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STATE OF NEW HAMPSHIRE  
 DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 DIVISION OF PUBLIC HEALTH SERVICES

Lori A. Shibinette  
 Commissioner

Patricia M. Tilley  
 Director

29 HAZEN DRIVE, CONCORD, NH 03301  
 603-271-4501 1-800-852-3345 Ext. 4501  
 Fax: 603-271-4827 TDD Access: 1-800-735-2964  
 www.dhhs.nh.gov

June 9, 2022

His Excellency, Governor Christopher T. Sununu  
 and the Honorable Council  
 State House  
 Concord, New Hampshire 03301

**REQUESTED ACTION**

Authorize the Department of Health and Human Services, Division of Public Health Services, to enter into a contract with University of Massachusetts (VC#177576-B008), Worcester, MA, in the amount of \$4,754,820 for newborn screening laboratory services, with the option to renew for up to three (3) additional years, effective July 1, 2022, or upon Governor and Council approval, whichever is later, through June 30, 2025. 100% Other Funds (Newborn Screening Revolving Funds).

Funds are available in the following account for State Fiscal Year 2023, and are anticipated to be available in State Fiscal Years 2024 and 2025, upon the availability and continued appropriation of funds in the future operating budget, with the authority to adjust budget line items within the price limitation and encumbrances between state fiscal years through the Budget Office, if needed and justified.

**05-095-090-902010-5240 HEALTH & SOCIAL SERVICES, DEPARTMENT OF HEALTH & HUMAN SERVICES, HHS: PUBLIC HEALTH DIV, BUREAU OF COMM HEALTH & SERV, NEWBORN SCREENING REVOL FUNDS**

State Fiscal Year	Class / Account	Class Title	Job Number	Total Amount
2023	102-500731	Contracts for Program Svcs	90080013	\$1,536,920
2024	102-500731	Contracts for Program Svcs	90080013	\$1,584,380
2025	102-500731	Contracts for Program Svcs	90080013	\$1,633,520
			<b>Total</b>	<b>\$4,754,820</b>

**EXPLANATION**

The purpose of this request is to provide newborn screening laboratory services. Since the establishment of RSA 132:10a in 1965, the State of New Hampshire has been responsible for the screening of all infants born in the state. The goal of newborn screening is the prevention of disability and untimely death of newborns from undiagnosed metabolic and genetic disorders.

His Excellency, Governor Christopher T. Sununu  
and the Honorable Council  
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New Hampshire is currently screening all infants born in the state for a panel of thirty-seven (37) disorders.

Approximately 36,000 infants will be served combined during State Fiscal Years 2023, 2024, and 2025.

The Contractor will provide laboratory services for all newborns born in the State of New Hampshire. The Department requested, in the Request for Proposal, the Contractor to outline their all-inclusive rate per test and itemize the cost associated with that rate. This allows the Department to anticipate cost per month and negotiate rates as needed.

The Contractor supplies Department approved filter paper collection kits to birthing centers, hospitals, and medical provider offices as required for the collection and identification of blood samples, and for gathering the necessary clinical information. A few drops of blood are taken from an infant's heel 24-48 hours after birth, in accordance with RSA 132:10a. Families have the option to decline screening. The Contractor will coordinate a courier service to all designated birthing facilities in New Hampshire for transporting blood samples to the testing facility including pickup and delivery seven (7) days a week. Once the results are available, the Contractor provides the results to the Department.

The Department will monitor contracted services using the following performance measures:

- At least ninety-eight percent (98%) of Congenital Adrenal Hyperplasia results will be reported to the New Hampshire Newborn Screening Program within three (3) days of the contractor receiving the dried blood specimen.
- At least ninety-five percent (95%) of all screening reports will have a report date within seven days of specimen.

The Department selected the Contractor through a competitive bid process using a Request for Proposals (RFP) that was posted on the Department's website from September 1, 2021 through October 13, 2021. The Department received one (1) response that was reviewed and scored by a team of qualified individuals. The Scoring Sheet is attached.

As referenced in Exhibit A of the attached agreement, the parties have the option to extend the agreement for up to three (3) additional years, contingent upon satisfactory delivery of services, available funding, agreement of the parties, and Governor and Council approval.

Should the Governor and Executive Council not authorize this request, New Hampshire will be out of compliance with the mandate established in RSA 132:10a, and New Hampshire children may be in jeopardy of serious harm, potentially even death and could result increased costs to state.

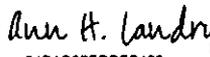
Area served: Statewide

His Excellency, Governor Christopher T. Sununu  
and the Honorable Council  
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Source of Federal Funds: 100% Other Funds (Newborn Screening Revolving Funds)

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

Respectfully submitted,

DocuSigned by:  
  
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Lori A. Shibinette  
Commissioner

**New Hampshire Department of Health and Human Services  
Division of Finance and Procurement  
Bureau of Contracts and Procurement  
Scoring Sheet**

**Project ID #** RFP-2022-DPHS-02-NEWBO

**Project Title** Newborn Screening Laboratory Services

	Maximum Points Available	UMass	
<b>Technical</b>			
5.2.1. Experience (Q1)	25	25	
5.2.2. Confidentiality (Q2)	40	35	
5.2.3. Work plan (Q3)	25	20	
5.2.4. Courier Services (Q4)	40	20	
5.2.5. System (Q5)	15	12	
5.2.6. Capacity (Q6)	40	40	
<b>Subtotal - Technical</b>	<b>185</b>	<b>152</b>	
<b>Cost</b>			
5.3.1. Appendix D - Rate Sheet	150	150	
<b>Subtotal - Cost</b>	<b>150</b>	<b>150</b>	
<b>TOTAL POINTS</b>	<b>335</b>	<b>302</b>	

**Reviewer Name**

1 Paula M. Minnehan

2 Amanda Merrill

3 Courtney Keane

4 Colleen Pouliot

**Title**

Senior Vice President, State Government Relations

Program Coordinator

Program Manager

Registered Nurse



**STATE OF NEW HAMPSHIRE**  
**DEPARTMENT OF INFORMATION TECHNOLOGY**  
27 Hazen Dr., Concord, NH 03301  
Fax: 603-271-1516 TDD Access: 1-800-735-2964  
[www.nh.gov/doit](http://www.nh.gov/doit)

**Denis Goulet**  
*Commissioner*

April 27, 2022

Lori A. Shabinette, Commissioner  
Department of Health and Human Services  
State of New Hampshire  
129 Pleasant Street  
Concord, NH 03301

Dear Commissioner Shabinette:

This letter represents formal notification that the Department of Information Technology (DoIT) has approved your agency's request to enter into a contract with University of Massachusetts of Worcester, MA, as described below and referenced as DoIT No. 2021-038.

The Department of Health and Human Services requests approval to enter into a contract with University of Massachusetts for newborn screening laboratory services. Since the establishment of RSA 132:10a in 1965, the State of New Hampshire has been responsible for the screening of all infants born in the state. New Hampshire is currently screening all infants born in the state for a panel of thirty-seven (37) disorders.

The cost of the contract is not to exceed \$4,754,820.00 and it shall become effective upon Governor and Council approval through June 30, 2025.

A copy of this letter should accompany the Department of Health and Human Services' submission to Governor and Executive Council for approval.

Sincerely,

A handwritten signature in black ink, appearing to read "Denis Goulet", with a horizontal line extending to the right.

Denis Goulet

DG/RA  
DoIT #2021-038  
cc: Matthew Ensign, DoIT

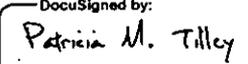
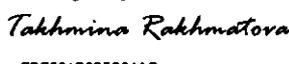
Subject: a\$Newborn Screening Laboratory Services (RFP-2022-DPHS-02-NEWBO-01)

**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 129 Pleasant Street Concord, NH 03301-3857	
1.3 Contractor Name University of Massachusetts		1.4 Contractor Address 377 Plantation Street Worcester, MA 01605	
1.5 Contractor Phone Number (774) 455-4600	1.6 Account Number 05-095-090-902010-5240	1.7 Completion Date June 30, 2025	1.8 Price Limitation \$4,754,820
1.9 Contracting Officer for State Agency Robert W. Moore, Director		1.10 State Agency Telephone Number (603) 271-9631	
1.11 Contractor Signature DocuSigned by:  Date: 6/14/2022		1.12 Name and Title of Contractor Signatory Patti A. Onorato Deputy Executive Vice Cha	
1.13 State Agency Signature DocuSigned by:  Date: 6/14/2022		1.14 Name and Title of State Agency Signatory Patricia M. Tilley Director	
1.15 Approval by the N.H. Department of Administration, Division of Personnel (if applicable) By: _____ Director, On: _____			
1.16 Approval by the Attorney General (Form, Substance and Execution) (if applicable) By:  On: 6/15/2022			
1.17 Approval by the Governor and Executive Council (if applicable) G&C Item number: _____ G&C Meeting Date: _____			

**2. 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 B 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 1.17, 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 1.13 ("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 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 for Services provided in EXHIBIT B, in whole or in part. 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 reduce or terminate the Services under this Agreement immediately upon giving the Contractor notice of such reduction or termination. The State shall not be required to transfer funds from any other account or source 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 C 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 applicable 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 employment opportunity laws. In addition, if this Agreement is funded in any part by monies of the United States, the Contractor shall comply with all federal executive orders, rules, regulations and statutes, and with any rules, regulations and guidelines as the State or the United States issue to implement these regulations. The Contractor shall also comply with all applicable intellectual property 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. The Contractor 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 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.

Contractor Initials   
Date 6/14/2022

**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 cured, 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 give the Contractor a written notice specifying the Event of Default and 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 give the Contractor a written notice specifying the Event of Default, treat the Agreement as breached, terminate the Agreement and pursue any of its remedies at law or in equity, or both.

8.3. 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.

**9. TERMINATION.**

9.1 Notwithstanding paragraph 8, the State may, at its sole discretion, terminate the Agreement for any reason, in whole or in part, by thirty (30) days written notice to the Contractor that the State is exercising its option to terminate the Agreement.

9.2 In the event of an early termination of this Agreement for any reason other than the completion of the Services, the Contractor shall, at the State's discretion, 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 B. In addition, at the State's discretion, 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.

**10. DATA/ACCESS/CONFIDENTIALITY/PRESERVATION.**

10.1 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.

10.2 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.

10.3 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.

