resource Mothers Program
2001-04	NICHD Contract No1-HD-1-3326	Co-Investigator	Maternal PKU Resource Mothers Program
2002-04	Scientific Hospital Supplies CHB Project #84171	PI	Assessment of Phlexy-10 Phenylalanine-free Amino Acid Tablets
2004-05	BioMarin Pharmaceuticals, Inc. Contract signed, # pending	PI	Clinical Trial of BH4 Cofactor in the Treatment of Phenylketonuria
2004-07	HRSA/MCHB Grant 1 U22MC03959-01-00	Co-Investigator	Heritable Disorders
2009-	BioMarin Pharmaceuticals, Inc. Unrestricted industry grant	PI	Untreated Mild-Hyperphenylalinemia Study
2009-	BioMarin Pharmaceuticals, Inc. Unrestricted industry grant	PI	PKUDOS Registry

C. CURRENT RESEARCH ACTIVITY

NEWBORN SCREENING

My major research activity is the evaluation of expanded newborn screening for inborn errors of metabolism. The expansion of newborn screening has been made possible by the recent application of tandem mass spectrometry to the dried blood filter paper specimen used in newborn screening. This allows screening for 20-30 disorders of amino acid, organic acid and fatty acid metabolism in addition to the 7-9 disorders previously screened. I led the effort to convince Massachusetts to expand screening but realize the issues this expansion raises. Our studies are addressing these issues by examining the medium and long term follow up of the Massachusetts and Pennsylvania infants and their families, their medical, biochemical and neuropsychological outcomes in relation to early treatment, the specific biochemical and molecular diagnoses in relation to the newborn screening findings, the parental responses to diagnosis and treatment, and the effects of false-positive screening results on the child and the family. The results in the cohort detected by screening are being compared to identically examined cohorts who are clinically identified in other New England states. These studies are currently funded by NIH (ELSI) (RO1 HGO2085) and NICHD contract No1-HD-1-3326 (180-182 187, and reviews 90, 95, 100 describe preliminary results of these studies).

TERATOGENICITY AND ITS PREVENTION IN THE MATERNAL INBORN ERRORS OF METABOLISM

Our research in this area includes long-term follow up of offspring from treated maternal PKU and untreated non-PKU maternal mild hyperphenylalaninemic pregnancies, correlating the outcome with maternal genotype and biochemical control during the pregnancies. We are continuing to examine teratogenesis in other maternal inborn errors, notably homocystinuria (186), histidinemia (198), Hartnup disorder (91), and hypermethioninemia due to MAT I/III deficiency (191).

USE OF TYROSINE ENHANCEMENT IN THE THERAPY OF PHENYLKETONURIA

The role of reduced tyrosine in the pathogenesis of phenylketonuria has long been a question. Tyrosine would seem to be important. In phenylketonuria it cannot be biosynthesized. Its concentration in phenylketonuria is virtually always reduced in body fluids. Tyrosine is not only a protein amino acid but is the precursor of the catecholamine neurotransmitters. CSF levels of catecholamine metabolites in PKU are low. Thus, the often sub-optimal cognitive and achievement outcomes in children and adults with treated phenylketonuria have been linked to tyrosine deficiency. Our studies have shown that tyrosine supplementation produces a biphasic rather than consistent response in the blood tyrosine concentration, resulting in substantial periods when the blood tyrosine level is low and insufficient to overcome blood:brain barrier inhibition to tyrosine transport in the face of the mild increase in blood phenylalanine of treated phenylketonuria. The challenge is to induce a consistently normal or mildly increased level of tyrosine in treated phenylketonuria. For this we are proposing to examine nitisinone,

a medication that which inhibits tyrosine degradation proximally and is used effectively and safely in the treatment of the metabolic disorder tyrosinemia I by reducing the toxic distal metabolites. However, patients receiving NTBC have an increased concentration of tyrosine. We have sought to exploit this latter effect of NTBC to consistently raise the tyrosine level in PKU. Our preliminary studies have involved examining NTBC in the PAH^{enu2} mouse model for phenylketonuria. We have shown that in this model it is safe and consistently raises the blood and brain tyrosine levels. Brain catecholamine levels were also raised in the NTBC-treated mice. Swedish Orphan, the distributors of NTBC, has agreed to provide the NTBC to us for human studies. Presently we are working with Swedish Orphan, FDA and Children's Hospital to initiate these studies.