**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.**

12.1 The Contractor shall not assign, or otherwise transfer any interest in this Agreement without the prior written notice, which shall be provided to the State at least fifteen (15) days prior to the assignment, and a written consent of the State. For purposes of this paragraph, a Change of Control shall constitute assignment. "Change of Control" means (a) merger, consolidation, or a transaction or series of related transactions in which a third party, together with its affiliates, becomes the direct or indirect owner of fifty percent (50%) or more of the voting shares or similar equity interests, or combined voting power of the Contractor, or (b) the sale of all or substantially all of the assets of the Contractor.

12.2 None of the Services shall be subcontracted by the Contractor without prior written notice and consent of the State. The State is entitled to copies of all subcontracts and assignment agreements and shall not be bound by any provisions contained in a subcontract or an assignment agreement to which it is not a party.

**13. INDEMNIFICATION.** Unless otherwise exempted by law, the Contractor shall indemnify and hold harmless the State, its officers and employees, from and against any and all claims, liabilities and costs for any personal injury or property damages, patent or copyright infringement, or other claims asserted against the State, its officers or employees, which arise out of (or which may be claimed to arise out of) the acts or omission<sup>DS</sup> of the

Contractor Initials PO  
Date 6/14/2022

Contractor, or subcontractors, including but not limited to the negligence, reckless or intentional conduct. The State shall not be liable for any costs incurred by the Contractor arising under this paragraph 13. 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 continuously maintain in force, and shall require any subcontractor or assignee to obtain and maintain in force, the following insurance:

14.1.1 commercial general liability insurance against all claims of bodily injury, death or property damage, in amounts of not less than \$1,000,000 per occurrence and \$2,000,000 aggregate or excess; and

14.1.2 special cause of loss coverage form covering all property subject to subparagraph 10.2 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.

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 ten (10) days prior to the expiration date of each insurance policy. The certificate(s) of insurance and any renewals thereof shall be attached and are incorporated herein by reference.

**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. The 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. 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.

**17. 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.

**18. CHOICE OF LAW AND FORUM.** This Agreement shall be governed, interpreted and 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. Any actions arising out of this Agreement shall be brought and maintained in New Hampshire Superior Court which shall have exclusive jurisdiction thereof.

**19. CONFLICTING TERMS.** In the event of a conflict between the terms of this P-37 form (as modified in EXHIBIT A) and/or attachments and amendment thereof, the terms of the P-37 (as modified in EXHIBIT A) shall control.

**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 or modifying provisions set forth in the attached EXHIBIT A 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 with respect to the subject matter hereof.

**New Hampshire Department of Health and Human Services  
Newborn Screening Laboratory Services  
EXHIBIT A**

**Revisions to Standard Agreement Provisions**

**1. Revisions to Form P-37, General Provisions**

1.1. Paragraph 3, Subparagraph 3.1, Effective Date/Completion of Services, is amended as follows:

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 as indicated in block 1.17, this Agreement, and all obligations of the parties hereunder, shall become effective on July 1, 2022 ("Effective Date").

1.2. Paragraph 3, Effective Date/Completion of Services, is amended by adding subparagraph 3.3 as follows:

3.3. The parties may extend the Agreement for up to three (3) additional years from the Completion Date, contingent upon satisfactory delivery of services, available funding, agreement of the parties, and approval of the Governor and Executive Council.

1.3. Paragraph 12, Assignment/Delegation/Subcontracts, is amended by adding subparagraph 12.3 as follows:

12.3. Subcontractors are subject to the same contractual conditions as the Contractor and the Contractor is responsible to ensure subcontractor compliance with those conditions. The Contractor shall have written agreements with all subcontractors, specifying the work to be performed and how corrective action shall be managed if the subcontractor's performance is inadequate. The Contractor shall manage the subcontractor's performance on an ongoing basis and take corrective action as necessary. The Contractor shall annually provide the State with a list of all subcontractors provided for under this Agreement and notify the State of any inadequate subcontractor performance.

**2. Revisions to Standard Exhibits**

2.1. Subparagraph 25, Force Majeure, is hereby added to read as follows:

25. Neither Contractor nor the State shall be responsible for delays or failures in performance resulting from events beyond the control of such Party and without fault or negligence of such Party. Such events shall include, but not be limited to, acts of God, strikes, lock outs, riots, and acts of War, epidemics, acts of Government, fire, power failures, nuclear accidents, earthquakes, and unusually severe weather.

Except in the event of the foregoing, Force Majeure events shall not include the Contractor's inability to hire or provide personnel needed for the Contractor's performance under the Contract.

**New Hampshire Department of Health and Human Services  
Newborn Screening Laboratory Services  
EXHIBIT B**

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**Scope of Services**

**1. Statement of Work**

1.1. The Contractor shall provide newborn screening laboratory services for infants born in New Hampshire. The Contractor shall test for the following metabolic disorders in accordance with NH RSA 132:10-a, which includes, but is not limited to:

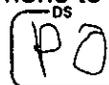
- 1.1.1. 3-Hydroxy-3-Methylglutaryl-CoA Lysase Deficiency.
- 1.1.2. 3-Methylcrotonyl-CoA Carboxylase Deficiency.
- 1.1.3. Argininosuccinic Aciduria.
- 1.1.4. Argininemia.
- 1.1.5. Biotinidase.
- 1.1.6. Carnitine Uptake Defect.
- 1.1.7. Carnitine Palmitoyltransferase II Deficiency.
- 1.1.8. Citrullinemia I (ASA Synthetase Def).
- 1.1.9. Cobalamin A, B.
- 1.1.10. Congenital Adrenal Hyperplasia (CAH).
- 1.1.11. Congenital Toxoplasmosis.
- 1.1.12. Cystic Fibrosis (CF).
- 1.1.13. Galactosemia.
- 1.1.14. Glutaric Aciduria Type I.
- 1.1.15. Homocystinuria (HCY).
- 1.1.16. Hyperornithinemia.
- 1.1.17. Hyperammoninemia.
- 1.1.18. Homocitrullinemia Syndrome.
- 1.1.19. Isovaleric Acidemia.
- 1.1.20. Long Chain 3-hydroxyacyl-CoA Dehydrogenase Deficiency.
- 1.1.21. Maple Syrup Urine Disease (MSUD).
- 1.1.22. Medium Chain Acyl CoA Dehydrogenase Deficiency (MCAD).
- 1.1.23. Methylmalonic Acidemia.
- 1.1.24. Mitochondrial Acetoacetyl-CoA Thiolase Deficiency.
- 1.1.25. Multiple Acyl-CoA Dehydrogenase Deficiency.
- 1.1.26. Multiple Carboxylase Deficiency.



**New Hampshire Department of Health and Human Services  
Newborn Screening Laboratory Services  
EXHIBIT B**

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- 1.1.27. Phenylketonuria (PKU).
- 1.1.28. Propionic Acidemia.
- 1.1.29. Sickle Cell Disease (Hemoglobinopathies – 3 types).
- 1.1.30. Trifunctional Protein Deficiency.
- 1.1.31. Tyrosinemia type I.
- 1.1.32. Very Long Chain Acyl-CoA Dehydrogenase Deficiency.
- 1.1.33. Severe Combined Immunodeficiency Disease (SCID).
- 1.1.34. Spinal Muscular Atrophy (SMA).
- 1.1.35. Pompe Disease.
- 1.1.36. Mucopolysaccharidosis type I (MPS I).
- 1.1.37. X-linked Adrenoleukodystrophy (X-ALD).
- 1.2. The Contractor shall maintain Clinical Laboratory Improvement Amendments (CLIA) Laboratory Certification and provide documentation of such CLIA Laboratory Certification to the Department.
- 1.3. The Contractor shall provide documentation of participation in the Centers for Disease Control and Prevention or the Association of Public Health Laboratories Newborn Screening Quality Assurance Program or other acceptable proficiency-testing program.
- 1.4. The Contractor shall carry out the laboratory analysis utilizing standardized, approved laboratory methods for the disorders listed in Section 1.1.1. In collaboration with the Department, if either party identifies an additional disorder not listed in Section 3.1.1., the following items shall be considered to add to the newborn screening panel, including but not limited to:
  - 1.4.1. The disorder is well defined with a known incidence.
  - 1.4.2. The disorder is associated with significant morbidity and/or mortality.
  - 1.4.3. The disorder can be detected with a screening test that is ethical, safe, accurate, and cost-effective.
  - 1.4.4. Effective treatment exists for the disorder, and that early treatment, meaning before the onset of symptoms, is more effective in improving health and outcomes than later treatment.
- 1.5. The Contractor shall supply approved filter paper collection kits to the Department for distribution to participating facilities, as required for the collection and identification of blood samples, and for gathering the necessary clinical information.
- 1.6. The Contractor shall supply pre-addressed envelopes for mailing specimens to the lab via the courier to the participating facility.



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- 1.7. The Contractor shall provide a courier service to transport blood samples from all designated birthing facilities in New Hampshire to the testing facility. Pickup and delivery must occur Sunday through Saturday using a high priority delivery option. The Contractor shall ensure blood samples being transported to the laboratory are posted by overnight mail, in accordance with U.S. Postal Service regulations, within 24 hours of collection.
- 1.8. The Contractor shall monitor courier services for performance and timeliness.
- 1.9. The Contractor shall provide the newborn screening program direct access to the courier service trip data, which includes but is not limited to:
  - 1.9.1. Specimen location.
  - 1.9.2. Transit history.
- 1.10. The Contractor shall report all screening test results within seven (7) days of receipt of the specimen from the New Hampshire birth hospitals and/or community-based health care providers to the Department's Newborn Screening Program.
- 1.11. The Contractor shall report to the Newborn Screening Program all out-of-range test results according to the urgency of the laboratory findings, upon completion of screening results. In addition, the laboratory shall make available to the Newborn Screening Program, condition-specific fact sheets, as a resource on the probable significance of the findings and recommendations for appropriate follow-up action.
- 1.12. Specimen Requirements
  - 1.12.1. The Contractor shall adhere to all legal requirements governing human subjects' research, when considering clinical or sociological research using clients as subjects. The Contractor shall inform the Department prior to initiating any research related to the awarded Agreement. No such samples may be used for other research or DNA testing purposes unless authorized by the infant's parent or guardian.
  - 1.12.2. The Department shall retain full ownership of all residual screening specimens. Decisions about retention/use of dried blood spots (DBS) are at the sole discretion of the Department, and must be consistent with the Newborn Screening Program New Hampshire Administrative Rules He-P 3008. Additional testing of specimens for other disorders is prohibited without express permission from the Department.
  - 1.12.3. The Contractor shall maintain storage of New Hampshire's residual screening specimens in an appropriate, climate-controlled, secure facility, in sealed bags of low gas permeability containing a desiccant and humidity indicator at -20C for six (6) months and must be consistent with the Newborn Screening Program New Hampshire Administrative Rule He-P 3008.

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- 1.12.4. The Contractor shall ensure residual DBS are destroyed six (6) months after the collection date, in a manner consistent with applicable state and federal requirements relating to disposal of human blood and body fluids per the Occupational Safety and Health Administration regulations 29 CFR, standard number 1910.1030.
- 1.12.5. In the event that the storage environment of any DBS is found to have deviated from the required conditions described above, such that the stability of the specimen is likely to have been affected, the DBS shall be destroyed and the Newborn Screening Program shall be notified immediately.
- 1.12.6. The Contractor shall describe and provide the Department with a contingency plan of operations to ensure maintenance of screening services in the event of a major disaster or emergency.
- 1.12.7. **Staffing Requirements**
  - 1.12.8. The Contractor shall ensure all persons performing DBS collection for newborn screening comply with the proper collection, handling, short-term storage, and transport of DBS in accordance with the Clinical and Laboratory Standards Institute (CLSI) "NBS 01-A6, Blood Collection on Filter Paper for Newborn Screening Programs, Approved Standard-Sixth Edition", including any updates.
  - 1.12.9. The Contractor shall maintain a listing of "on call" qualified specialists who are available by email and/or phone response, seven days/week, 24 hours/day to provide medical consultation as needed to the Newborn Screening Program and/or the physician of record.
  - 1.12.10. The Contractor shall provide urgent contact coverage for the Newborn Screening Program upon request when Newborn Screening Program staff is unavailable after normal work hours, weekends, holidays, and short-term weather emergencies, for notifying providers of out of range lab results.
  - 1.12.11. The Contractor may provide coverage for both urgent and non-urgent out of range results during other time periods. The Contractor may invoice the state for these additional services, if both the State and the Contractor agree to the specific terms.
  - 1.12.12. The Contractor shall notify the Department within one (1) month of hire when a new administrator or coordinator or any staff person essential to carrying out this scope of services is hired to work in the program. A resume of the employee shall accompany this notification.
  - 1.12.13. The Contractor shall notify the Department if any of the critical positions required for the delivery of these services are vacant for

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more than three months.

**1.13. Meetings and Trainings**

- 1.13.1. The Contractor shall provide assistance to the Newborn Screening Program staff and others, upon request, on issues related to supporting the infrastructure and facilitating the Newborn Screening Program's operations, including the provision of in-services and educational programs.
- 1.13.2. The Contractor shall provide technical support for the Newborn Screening Program on computer issues as needed and as it relates to the interface between the Department's system and the laboratory-computerized system.
- 1.13.3. The Contractor shall provide technical support and assistance upon request to the Department in support of the work of the New Hampshire Newborn Screening Advisory Committee. Either the director or assistant director of the Contractor's laboratory must attend the biannual committee meeting. The program must contact the lab to confirm availability before setting the date for the meeting.
- 1.13.4. The Contractor shall provide technical support for the Newborn Screening Program's management information system on accessing the laboratory results database.

**1.14. On Site Reviews**

- 1.14.1. The Contractor shall allow a team or individual authorized by the Department to periodically review their systems of governance, administration, data collection and submission, clinical and financial management in order to ensure systems are adequate to provide the contracted services.

**1.14.2. Information Technology Requirements**

- 1.14.3. The Contractor shall maintain all newborn laboratory test and result data in a computerized record system accessible to the laboratory performing the services and to the Newborn Screening Program, for a period no less than 21 years from the date of the test.
- 1.14.4. The Contractor shall meet all applicable information technology requirements for information technology systems in order to collect, store, and distribute client data. Any new Information Technology systems used or developed to support the services in this scope of services must conform to the requirements in Exhibit B-2 - Information Technology Requirements, when implemented.
- 1.14.5. The Contractor shall provide critical data elements, listed in Exhibit B-2 - Information Technology Requirements, necessary to ~~and~~

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determined by the New Hampshire Maternal and Child Health Section (MCHS) Data Linkage Project on a daily basis, or other schedule determined by MCHS, to enable the state to match the screening results with the electronic birth certificate (EBC).

1.14.6. The Contractor shall comply with minor modifications and/or additions to the proposed activities and report format as requested by MCHS. The MCHS will provide the Contractor with advance notice of such changes and the Contractor is not expected to incur any substantial costs relative to such changes.

1.14.7. The Contractor shall participate in Department planning, as needed, including planning for Electronic Medical Record (EMR) enhancements and Health Information Exchange (HIE). The Contractor shall provide an annual report on the following, which includes, but is not limited to the:

1.14.7.1.1. Number of screens.

1.14.7.1.2. Number of re-screens.

1.14.7.1.3. Presumptive positives cases categorized by specific disorders.

1.14.7.1.4. Unsatisfactory results categorized by cause.

1.14.7.1.5. If any goals were not met a corrective action plan must be submitted.

1.14.8. The Contractor shall provide all test results to the Newborn Screening Program via a secure web connection approved by the Department.

1.15. Contract End-of-Life Data Migration Services

1.15.1. Before termination, cancellation, expiration or other conclusion of the awarded Agreement, the Contractor must cooperate in good faith to effectuate a smooth secure transition of the Services to the Department and, if applicable, a new Contractor engaged by the Department to assume the services (for this section known as "Recipient").

1.15.2. If applicable, the Contractor shall use reasonable efforts to assist Recipient, in connection with the transition from the performance of services by the Contractor and its affiliates to the performance of such services, which may include assistance with the transfer of records, migration of historical data, the transition of any such service from the hardware, software, network and telecommunications equipment and internet-related information technology infrastructure ("Internal IT Systems") of Contractor to the Internal IT Systems of Recipient and cooperation with and assistance to any third-party consultants

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engaged by Recipient in connection with such transition ("Migration Services"), taking into account the need to minimize the cost of such migration and the disruption to the ongoing business activities of the parties hereto and their affiliates.

- 1.15.3. If a system, database, hardware, software, and/or software licenses (Tools) was purchased or created to manage, track, and/or store NH DHHS data in relationship to this contract said Tools will be inventoried and returned to the Department, along with the inventory document, once migration of Department data is complete.
- 1.15.4. The internal planning of the migration services by the Contractor and its affiliates and migration services shall be provided to Recipient. Any such migration services shall be deemed to be Services for purposes of the awarded Contract.
- 1.15.5. Should the data migration extend beyond the end of the Contract, the Contractor and its affiliates must agree Contract Security Requirements, and if applicable, NH DHSS Business Associate Agreement terms and conditions remain in effect until the data migration is accepted as complete by the Department
- 1.15.6. In the event the Contractor has comingled confidential data and the destruction or migration is not feasible, the State and Contractor will jointly evaluate regulatory and professional standards for retention requirements prior to destruction.

## **2. Exhibits Incorporated**

- 2.1. The Contractor shall use and disclose Protected Health Information in compliance with the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) (45 CFR Parts 160 and 164) under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and in accordance with the attached Exhibit I, Business Associate Agreement, which has been executed by the parties.
- 2.2. The Contractor shall manage all confidential data related to this Agreement in accordance with the terms of Exhibit K, DHHS Information Security Requirements.
- 2.3. The Contractor shall comply with all Exhibits D through K, which are attached hereto and incorporated by reference herein.

## **3. Reporting Requirements**

- 3.1. The Contractor shall use a secure web connection to report on the following to the Department:
  - 3.1.1. Date specimen was drawn at the New Hampshire birth hospitals and/or community-based health care providers.

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- 3.1.2. Date each specimen is received by the Contractor from the New Hampshire birth hospitals and/or community-based health care providers.
- 3.1.3. Date the laboratory tests were completed.
- 3.1.4. Date results of the laboratory analyses were reported to the New Hampshire Newborn Screening Program.
- 3.2. The Contractor shall provide sufficient data, upon request, on the occurrence of disorders not mandated for testing by the Department to assist the Newborn Screening Program in making appropriate decisions about what services it offers.
- 3.3. The Contractor may be required to collect and share other key data and metrics with the Department in a manner specified by the Department.

**4. Performance Measures**

- 4.1. The Contractor shall ensure that following performance measures are annually achieved and monitored monthly to measure the effectiveness of the Agreement:
  - 4.1.1. At least ninety-eight (98%) of Congenital Adrenal Hyperplasia results are reported to the New Hampshire Newborn Screening Program within three (3) days of the Contractor receiving the dried blood specimen.
  - 4.1.2. At least ninety-five percent (95%) of all screening reports have a report date within seven (7) days from receipt of specimen.
  - 4.1.3. One hundred percent (100%) attendance at all advisory committee meetings
- 4.2. Annually, The Contractor shall submit to the Department a performance outcome report in accordance with Exhibit B-1 – Performance Measure Outcome Report Template.
- 4.3. The Contractor shall actively and regularly collaborate with the Department to enhance contract management and improve results.

**5. Additional Terms**

**5.1. Impacts Resulting from Court Orders or Legislative Changes**

- 5.1.1. The Contractor agrees that, to the extent future state or federal legislation or court orders may have an impact on the Services described herein, the State has the right to modify Service priorities and expenditure requirements under this Agreement so as to achieve compliance therewith.

**5.2. Federal Civil Rights Laws Compliance: Culturally and Linguistically Appropriate Programs and Services**

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- 5.2.1. The Contractor shall submit, within ten (10) days of the Agreement Effective Date, a detailed description of the communication access and language assistance services to be provided to ensure meaningful access to programs and/or services to individuals with limited English proficiency; individuals who are deaf or have hearing loss; individuals who are blind or have low vision; and individuals who have speech challenges.

**5.3. Credits and Copyright Ownership**

- 5.3.1. All documents, notices, press releases, research reports and other materials prepared during or resulting from the performance of the services of the Agreement shall include the following statement, "The preparation of this (report, document etc.) was financed under an 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."

- 5.3.2. All materials produced or purchased under the Agreement shall have prior approval from the Department before printing, production, distribution or use.

- 5.3.3. The Department shall retain copyright ownership for any and all original materials produced, including, but not limited to:

- 5.3.3.1. Brochures.
- 5.3.3.2. Resource directories.
- 5.3.3.3. Protocols or guidelines.
- 5.3.3.4. Posters.
- 5.3.3.5. Reports.