D. REPORT OF TEACHING

LOCAL CONTRIBUTIONS

MEDICAL SCHOOL

1992-95	HMS I GER (now GDRB) Course	Tutor	8 Students	18 hrs/wk 9 wks/yr
1990-95	HST Biochemical Genetics Course	Lecturer	6-8 Medical Students 3-4 Undergraduates	Hrs/wk 2 wks/yr
1996-99	HMS III Introduction to Pediatrics Tutor (CHB)		4 Students	12 hrs/yr
1996-99	HST Neurobiology 205	Lecturer	6 Medical Students 6 Undergraduates	10 hrs 2 times/yr
2004	Bedside Teaching (CHB)	Teaching Attending	Residents, Students, (~12)	5 hrs/wk 2 wks/yr

GRADUATE MEDICAL COURSES

1968-	Biochemical Genetics (HMS Medical Genetics Training Program)	Lecturer, Mentor	4-6 Fellows 1-2 Residents 1-2 Medical Students	6 hrs/wk 40 wks/yr
1968-	Newborn Screening (State Laboratory Institute)	Lecturer	1-2 Fellows 1-2 Residents 1 Medical Student	2 hrs/wk 40 wks/yr
2000	HMS Medical Genetics Training Program, Biochemical Genetics Program	Director and Lecturer	12 Fellows 1-2 Residents 1-2 Medical Students	3-4 hrs/wk 14 wks/yr
2000	HMS Neuroresearch Seminar	Lecturer	5 Fellows 8 Residents	5 hrs

2000-	HMS Medical Genetics Training Program, Biochemical Genetics Journal Club		12-15 Fellows	4 hrs/mo 7 mo/yr

LOCAL INVITED TEACHING PRESENTATIONS

1968-92	Genetics Pre-Clinic Conference (MGH) Seminar	Lecturer	2-3 Fellows 4-5 Senior Staff (varied) 1-2 Resident 1-2 Medical Students	1-10 hrs/year
1977	Clinical Pathology Presentation (CHB)		Residents, Fellows, Students, Staff (~100)	10 hours
1978-	Seminar in Genetics, Metabolism (CHB)	Lecturer	Residents, Fellows, Students, (~5-10)	100 hrs/yr
1978-	Pediatric Practice Lectures (CHB)	Lecturer	Attendings, Staff (~25)	8 hrs/yr
1996	Grand Rounds (MGH for Children)	Lecturer	Residents, Students, Staff (~50-75)	
1996	Grand Rounds (Medicine, MGH)	Lecturer	Residents, Students, Staff (~150)	
2003	Helen S. Jones Lecture	Lecturer	Residents, Students, Staff (~150)	
1968-	Grand Rounds (numerous local medical centers and hospitals)	Lecturer	Residents, Students, Staff	4 hrs/mo 6 mo/yr

CONTINUING MEDICAL EDUCATION COURSES

1986-2003	HMS Human Teratogens	Lecturer	6 hrs/yr
1990	HMS Pediatric Endocrinology	Lecturer	6 hrs
1989-91	MGH Child Neurology	Lecturer	8 hrs/yr
1995	New York Univ, Neurogenetics	Lecturer	10 hrs
1996	Univ of Minnesota, Pediatrics	Lecturer	8 hrs
1999	New York Univ, Neurogenetics	Lecturer	10 hrs

ADVISOR IN A CLINICAL SETTING

1994-	Mentor to Fellows in HMS Medical Genetics Training Program	50 hrs/yr

TEACHING LEADERSHIP ROLE

2000-	Biochemical Genetics Course, HMS Medical Genetics Training Program	Director	Introduced case teaching into course with patient presentations. Course was enthusiastically graded by fellows.

TRAINEES

1983-85	Mira Irons	Clinical Director, Div of Genetics, CHB Associate Prof of Pediatrics, HMS	Boston
1983-86	Barbara Pober	Under consideration for Assoc Prof of Pediatrics, HMS (Formerly Assoc Prof of Pediatrics, Yale University School of Medicine) Geneticist, Dept of Surgery and Division of Genetics, CHB Pediatrician, MGH	Boston
1984-87	Alan Guttmacher	Senior Clinical Advisor to Director, National Human Genome Research Institute, NIH	
1985-87	Holmes Morton	Director and Founder, Clinic for Special Children	Strasburg, PA
1985-88	Mark Korson	Director of Biochemical Genetics, Tufts-New England Medical Center Associate Prof of Pediatrics, Tufts University School of Medicine	Boston
1987-89	Kenneth Kupke	Director of Newborn Medicine, Scottish Rite Medical Center	Atlanta
1987-89	Matthew Warman	Associate Professor of Pediatrics, Western Reserve School of Medicine Director, Center for Genetic Bone Disease	Cleveland
1990-93	Stuart Shapira	Assoc Prof of Genetics and Metabolic Disorders and Chief, Div of Genetics, Univ of Texas Health Science Center	San Antonio
1990-93	Frances Dougherty	Director of Biochemical Genetics, Horizon Molecular Medicine	Atlanta
1993-96	Ellis Neufeld	Clinical Director, Div of Hematology, CHB Associate Prof of Pediatrics, HMS	Boston

1995-99	Sook Za Kim	Prof of Genetics and Director of Biochemical Genetics and Newborn Screening Program Chungnam National Univ	Korea
1997-2001	Judith Peterschmitt	Associate Medical Director for Clinical Research, Genzyme Corp	Cambridge, MA
1999-2001	Simone Albers-Bremer	Assistant Prof of Pediatrics, Universitaets-Kinderklinik Universitat Müenster	Müenster, Germany
2002-2003	Jonathan Picker	Instructor in Pediatrics, HMS Staff Physician, Genetics, CHB	Boston
2001-2004	Edward Neilan	Instructor in Pediatrics, HMS Staff Physician, Genetics, CHB	Boston
2008-2009	Philip James	Instructor in Pediatrics, HMS Staff Physician, Clinical and Biochemical Genetics CHB	Boston
2008-2009	Joseph Thakuria	Instructor in Pediatrics, HMS Staff Physician, Clinical and Biochemical Genetics MGH	Boston

REGIONAL, NATIONAL, OR INTERNATIONAL CONTRIBUTIONS (REPRESENTATIVE)

INVITED PRESENTATIONS

1967-79	Lecturer in Pediatric Metabolic Disease	Boston Univ Graduate School of Dentistry
1975	Visiting Professor	Japanese Society for Metabolic Disorders
1976	Visiting Professor of Pediatrics	Univ of British Columbia
1991	McDonald Oration	Princess Margaret Hospital for Children, Perth, Australia
1991	Plenary Presentation	Metabolic Information Network Washington
1991	Plenary Presentation	8th National Neonatal Screening Symposium, Saratoga Springs, NY
1993	Plenary Presentation	Southeast Regional Genetics Meeting Emory Univ, Atlanta, GA
1993	Plenary Presentation	9th International Neonatal Screening Symposia, Lille, France

1994	Louis Sauer Visiting Professor	The Evanston Hospital Evanston, IL

INVITED PRESENTATIONS (CONT)

1996	SHS Lecture and Visiting Professor	The Children's Hospital Dublin, Ireland
1997	Visiting Professor	Chungham National Univ Korea
1997	Plenary Presentation	7th International Congress of Inborn Errors of Metabolism Vienna, Austria
1997	University Lecture	Chungham National University Korea
1997	Plenary Presentation	European Society of PKU Prague, Czech Republic
1999	Meinhard Robinow Visiting Prof and Lecturer	Children's Medical Center Dayton, OH
2000	Robert Guthrie Memorial Lecture	Children's Hospital of Buffalo Buffalo, NY
2001	Plenary Presentation	Genetic Screening for Primary Immunodeficiency Diseases, CDC Atlanta, GA
2002	Keynote Lecture	5th Meeting of the International Society for Neonatal Screening Genoa, Italy
2002	Plenary Presentation	Newborn Screening Society of Mexico Monterrey, Mexico
2002	Visiting Professor	Medical College of Georgia Augusta, GA
2002	Plenary Presentation	40th Anniversary Meeting of the Society for the Study of Inborn Errors of Metabolism Dublin, Ireland
2002	Plenary Presentation	Annual Meeting of the American Society of Law, Medicine and Ethics Boston, MA
2002	Plenary Presentation	4th Annual Braden E. Griffin Memorial Symposium, New England Association of Neonatalogists Marlboro, MA

2002	Plenary Presentation	National Coalition for PKU and Allied Disorders Orlando, FL

INVITED PRESENTATIONS (CONT)

2003	Plenary Session, Presentation and Chairman	3rd National Meeting on Newborn Screening by Tandem Mass Spectrometry Berkeley, CA
2004	Thomas E. Cone, Jr, MD Lecture	American Academy of Pediatrics San Francisco, CA
2013	Asbjørn Følling Lecture	European Society for Phenylketonuria
1970-	Grand Rounds at Medical Centers	Most frequent topics have been newborn screening, maternal PKU and other maternal inborn errors, and diagnosis of metabolic disorders in the U.S. and Canada