- 5.3.4. The Contractor shall not reproduce any materials produced under the Agreement without prior written approval from the Department.

**5.4. Operation of Facilities: Compliance with Laws and Regulations**

- 5.4.1. 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

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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 Agreement 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.

**6. Records**

- 6.1. The Contractor shall keep records that include, but are not limited to:
- 6.1.1. Books, records, documents and other electronic or physical 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.
  - 6.1.2. All records must 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.
  - 6.1.3. Statistical, enrollment, attendance or visit records for each recipient of services, 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.
  - 6.1.4. Medical records on each patient/recipient of services.
- 6.2. During the term of this Agreement 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 Agreement for purposes of audit, examination, excerpts and transcripts. Upon the purchase by the Department of the maximum number of units provided for in the Agreement and upon payment of the price limitation hereunder, the Agreement and all the obligations of the parties hereunder (except such obligations as, by the terms of the Agreement are to be performed after the end of the term of this Agreement and/or survive the termination of the Agreement) 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

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expenses as are disallowed or to recover such sums from the Contractor.

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## Exhibit B-1 Performance Measure Outcome Report Template

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For each State Fiscal Year Performance Measure listed below, please provide a brief narrative description of your progress in meeting each measure, if you were able to meet the measure and if not, what obstacles or problems prevented this. Please provide any specifics (i.e. number of presentations, etc.) as appropriate to the measure.

### Performance Measure #1

At least ninety-eight (98%) of Congenital Adrenal Hyperplasia results will be reported to the New Hampshire Newborn Screening Program within three (3) days of the contractor receiving the dried blood specimen.

### Performance Measure #1 Progress Outcome:

### Performance Measure #2

At least ninety-five percent (95%) of all screening reports will have a report date within seven days from receipt of specimen.

### Performance Measure #2 Progress Outcome:

### Performance Measure #3

Attend 100% of advisory committee meetings.

### Performance Measure #3 Progress Outcome:

Please email this Performance Measure Report *electronically* annually to Shari Campbell, MCH Program Specialist, at [shari.campbell@dhhs.nh.gov](mailto:shari.campbell@dhhs.nh.gov). Thank you.

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## Exhibit B-2 - IT Requirements

APPLICATION REQUIREMENTS					
State Requirements			Vendor		
Req #	Requirement Description	Criticality	Vendor Response	Delivery Method	Comments
<b>GENERAL SPECIFICATIONS</b>					
A1.1	Ability to access data using open standards access protocol (please specify supported versions in the comments field).	M	Yes	Standard	Printing reports is only available via VMWare Horizon Client. VMWare client is already in use by NHNBS at no additional cost
A1.2	Data is available in commonly used format over which no entity has exclusive control, with the exception of National or International standards. Data is not subject to any copyright, patent, trademark or other trade secret regulation.	M	Yes	Standard	Reports are generated as PDF files. Data exports are standard text files with a tab-delimited format. Data stored in MS SQL
A1.3	Web-based compatible and in conformance with the following W3C standards: HTML5, CSS 2.1, XML 1.1	M	Yes	Standard	The one web component of the Limes application is through VMWare which follows all current standards and is patched regularly
<b>APPLICATION SECURITY</b>					
A2.1	Verify the identity or authenticate all of the system client applications before allowing use of the system to prevent access to inappropriate or confidential data or services.	M	Yes	Standard	Through VMWare, clients are presented with ONLY the LIMS application. Clients cannot launch additional applications.
A2.2	Verify the identity and authenticate all of the system's human users before allowing them to use its capabilities to prevent access to inappropriate or confidential data or services.	M	Yes	Standard	Application validates users against Active Directory plus multi-factor authentication
A2.3	Enforce unique user names.	M	Yes	Standard	All user names must be unique
A2.4	Enforce complex passwords for Administrator Accounts in accordance with DoIT's statewide <i>User Account and Password Policy</i>	M	Yes	Standard	Password Requirements: User accounts must be at least 10 characters in length and contain three of the following: Upper-case letter, Lower-case letter, Special Character or Number, Cannot be one of your last 10 passwords. Passwords expire every 60 days. Password requirements are configurable.
A2.5	Enforce the use of complex passwords for general users using capital letters, numbers and special characters in accordance with DoIT's statewide <i>User Account and Password Policy</i> .	M	Yes	Standard	Password Requirements: User accounts must be at least 10 characters in length and contain three of the following: Upper-case letter, Lower-case letter, Special Character or Number, Cannot be one of your last 10 passwords. Passwords expire every 60 days. Password requirements are configurable.
A2.6	Encrypt passwords in transmission and at rest within the database.	M	Yes	Standard	The passwords are encrypted at rest and in transmission.
A2.7	Establish ability to expire passwords after a definite period of time in accordance with DoIT's statewide <i>User Account and Password Policy</i>	M	Yes	Standard	Password Requirements: User accounts must be at least 10 characters in length and contain three of the following: Upper-case letter, Lower-case letter, Special Character or Number, Cannot be one of your last 10 passwords. Passwords expire every 60 days. Password requirements are configurable.

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## Attachment 1: Project Requirements

## Appendix G - IT Requirements

Req #	Requirement Description	Criticality	Vendor Responses	Delivery Method	Comments
A2.8	Provide the ability to limit the number of people that can grant or change authorizations	M	Yes	Standard	We have the ability to limit the number of people who can grant to change authorization. Access to applications requires both domain account and an application account. There are limited persons who can generate and/or modify either account type.
A2.9	Establish ability to enforce session timeouts during periods of inactivity.	M	Yes	Standard	We can enforce session timeouts after a period of inactivity.
A2.10	The application shall not store authentication credentials or sensitive data in its code.	M	Yes	Standard	Application does not store authentication credentials
A2.11	Log all attempted accesses that fail identification, authentication and authorization requirements.	M	Yes	Standard	There is logging at both the network and application logins
A2.12	The application shall log all activities to a central server to prevent parties to application transactions from denying that they have taken place.	M	No	Future	Logs are retained in a separate instance of the database. Within 90 days we will be sending logs to a secure central server.
A2.13	All logs must be kept for 12 months.	M	Yes	Standard	Logs are kept for a minimum of 12 months
A2.14	The application must allow a human user to explicitly terminate a session. No remnants of the prior session should then remain.	M	Yes	Standard	If the user wishes to close out the session, it can be done via the VMWare Horizon application.
A2.15	Do not use Software and System Services for anything other than they are designed for.	M	Yes	Standard	Policies and workforce agreements address acceptable and minimum use.
A2.16	The application Data shall be protected from unauthorized use when at rest	M	Yes	Standard	Data is encrypted as rest. Access is restricted to authorized users.
A2.17	The application shall keep any sensitive Data or communications private from unauthorized individuals and programs.	M	Yes	Standard	The application grants access only to authorized users
A2.18	Subsequent application enhancements or upgrades shall not remove or degrade security requirements	M	Yes	Standard	We agree that future enhancements or upgrades shall not degrade security requirements. Our information security department enforces version currency and regular patching of all systems, additionally all changes must be approved by IT security and business stakeholders before implementation.
A2.19	Utilize change management documentation and procedures	M	Yes	Standard	Change management documentation and procedures are and will continue to be used.
A2.20	Web Services : The service provider shall use Web services exclusively to interface with the State's data in near real time when possible.	M	Yes	Standard	Not applicable: There are no web services in our current LIMS solution

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Exhibit B-2 - IT Requirements

TESTING					
State Requirements			Vendor		
Req #	Requirement Description	Criticality	Vendor Response	Delivery Method	Comments
<b>APPLICATION SECURITY TESTING</b>					
T1.1	All components of the Software shall be reviewed and tested to ensure they protect the State's web site and its related Data assets.	M	Yes	Standard	Application runs on virtual computers at UMass Chan Medical School site. Software does not run on the end user's computers or devices.
T1.2	The Vendor shall be responsible for providing documentation of security testing, as appropriate. Tests shall focus on the technical, administrative and physical security controls that have been designed into the System architecture in order to provide the necessary confidentiality, integrity and availability.	M	Yes	Standard	Documentation can be provided for tests performed.
T1.3	Provide evidence that supports the fact that Identification and Authentication testing has been recently accomplished; supports obtaining information about those parties attempting to log onto a system or application for security purposes and the validation of users	M	Yes	Standard	We have Active Directory logs. See attachment F.A.1 called 'available fields on login events'.
T1.4	Test for Access Control; supports the management of permissions for logging onto a computer or network	M	Yes	Standard	Specific permissions can be and are assigned to groups. Users can be assigned to one or more groups to obtain the specific access required.
T1.5	Test for encryption; supports the encoding of data for security purposes, and for the ability to access the data in a decrypted format from required tools.	M	Yes	Standard	Data is encrypted at rest. Tools are available to read the data in a decrypted format as necessary.
T1.6	Test the Intrusion Detection; supports the detection of illegal entrance into a computer system	M	Yes	Standard	UMass Chan Medical School employs IPS/IDS threat prevention and detection technology that examines network traffic flows to detect and prevent vulnerability exploits. Security Incident & Event Management (SEIM) platforms consumes security events and critical system logs to correlate to determine and alert on anomalous activity.
T1.7	Test the Verification feature; supports the confirmation of authority to enter a computer system, application or network	M	Yes	Standard	Authentication is based on users Active Directory status. Only those with active status are allowed to access UMass Chan Medical School network.
T1.8	Test the User Management feature; supports the administration of computer, application and network accounts within an organization.	M	Yes	Standard	Authentication is based on users Active Directory status. Only those with active status are allowed to access UMass Chan Medical School network.
T1.9	Test Role/Privilege Management; supports the granting of abilities to users or groups of users of a computer, application or network	M	Yes	Standard	During quarterly access recertification, roles and privileges are validated.
T1.10	Test Audit Trail Capture and Analysis; supports the identification and monitoring of activities within an application or system	M	Yes	Standard	All activity within the system is recorded including the user, the action and the timestamp.
T1.11	Test Input Validation; ensures the application is protected from buffer overflow, cross-site scripting, SQL injection, and unauthorized access of files and/or directories on the server.	M	Yes	Standard	The servers are patched and scanned regularly for vulnerabilities.

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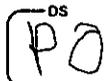
Exhibit B-2 - IT Requirements

T.1.12	For web applications, ensure the application has been tested and hardened to prevent critical application security flaws. ( At a minimum, the application shall be tested against all flaws outlined in the Open Web Application Security Project (OWASP) Top Ten ( <a href="http://www.owasp.org/index.php/OWASP_Top_Ten_Project">http://www.owasp.org/index.php/OWASP_Top_Ten_Project</a> ))	M	Yes	Standard	Our entry point to the Laboratory Information Management System (LIMS) system is via virtual desktop infrastructure (VDI). The images are scanned once per month and patches and remediation are incorporated as needed.
T1.13	Provide the State with validation of 3rd party security reviews performed on the application and system environment. The review may include a combination of vulnerability scanning, penetration testing, static analysis of the source code, and expert code review (please specify proposed methodology in the comments field).	M	Yes	Standard	We have a current SOC 2 Type 2 Report. We can provide a copy upon request. We perform continuous internal vulnerability scans.
T1.14	Prior to the System being moved into production, the Vendor shall provide results of all security testing to the Department of Information Technology for review and acceptance.	M	Yes	Standard	The current version of our LIMS system has been in production since early 2020. All enhancements undergo our internal Change Management Process. UMASS Chan IT will perform additional security testing should any new version of our LIMS system be implemented and will share the results with NH.
T1.15	Vendor shall provide documented procedure for migrating application modifications from the User Acceptance Test Environment to the Production Environment.	M	Yes	Standard	See Change Control Procedure provided (Attachment F.A.2)
<b>STANDARD TESTING</b>					
T2.1	The Vendor must test the software and the system using an industry standard and State approved testing methodology.	M	No	Future	We could not answer Yes because we are unsure what the "State approved testing methodology" includes. When the Specimen Gate Application (already in use) was implemented in 2020, a testing plan was created for each functionality, and testing results recorded. All changes undergo our robust internal change control process. If NHNBS can provide the referenced State approved testing methodology, we will assure that any future testing (changes and version) comply.
T2.2	The Vendor must perform application stress testing and tuning.	M	Yes	Standard	Application stress testing and tuning was performed prior to moving to Production in 2020 and is installed on scalable hardware to address future needs
T2.3	The Vendor must provide documented procedure for how to sync Production with a specific testing environment.	M	Yes	Standard	See attachment F.A.3. 'SQL Data Masking Procedure
T2.4	The vendor must define and test disaster recovery procedures.	M	Yes	Standard	NENSP agrees to define and test its disaster recovery procedures

TR - TESTING

Contractor Initials PO<sup>OS</sup>  
 Date 6/14/2022

HOSTING-CLOUD REQUIREMENTS					
State Requirements					
Req #	Requirement Description	Criticality	Vendor Response	Deliverables	Comments (if any)
<b>OPERATIONS</b>					
H1.1	Vendor shall provide an ANSI/TIA-942 Tier 3 Data Center or equivalent. A (Tier 3 data center requires 1) Multiple independent distribution paths serving the IT equipment, 2) All IT equipment must be dual-powered and fully compatible with the topology of a site's architecture and 3) Concurrently maintainable site infrastructure with expected availability of 99.982%.	M	Yes	Standard	We have dual power feeds to the facility, the facility is concurrently maintainable and we have diverse distribution paths.
H1.2	Vendor shall maintain a secure hosting environment providing all necessary hardware, software, and internet bandwidth to manage the application and support users with permission based logins.	M	Yes	Standard	The HENSP LIMS system meets these requirements
H1.3	The Data Center must be physically secured - restricted access to the site to personnel with controls such as biometric, badge, and other security solutions. Policies for granting access must be in place and followed. Access shall only be granted to those with a need to perform tasks in the Data Center.	M	Yes	Standard	Our Data Center meets all of these requirements
H1.4	Vendor shall install and update all server patches, updates, and other utilities within 60 days of release from the manufacturer.	M	Yes	Standard	All server patches are deployed within 30 days of release
H1.5	Vendor shall monitor System, security, and application logs.	M	Yes	Standard	Monitoring is performed
H1.6	Vendor shall manage the sharing of data resources.	M	Yes	Standard	All sharing of Data resources are managed by Amass Chan IT
H1.7	Vendor shall manage daily backups, off-site data storage, and restore operations.	M	Yes	Standard	All daily backups, off-site data storage and restore operations are managed by Amass Chan IT department
H1.8	The Vendor shall monitor physical hardware.	M	Yes	Standard	All physical hardware is monitored
H1.9	Remote access shall be customized to the State's business application. In instances where the State requires access to the application or server resources not in the DMZ, the Vendor shall provide remote desktop connection to the server through secure protocols such as a Virtual Private Network (VPN).	M	Yes	Standard	Access is currently provided via VPNs. Alternate secure access to application can be provided as necessary.
H1.10	The Vendor shall report any breach in security in conformance with State of NH RSA 359 C:20. Any person engaged in trade or commerce that is subject to RSA 358-A:3, 1 shall also notify the regulator which has primary regulatory authority over such trade or commerce. All other persons shall notify the New Hampshire attorney general's office.	M	Yes	Standard	Any security breach will be reported as described.
<b>DISASTER RECOVERY</b>					
H2.1	Vendor shall have documented disaster recovery plans that address the recovery of lost State data as well as their own. Systems shall be architected to meet the defined recovery needs.	M	Yes	Standard	HENSP agrees to have documented business continuity planning in place.
H2.2	The disaster recovery plan shall identify appropriate methods for procuring additional hardware in the event of a component failure. In most instances, systems shall offer a level of redundancy so the loss of a drive or power supply will not be sufficient to terminate services however, these failed components will have to be replaced.	M	Yes	Standard	Redundancies are built into our hardware. We also have contracts with our hardware vendors to supply replacement hardware in the event of failure.
H2.3	Vendor shall adhere to a defined and documented back-up schedule and procedure.	M	Yes	Standard	UMASS Chan IT adheres to scheduled backup schedule and procedures
H2.4	Back-up copies of data are made for the purpose of facilitating a restore of the data in the event of data loss or System failure.	M	Yes	Standard	The HENSP LIMS database employs a high availability SQL server with at least one complete copy of all data.
H2.5	Scheduled backups of all servers must be completed regularly. The minimum acceptable frequency is differential backup daily, and complete backup weekly.	M	Yes	Standard	The Amass Chan IT backup schedule meets or exceeds these requirements
<b>HOSTING SECURITY</b>					
H3.1	The Vendor shall employ security measures ensure that the State's application and data is protected.	M	Yes	Standard	Security measures are in place to ensure the application and data are protected.
H3.2	If State data is housed on multiple servers, data exchanges between and among servers must be encrypted.	M	Yes	Standard	All communication between servers use encryption.
H3.3	All servers and devices must have currently-supported and hardened operating systems, the latest anti-viral, anti-hacker, anti-spam, anti-spionage, and anti-malware utilities. The environment, as a whole, shall have aggressive intrusion-detection and firewall protection.	M	Yes	Standard	UMass Chan employs IPS/IDS threat prevention and detection technology that examines network traffic flows to detect and prevent vulnerability exploits. Security Incident & Event Management (SIEM) platforms consumes security events and critical system logs to correlate to determine and alert on anomalous activity.

Contractor Initials  OS  
 Date 6/14/2022

R1.4	All components of the infrastructure shall be reviewed and tested to ensure they protect the State's hardware, software, and its related data assets. Tests shall focus on the technical, administrative and physical security controls that have been designed into the System architecture in order to provide confidentiality, integrity and availability.	M	Yes	Standard	All systems and endpoint are regularly scanned for vulnerabilities and are remediated accordingly.
R1.5	The Vendor shall ensure its complete cooperation with the State's Chief Information Officer in the detection of any security vulnerability of the hosting infrastructure.	M	Yes	Standard	We will cooperate with NH's Chief Information Officer as necessary.
R1.6	The Vendor shall authorize the State to perform scheduled and random security audits, including vulnerability assessments, of the Vendor' hosting infrastructure and/or the application upon request.	M	Yes	Standard	All requests must be submitted to UMass Chan with 30 days notice and limited to one time per year. Additionally, the framework we will be audited against must be defined. UMass Chan adheres to the NIST 800-53 moderate level framework.
R1.7	All servers and devices must have event logging enabled. Logs must be protected with access limited to only authorized administrators. Logs shall include System, Application, Web and Database logs.	M	Yes	Standard	All servers and computers deployed as part of the HENSP LIMS system meet these requirements.
R1.8	Operating Systems (OS) and Databases (DB) shall be built and hardened in accordance with guidelines set forth by CIS, NIST or NSA.	M	Yes	Standard	Our OS and DB are hardened according to NIST.
R1.9	The Vendor shall notify the State's Project Manager of any security breaches within two (2) hours of the time that the Vendor learns of their occurrence.	M	Yes	Standard	UMASS Chan IT agree to notify the State of NH of any breach within 2 hours after learning of said breach.
R1.10	The Vendor shall be solely liable for costs associated with any breach of State data housed at their location(s) including but not limited to notification and any damages assessed by the courts.	M	Yes	Standard	UMASS Chan agrees to be liable for our costs associated with any breach of NH data housed at our location and any other costs assigned to UMass Chan by a court of competent jurisdiction or settlement agreed to by UMass Chan.

  
 Contractor Initials \_\_\_\_\_  
 Date 6/14/2022

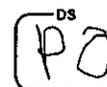
**New Hampshire Department of Health and Human Services  
Newborn Screening Laboratory Services  
EXHIBIT C**

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**Payment Terms**

1. This Agreement is funded by:
  - 1.1. 100% Other funds (Newborn Screening Revolving Funds).
2. For the purposes of this Agreement:
  - 2.1. The Department has identified the Contractor as a Subrecipient, in accordance with 2 CFR 200.331.
  - 2.2. The Department has identified this Agreement as NON-R&D, in accordance with 2 CFR §200.332.
3. Payment shall be on a cost reimbursement basis for actual expenditures incurred in the fulfillment of this Agreement, and shall be in accordance with the approved line item, as specified in Exhibits C-1, Budget.
4. The Contractor shall submit an invoice and supporting documents to the Department no later than the fifteenth (15th) working day of the following month. The Contractor shall:
  - 4.1. Ensure the invoice is presented in a form that is provided by the Department or is otherwise acceptable to the Department.
  - 4.2. Ensure the invoice identifies and requests payment for allowable costs incurred in the previous month.
  - 4.3. Provide supporting documentation of allowable costs that may include, but is not limited to, time sheets, payroll records, receipts for purchases, and proof of expenditures, as applicable.
  - 4.4. Ensure the invoice is completed, dated and returned to the Department with the supporting documentation for authorized expenses, in order to initiate payment.
5. In lieu of hard copies, all invoices may be assigned an electronic signature and emailed to [DPHSCContractBilling@dhhs.nh.gov](mailto:DPHSCContractBilling@dhhs.nh.gov), or invoices may be mailed to:

Financial Manager  
Department of Health and Human Services  
129 Pleasant Street  
Concord, NH 03301
6. The Department shall make payment to the Contractor within thirty (30) days of receipt of each invoice, subsequent to approval of the submitted invoice and if sufficient funds are available, subject to Paragraph 4 of the General Provisions Form Number P-37 of this Agreement.