PROFESSIONAL SOCIETY MEETING COMMITTEES

1987	International Organizing Committee 4th International Congress of Inborn Errors of Metabolism	Sendai, Japan
1988	International Scientific Committee International Screening Symposium of Inborn Errors of Metabolism	Sao Paulo, Brazil
1990-94	Advisory Panel on Perinatal Pediatrics International Pediatric Assoc	
1990	International Scientific Committee 1st Meeting of the International Society of Neonatal Screening	Tokyo, Japan
1991	International Scientific Committee 5th International Congress of Inborn Errors of Metabolism	Monterey, CA
1991	International Committee 8th International Neonatal Screening Symposium	NSW, Australia
1991-94	Prenatal Pediatrics and Developmental International Pediatric Abnormalities Panel Assoc	
1993	International Scientific Committee 2nd meeting of the International Society of Neonatal Screening	Lille, France
1993	International Organizing Committee 1st Asian Pacific Meeting of the International Society of Neonatal Screening	Sapporo, Japan
1994	International Organizing Committee 6th International Congress of Inborn Errors of Metabolism	Milan, Italy

1996	Scientific Advisory Committee, Chairman 3rd International Meeting of the International Society for Neonatal Screening, Boston Inborn Errors of Metabolism	Milan, Italy

PROFESSIONAL SOCIETY MEETING COMMITTEES (CONT)

1997	International Scientific Committee 7th International Congress of Inborn Errors of Metabolism,	Vienna, Austria
2002	Scientific Advisory Board 5th meeting of the International Society of Neonatal Screening	Genoa, Italy
2003-2004	International Organizing Committee, 5th Asia Pacific Regional Meeting of the International Society for Neonatal Sreeening	Shanghai, China
2007	Scientific Committee, International Symposium on PKU and other hyperphenylalaninemias	Fulda, Germany
2009	International Scientific Committee, Phenylketonuria Conference	Munich, Germany
2009	Scientific Committee, Latin American Congress of the International Society for Neonatal Screening	Cancun, Mexico

TEACHING AWARDS

None

MAJOR CURRICULUM OFFERINGS

- HMS Genetics Trainees
  Formal Biochemical genetics course (15 lectures with several case presentations)
- Genetics fellows
  Developed and conducted lectures and case presentations on biochemical genetics for fellows at Children's Hospital since coming to Children's in 1978.

E. REPORT OF TEACHING

DESCRIPTION OF CLINICAL PRACTICE

Exclusive clinical focus has been in biochemical genetics. At the MGH I saw patients in the Genetics Clinic and at other times referred for problems believed to be of biochemical genetic nature and infants referred for newborn screening findings. Also was inpatient metabolic consultant for the Children's and Neurology services. At Children's Hospital I assumed this role as Director of the Metabolic Program from 1978 until 1988 when I turned over directorship for the clinic to Dr. Mark Korson. Since 1988 I have continued to see patients in the clinic, adding women with maternal PKU and other maternal inborn errors pregnancies and the offspring from these pregnancies.

PATIENT LOAD

From 1978-88 I saw about 25 patients per week with or suspected of having biochemical genetic disorders. Before 1978 and since 1988, I have seen about 10-15 patients per week. The problems these patients have are complex, requiring an understanding of their symptoms in relation to biochemical genetic disorders and the pathways, catabolic enzymes and molecular characteristics of the disorders. This is essential for diagnosis, choosing appropriate biochemical and molecular assays, treatment, biochemical monitoring, prognosis, and counseling and other aspects of the clinical follow up after diagnosis.

CLINICAL CONTRIBUTIONS

I have made numerous contributions to clinical diagnosis. Among these are the descriptions of B_{12} metabolic defect (13, 16), macular degeneration associated with cblC defect (81), vitreous hemorrhage as a clinical feature of galactosemia (150), clinical characteristics of tyrosinemia I (175) and of homocystinuria (88; review 92), a simple skin test to confirm histidinemia (14), the cutaneous features of prolidase deficiency (83), E. coli sepsis as a clinical feature of galactosemia (52), and the teratogenic phenotype of maternal PKU (review 78). My chapters on disorders of histidine metabolism (review 91) and on Hartnup disorder (review 93) serve as the major comprehensive descriptions of clinical diagnosis in these inborn errors. The forthcoming chapter on phenylketonuria which I co-author will be the definitive description of that key metabolic disorder (review 106).

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