**New Hampshire Department of Health and Human Services  
Newborn Screening Laboratory Services  
EXHIBIT C**

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7. The final invoice shall be due to the Department no later than forty (40) days after the contract completion date specified in Form P-37, General Provisions Block 1.7 Completion Date.
8. The Contractor must provide the services in Exhibit B, Scope of Services, in compliance with funding requirements.
9. The Contractor agrees that funding under this Agreement may be withheld, in whole or in part in the event of non-compliance with the terms and conditions of Exhibit B, Scope of Services.
10. Notwithstanding anything to the contrary herein, the Contractor agrees that funding under this agreement may be withheld, in whole or in part, in the event of non-compliance with any Federal or State law, rule or regulation applicable to the services provided, or if the said services or products have not been satisfactorily completed in accordance with the terms and conditions of this agreement.
11. Notwithstanding Paragraph 17 of the General Provisions Form P-37, changes limited to adjusting amounts within the price limitation and adjusting encumbrances between State Fiscal Years and budget class lines through the Budget Office may be made by written agreement of both parties, without obtaining approval of the Governor and Executive Council, if needed and justified.
12. Audits
  - 12.1. The Contractor must email an annual audit to [melissa.s.morin@dhhs.nh.gov](mailto:melissa.s.morin@dhhs.nh.gov) if any of the following conditions exist:
    - 12.1.1. Condition A - The Contractor expended \$750,000 or more in federal funds received as a subrecipient pursuant to 2 CFR Part 200, during the most recently completed fiscal year.
    - 12.1.2. Condition B - The Contractor is subject to audit pursuant to the requirements of NH RSA 7:28, III-b, pertaining to charitable organizations receiving support of \$1,000,000 or more.
    - 12.1.3. Condition C - The Contractor is a public company and required by Security and Exchange Commission (SEC) regulations to submit an annual financial audit.
  - 12.2. If Condition A exists, the Contractor shall submit an annual single audit performed by an independent Certified Public Accountant (CPA) to the Department within 120 days after the close of the Contractor's fiscal year, conducted in accordance with the requirements of 2 CFR Part 200, Subpart F of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal awards.

<sup>DS</sup>  


**New Hampshire Department of Health and Human Services  
Newborn Screening Laboratory Services  
EXHIBIT C**

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- 12.3. If Condition B or Condition C exists, the Contractor shall submit an annual financial audit performed by an independent CPA within 120 days after the close of the Contractor's fiscal year.
- 12.4. 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.

<sup>DS</sup>  
PO

EXHIBIT C-1

New Hampshire Department of Health and Human Services			
Contractor Name:	University of Massachusetts		
Project Title:	RFP-2022-DPHS-02-NEWBO-01		
Budget Request for:	Newborn Screening Laboratory Services		
Amount Per Test	State Fiscal Year 2023	State Fiscal Year 2024	State Fiscal Year 2025
Salary/Wages	\$ 35.22	\$ 36.31	\$ 37.44
Employee Benefits	\$ 10.83	\$ 11.17	\$ 11.51
Lab Testing (lab supplies, lab instrument depreciation and maintenance)	\$ 31.73	\$ 32.71	\$ 33.72
Paper Filters	\$ 0.80	\$ 0.82	\$ 0.85
Courier Services (specimen shipping)	\$ 5.96	\$ 6.15	\$ 6.34
Educational	\$ -	\$ -	\$ -
Office	\$ 6.17	\$ 6.36	\$ 6.56
Telephone	\$ 0.01	\$ 0.01	\$ 0.01
Software (Includes software depreciation, maintenance, updates)	\$ 4.56	\$ 4.70	\$ 4.84
IT	\$ 1.07	\$ 1.10	\$ 1.14
Insurance	\$ 0.65	\$ 0.67	\$ 0.69
Administration	\$ 1.81	\$ 1.86	\$ 1.92
Overhead	\$ 10.97	\$ 11.31	\$ 11.66
<b>TOTAL PER TEST RATE (per specimen):</b>	<b>\$ 109.78</b>	<b>\$ 113.17</b>	<b>\$ 116.68</b>
<b>Total annual cost:</b>	<b>\$ 1,536,920</b>	<b>\$ 1,584,380</b>	<b>\$ 1,633,520</b>



New Hampshire Department of Health and Human Services  
Exhibit D

**CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS**

The Vendor 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



New Hampshire Department of Health and Human Services  
Exhibit D

- 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.

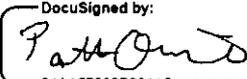
Place of Performance (street address, city, county, state, zip code) (list each location)

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

Vendor Name: UMass Chan Medical School

6/14/2022

Date

DocuSigned by:  
  
 Name: Patti A. Onorato  
 Title: Deputy Executive Vice Cha

Vendor Initials   
 Date 6/14/2022



New Hampshire Department of Health and Human Services  
Exhibit E

**CERTIFICATION REGARDING LOBBYING**

The Vendor 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-1.)
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.

Vendor Name: UMass Chan Medical School

6/14/2022

Date

DocuSigned by:

Name: Patti A. Onorato

Title: Deputy Executive Vice Cha

Vendor Initials

6/14/2022

Date

**New Hampshire Department of Health and Human Services**  
**Exhibit F**



**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

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New Hampshire Department of Health and Human Services  
Exhibit F

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

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

PRIMARY COVERED TRANSACTIONS

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

LOWER TIER COVERED TRANSACTIONS

- 13. By signing and submitting this lower tier proposal (contract), the prospective lower tier participant, as defined in 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:
  - 13.1. are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
  - 13.2. where the prospective lower tier participant is unable to certify to any of the above, such prospective participant shall attach an explanation to this proposal (contract).
- 14. The prospective lower tier participant further agrees by submitting this proposal (contract) that it will include this clause entitled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion - Lower Tier Covered Transactions," without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Contractor Name: UMass Chan Medical School

6/14/2022

Date

DocuSigned by:  
  
Name: Patti A. Onorato  
Title: Deputy Executive Vice Cha

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New Hampshire Department of Health and Human Services  
Exhibit G

**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.

Exhibit G

Contractor Initials

DS  
PO

Certification of Compliance with requirements pertaining to Federal Nondiscrimination, Equal Treatment of Faith-Based Organizations and Whistleblower protections



New Hampshire Department of Health and Human Services  
Exhibit G

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: UMass Chan Medical School

6/14/2022

Date

DocuSigned by:  
  
Name: Patti A. Onorato  
Title: Deputy Executive Vice Cha

Exhibit G

Contractor Initials

Certification of Compliance with requirements pertaining to Federal Nondiscrimination, Equal Treatment of Faith-Based Organizations and Whistleblower protections

New Hampshire Department of Health and Human Services  
Exhibit H



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: UMass Chan Medical School

6/14/2022

Date

DocuSigned by:

Name: Patti A. Onorato

Title: Deputy Executive Vice Cha



## New Hampshire Department of Health and Human Services

## Exhibit I

**HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY 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, Title XIII, 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.

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Exhibit I  
 Health Insurance Portability Act  
 Business Associate Agreement  
 Page 1 of 6

Contractor Initials

[Signature]

Date 6/14/2022



New Hampshire Department of Health and Human Services

Exhibit I

- I. "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

PO



New Hampshire Department of Health and Human Services

Exhibit I

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:
  - o The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification;
  - o The unauthorized person used the protected health information or to whom the disclosure was made;
  - o Whether the protected health information was actually acquired or viewed
  - o 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 (I). 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



New Hampshire Department of Health and Human Services

Exhibit I

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

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Contractor Initials PO

Date 6/14/2022



New Hampshire Department of Health and Human Services

Exhibit I

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. (PO)



New Hampshire Department of Health and Human Services

Exhibit I

- 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) l, 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.

Department of Health and Human Services

UMass Chan Medical School

The State by:

Name of the Contractor

Patricia M. Tilley

Patti Onorato

Signature of Authorized Representative

Signature of Authorized Representative

Patricia M. Tilley

Patti A. Onorato

Name of Authorized Representative  
Director

Name of Authorized Representative

Title of Authorized Representative

Deputy Executive Vice Cha

Title of Authorized Representative

6/14/2022

6/14/2022

Date

Date



New Hampshire Department of Health and Human Services  
Exhibit J

**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 \$30,000 and awarded on or after October 1, 2010, to report on data related to executive compensation and associated first-tier sub-grants of \$30,000 or more. If the initial award is below \$30,000 but subsequent grant modifications result in a total award equal to or over \$30,000, 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 Entity Identifier (SAM UEI; Formerly 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.

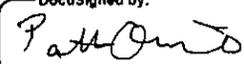
The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of The Federal Funding Accountability and Transparency Act, Public Law 109-282 and Public Law 110-252, and 2 CFR Part 170 (Reporting Subaward and Executive Compensation Information), and further agrees 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: University of  
Massachusetts

6/14/2022

Date

DocuSigned by:  
  
 Name: Patti A. Onorato  
 Title: Deputy Executive Vice Cha

DS  
PO



New Hampshire Department of Health and Human Services  
Exhibit J

**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.

MQE2JHHJW9Q8

1. The UEI (SAM.gov) number for your organization 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: _____

Contractor Initials PO  
Date 6/14/2022

# New Hampshire Department of Health and Human Services

## Exhibit K

### DHHS Information Security Requirements



#### A. Definitions

The following terms may be reflected and have the described meaning in this document:

1. "Breach" means the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, unauthorized access, or any similar term referring to situations where persons other than authorized users and for an other than authorized purpose have access or potential access to personally identifiable information, whether physical or electronic. With regard to Protected Health Information, "Breach" shall have the same meaning as the term "Breach" in section 164.402 of Title 45, Code of Federal Regulations.
2. "Computer Security Incident" shall have the same meaning "Computer Security Incident" in section two (2) of NIST Publication 800-61, Computer Security Incident Handling Guide, National Institute of Standards and Technology, U.S. Department of Commerce.
3. "Confidential Information" or "Confidential Data" means all confidential information disclosed by one party to the other such as all medical, health, financial, public assistance benefits and personal information including without limitation, Substance Abuse Treatment Records, Case Records, Protected Health Information and Personally Identifiable Information.

Confidential Information also includes any and all information owned or managed by the State of NH - created, received from or on behalf of the Department of Health and Human Services (DHHS) or accessed in the course of performing contracted services - of which collection, disclosure, protection, and disposition is governed by state or federal law or regulation. This information includes, but is not limited to Protected Health Information (PHI), Personal Information (PI), Personal Financial Information (PFI), Federal Tax Information (FTI), Social Security Numbers (SSN), Payment Card Industry (PCI), and or other sensitive and confidential information.

4. "End User" means any person or entity (e.g., contractor, contractor's employee, business associate, subcontractor, other downstream user, etc.) that receives DHHS data or derivative data in accordance with the terms of this Contract.
5. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder.
6. "Incident" means an act that potentially violates an explicit or implied security policy, which includes attempts (either failed or successful) to gain unauthorized access to a system or its data, unwanted disruption or denial of service, the unauthorized use of a system for the processing or storage of data; and changes to system hardware, firmware, or software characteristics without the owner's knowledge, instruction, or consent. Incidents include the loss of data through theft or device misplacement, loss or misplacement of hardcopy documents, and misrouting of physical or electronic

PO

New Hampshire Department of Health and Human Services

Exhibit K

DHHS Information Security Requirements



mail, all of which may have the potential to put the data at risk of unauthorized access, use, disclosure, modification or destruction.

7. "Open Wireless Network" means any network or segment of a network that is not designated by the State of New Hampshire's Department of Information Technology or delegate as a protected network (designed, tested, and approved, by means of the State, to transmit) will be considered an open network and not adequately secure for the transmission of unencrypted PI, PFI, PHI or confidential DHHS data:
8. "Personal Information" (or "PI") means information which can be used to distinguish or trace an individual's identity, such as their name, social security number, personal information as defined in New Hampshire RSA 359-C:19, biometric records, etc., alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc.
9. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164, promulgated under HIPAA by the United States Department of Health and Human Services.
10. "Protected Health Information" (or "PHI") has the same meaning as provided in the definition of "Protected Health Information" in the HIPAA Privacy Rule at 45 C.F.R. § 160.103.
11. "Security Rule" shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 C.F.R. Part 164, Subpart C, and amendments thereto.
12. "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.

**I. RESPONSIBILITIES OF DHHS AND THE CONTRACTOR**

**A. Business Use and Disclosure of Confidential Information.**

1. The Contractor must not use, disclose, maintain or transmit Confidential Information except as reasonably necessary as outlined under this Contract. Further, Contractor, including but not limited to all its directors, officers, employees and agents, must not use, disclose, maintain or transmit PHI in any manner that would constitute a violation of the Privacy and Security Rule.
2. The Contractor must not disclose any Confidential Information in response to a

New Hampshire Department of Health and Human Services

Exhibit K

DHHS Information Security Requirements



request for disclosure on the basis that it is required by law, in response to a subpoena, etc., without first notifying DHHS so that DHHS has an opportunity to consent or object to the disclosure.

3. If DHHS notifies the Contractor that DHHS 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 Contractor must be bound by such additional restrictions and must not disclose PHI in violation of such additional restrictions and must abide by any additional security safeguards.
4. The Contractor agrees that DHHS Data or derivative there from disclosed to an End User must only be used pursuant to the terms of this Contract.
5. The Contractor agrees DHHS Data obtained under this Contract may not be used for any other purposes that are not indicated in this Contract.
6. The Contractor agrees to grant access to the data to the authorized representatives of DHHS for the purpose of inspecting to confirm compliance with the terms of this Contract.

**II. METHODS OF SECURE TRANSMISSION OF DATA**

1. Application Encryption. If End User is transmitting DHHS data containing Confidential Data between applications, the Contractor attests the applications have been evaluated by an expert knowledgeable in cyber security and that said application's encryption capabilities ensure secure transmission via the internet.
2. Computer Disks and Portable Storage Devices. End User may not use computer disks or portable storage devices, such as a thumb drive, as a method of transmitting DHHS data.
3. Encrypted Email. End User may only employ email to transmit Confidential Data if email is encrypted and being sent to and being received by email addresses of persons authorized to receive such information.
4. Encrypted Web Site. If End User is employing the Web to transmit Confidential Data, the secure socket layers (SSL) must be used and the web site must be secure. SSL encrypts data transmitted via a Web site.
5. File Hosting Services, also known as File Sharing Sites. End User may not use file hosting services, such as Dropbox or Google Cloud Storage, to transmit Confidential Data.
6. Ground Mail Service. End User may only transmit Confidential Data via *certified* ground mail within the continental U.S. and when sent to a named individual.
7. Laptops and PDA. If End User is employing portable devices to transmit Confidential Data said devices must be encrypted and password-protected.
8. Open Wireless Networks. End User may not transmit Confidential Data via an open

New Hampshire Department of Health and Human Services

Exhibit K

DHHS Information Security Requirements



wireless network. End User must employ a virtual private network (VPN) when remotely transmitting via an open wireless network.

9. Remote User Communication. If End User is employing remote communication to access or transmit Confidential Data, a virtual private network (VPN) must be installed on the End User's mobile device(s) or laptop from which information will be transmitted or accessed.
10. SSH File Transfer Protocol (SFTP), also known as Secure File Transfer Protocol. If End User is employing an SFTP to transmit Confidential Data, End User will structure the Folder and access privileges to prevent inappropriate disclosure of information. One SFTP folders and sub-folders used for transmitting Confidential Data will be coded for 24-hour auto-deletion cycle and one SFTP folder will be coded for one week auto-deletion cycle (i.e. Confidential Data will be deleted every 24 hours).
11. Wireless Devices. If End User is transmitting Confidential Data via wireless devices, all data must be encrypted to prevent inappropriate disclosure of information.

**III. RETENTION AND DISPOSITION OF IDENTIFIABLE RECORDS**

The Contractor will only retain the data and any derivative of the data for the duration of this Contract. After such time, the Contractor will have 30 days to destroy the data and any derivative in whatever form it may exist, unless, otherwise required by law or permitted under this Contract. To this end, the parties must:

**A. Retention**

1. The Contractor agrees it will not store, transfer or process data collected in connection with the services rendered under this Contract outside of the United States. This physical location requirement shall also apply in the implementation of cloud computing, cloud service or cloud storage capabilities, and includes backup data and Disaster Recovery locations.
2. The Contractor agrees to ensure proper security monitoring capabilities are in place to detect potential security events that can impact State of NH systems and/or Department confidential information for contractor provided systems.
3. The Contractor agrees to provide security awareness and education for its End Users in support of protecting Department confidential information.
4. The Contractor agrees to retain all electronic and hard copies of Confidential Data in a secure location and identified in section IV. A.2
5. The Contractor agrees Confidential Data stored in a Cloud must be in a FedRAMP/HITECH compliant solution and comply with all applicable statutes and regulations regarding the privacy and security. All servers and devices must have currently-supported and hardened operating systems, the latest anti-viral, anti-hacker, anti-spam, anti-spyware, and anti-malware utilities. The environment, as a

Contractor Initials DS PO

6/14/2022

Date \_\_\_\_\_

New Hampshire Department of Health and Human Services

Exhibit K

DHHS Information Security Requirements



whole, must have aggressive intrusion-detection and firewall protection.

6. The Contractor agrees to and ensures its complete cooperation with the State's Chief Information Officer in the detection of any security vulnerability of the hosting infrastructure.

B. Disposition

1. If the Contractor will maintain any Confidential Information on its systems (or its sub-contractor systems), the Contractor will maintain a documented process for securely disposing of such data upon request or contract termination; and will obtain written certification for any State of New Hampshire data destroyed by the Contractor or any subcontractors as a part of ongoing, emergency, and or disaster recovery operations. When no longer in use, electronic media containing State of New Hampshire data shall be rendered unrecoverable via a secure wipe program in accordance with industry-accepted standards for secure deletion and media sanitization, or otherwise physically destroying the media (for example, degaussing) as described in NIST Special Publication 800-88, Rev 1, Guidelines for Media Sanitization, National Institute of Standards and Technology, U. S. Department of Commerce. The Contractor will document and certify in writing at time of the data destruction, and will provide written certification to the Department upon request. The written certification will include all details necessary to demonstrate data has been properly destroyed and validated. Where applicable, regulatory and professional standards for retention requirements will be jointly evaluated by the State and Contractor prior to destruction.
2. Unless otherwise specified, within thirty (30) days of the termination of this Contract, Contractor agrees to destroy all hard copies of Confidential Data using a secure method such as shredding.
3. Unless otherwise specified, within thirty (30) days of the termination of this Contract, Contractor agrees to completely destroy all electronic Confidential Data by means of data erasure, also known as secure data wiping.

IV. PROCEDURES FOR SECURITY

- A. Contractor agrees to safeguard the DHHS Data received under this Contract, and any derivative data or files, as follows:
  1. The Contractor will maintain proper security controls to protect Department confidential information collected, processed, managed, and/or stored in the delivery of contracted services.
  2. The Contractor will maintain policies and procedures to protect Department confidential information throughout the information lifecycle, where applicable, (from creation, transformation, use, storage and secure destruction) regardless of the media used to store the data (i.e., tape, disk, paper, etc.).

## New Hampshire Department of Health and Human Services

### Exhibit K

### DHHS Information Security Requirements



3. The Contractor will maintain appropriate authentication and access controls to contractor systems that collect, transmit, or store Department confidential information where applicable.
4. The Contractor will ensure proper security monitoring capabilities are in place to detect potential security events that can impact State of NH systems and/or Department confidential information for contractor provided systems.
5. The Contractor will provide regular security awareness and education for its End Users in support of protecting Department confidential information.
6. If the Contractor will be sub-contracting any core functions of the engagement supporting the services for State of New Hampshire, the Contractor will maintain a program of an internal process or processes that defines specific security expectations, and monitoring compliance to security requirements that at a minimum match those for the Contractor, including breach notification requirements.
7. The Contractor will work with the Department to sign and comply with all applicable State of New Hampshire and Department system access and authorization policies and procedures, systems access forms, and computer use agreements as part of obtaining and maintaining access to any Department system(s). Agreements will be completed and signed by the Contractor and any applicable sub-contractors prior to system access being authorized.
8. If the Department determines the Contractor is a Business Associate pursuant to 45 CFR 160.103, the Contractor will execute a HIPAA Business Associate Agreement (BAA) with the Department and is responsible for maintaining compliance with the agreement.
9. The Contractor will work with the Department at its request to complete a System Management Survey. The purpose of the survey is to enable the Department and Contractor to monitor for any changes in risks, threats, and vulnerabilities that may occur over the life of the Contractor engagement. The survey will be completed annually, or an alternate time frame at the Departments discretion with agreement by the Contractor, or the Department may request the survey be completed when the scope of the engagement between the Department and the Contractor changes.
10. The Contractor will not store, knowingly or unknowingly, any State of New Hampshire or Department data offshore or outside the boundaries of the United States unless prior express written consent is obtained from the Information Security Office leadership member within the Department.
11. Data Security Breach Liability. In the event of any security breach Contractor shall make efforts to investigate the causes of the breach, promptly take measures to prevent future breach and minimize any damage or loss resulting from the breach. The State shall recover from the Contractor all costs of response and recovery from

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PO

New Hampshire Department of Health and Human Services

Exhibit K

DHHS Information Security Requirements



the breach, including but not limited to: credit monitoring services, mailing costs and costs associated with website and telephone call center services necessary due to the breach.

12. Contractor must, comply with all applicable statutes and regulations regarding the privacy and security of Confidential Information, and must in all other respects maintain the privacy and security of PI and PHI at a level and scope that is not less than the level and scope of requirements applicable to federal agencies, including, but not limited to, provisions of the Privacy Act of 1974 (5 U.S.C. § 552a), DHHS Privacy Act Regulations (45 C.F.R. §5b), HIPAA Privacy and Security Rules (45 C.F.R. Parts 160 and 164) that govern protections for individually identifiable health information and as applicable under State law.
13. Contractor agrees to establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality of the Confidential Data and to prevent unauthorized use or access to it. The safeguards must provide a level and scope of security that is not less than the level and scope of security requirements established by the State of New Hampshire, Department of Information Technology. Refer to Vendor Resources/Procurement at <https://www.nh.gov/doit/vendor/index.htm> for the Department of Information Technology policies, guidelines, standards, and procurement information relating to vendors.
14. Contractor agrees to maintain a documented breach notification and incident response process. The Contractor will notify the State's Privacy Officer and the State's Security Officer of any security breach immediately, at the email addresses provided in Section VI. This includes a confidential information breach, computer security incident, or suspected breach which affects or includes any State of New Hampshire systems that connect to the State of New Hampshire network.
15. Contractor must restrict access to the Confidential Data obtained under this Contract to only those authorized End Users who need such DHHS Data to perform their official duties in connection with purposes identified in this Contract.
16. The Contractor must ensure that all End Users:
  - a. comply with such safeguards as referenced in Section IV A. above, implemented to protect Confidential Information that is furnished by DHHS under this Contract from loss, theft or inadvertent disclosure.
  - b. safeguard this information at all times.
  - c. ensure that laptops and other electronic devices/media containing PHI, PI, or PFI are encrypted and password-protected.
  - d. send emails containing Confidential Information only if encrypted and being sent to and being received by email addresses of persons authorized to receive such information.

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New Hampshire Department of Health and Human Services

Exhibit K

DHHS Information Security Requirements



- e. limit disclosure of the Confidential Information to the extent permitted by law.
- f. Confidential Information received under this Contract and individually identifiable data derived from DHHS Data, must be stored in an area that is physically and technologically secure from access by unauthorized persons during duty hours as well as non-duty hours (e.g., door locks, card keys, biometric identifiers, etc.).
- g. only authorized End Users may transmit the Confidential Data, including any derivative files containing personally identifiable information, and in all cases, such data must be encrypted at all times when in transit, at rest, or when stored on portable media as required in section IV above.
- h. in all other instances Confidential Data must be maintained, used and disclosed using appropriate safeguards, as determined by a risk-based assessment of the circumstances involved.
- i. understand that their user credentials (user name and password) must not be shared with anyone. End Users will keep their credential information secure. This applies to credentials used to access the site directly or indirectly through a third party application.

Contractor is responsible for oversight and compliance of their End Users. DHHS reserves the right to conduct onsite inspections to monitor compliance with this Contract, including the privacy and security requirements provided in herein, HIPAA, and other applicable laws and Federal regulations until such time the Confidential Data is disposed of in accordance with this Contract.

**V. LOSS REPORTING**

- A. The Contractor must notify NHDHHS Information Security via the email address provided in this Exhibit, of any known or suspected Incidents or Breaches immediately after the Contractor has determined that the aforementioned has occurred and that Confidential Data may have been exposed or compromised.
  - 1. Parties acknowledge and agree that unless notice to the contrary is provided by Department in its sole discretion to Contractor, this Section VI.1 constitutes notice by Contractor to Department of the ongoing existence and occurrence or attempts of Unsuccessful Security Incidents for which no additional notice to Department shall be required. "Unsuccessful Security Incidents" means, without limitation, pings and other broadcast attacks on Contractor's firewalls, port scans, unsuccessful log-on attempts, denial of service attacks, and any combination of the above, so long as no such incident results in unauthorized access, use or disclosure of PHI.
- B. Comply with all applicable state and federal suspected or known Confidential Data loss obligations and procedures. Per the terms of this Exhibit the Contractors and End User's security incident and breach response procedures must also address how the Contractor will:
  - 1. Identify incidents;
  - 2. Determine if Confidential Data is involved in incidents;

# New Hampshire Department of Health and Human Services

## Exhibit K

### DHHS Information Security Requirements



3. Report suspected or confirmed incidents to the Department as required in this Exhibit. The Department will provide the Contractor with a NH DHHS Security Contractor Incident Risk Assessment Report for completion.
  4. Within 24-hrs of initial notification to the Department, complete the initial NH DHHS Security Contractor Incident Risk Assessment Report and email it to the Department's Information Security Office at the email address provided herein;
  5. Identify and convene a core response group to determine the risk level of incidents and determine risk-based responses to incidents and mitigation measures, prepare to include the Department in the incident response calls throughout the incident response investigation;
  6. Identify incident/breach notification method and timing;
  7. Within one business week of the conclusion of the Incident/Breach response investigation a final written Incident Response Report and Mitigation Plan is submitted to the Department's Information Security Office at the email address provided herein;
  8. Address and report incidents and/or Breaches that implicate personal information (PI) to the Department in accordance with NH RSA 359-C:20 and this Agreement;
  9. Address and report incidents and/or Breaches per the HIPAA Breach Notification Rule, and the Federal Trade Commission's Health Breach Notification Rule 16 CFR Part 318 and this Agreement.
- C. All legal notifications required as a result of a breach of information, or potential breach, collected pursuant to this Contract shall be coordinated with the State. The Contractor shall ensure that any subcontractors used by the Contractor shall similarly notify the State of a Breach, or potential Breach immediately upon discovery, shall make a full disclosure, including providing the State with all available information, and shall cooperate fully with the State, as defined above.

#### VI. PERSONS TO CONTACT

A. DHHS Privacy Officer:

DHHSPrivacyOfficer@dhhs.nh.gov

B. DHHS Security Officer:

DHHSInformationSecurityOffice@dhhs.nh.gov

**EXTRACT FROM THE RECORDS OF  
UNIVERSITY OF MASSACHUSETTS**

**Granting Authority to Execute Contracts and All Other Instruments**

**I. Zunilka Barrett, Secretary of the Board of Trustees of the University of Massachusetts**, do hereby certify that the following is a true and complete copy of a vote duly adopted by the Board of Trustees of the University of Massachusetts at a meeting duly called and held on the fifth day of February, nineteen hundred and ninety-seven at the University of Massachusetts, Chancellor's Conference Room, Boston, Massachusetts:

"Further, to affirm that, except as to matters governed by the University of Massachusetts Intellectual Property Policy (Doc. T96-040), the Treasurer of the University of Massachusetts or his designee shall be the sole contracting officer of the University with the Authority to execute all contract, grants, restricted gifts (excluding endowments), and amendments thereto for sponsored programs in instruction, research, or public service, unless and until otherwise voted by the Board of Trustees."

I further certify that the Senior Vice President for Administration & Finance and Treasurer of the University, Lisa A. Calise, has retained the right to remain the sole contracting officer of the University of Massachusetts, but in her absence, she has designated Andrew W. Russell, Senior Assistant Vice President of Operations and Associate Treasurer.

I further certify that effective March 22, 2022, the following is a list of designated individuals authorized in accordance with the afore referenced votes to review and execute all grants and contracts for sponsored programs in instruction, research and public service that are applicable to and received on behalf of the University of Massachusetts for their respective campuses.

**Amherst Campus**

**Kumble R. Subbaswamy**, Chancellor, Amherst Campus, Amherst, Massachusetts,  
**Michael F. Malone**, Vice Chancellor, Research and Engagement Amherst Campus, Amherst, Massachusetts,  
**Jennifer A. Donais**, Assistant Vice Chancellor, Research and Engagement and Director of Research Compliance, Amherst Campus, Amherst, Massachusetts,  
**Marcia Day**, Director, Office of Pre-Award Services, Amherst Campus, Amherst, Massachusetts  
**Laura J. Howard**, Associate Director, Division of Continuing Education, Amherst Campus, Amherst, Massachusetts  
**Steven D. Goodwin**, Deputy Chancellor, Amherst Campus, Amherst, Massachusetts  
**John Fillio**, Assistant Director for the Office of Post Award Management, Amherst Campus, Amherst, Massachusetts  
**Alene Denson**, Director, Office of Post Award Management, Amherst Campus, Amherst, Massachusetts,

**Boston Campus**

**Marcelo Suárez-Orozco**, Chancellor, Boston Campus, Boston, Massachusetts,  
**Kathleen Kirleis**, Vice Chancellor for Administration and Finance, Boston Campus, Boston, Massachusetts,  
**Joseph Berger**, Provost & Vice Chancellor for Academic Affairs, Boston Campus, Boston,

Massachusetts,

**Bala Sundaram**, Vice Provost for Research and Strategic Initiatives and Dean of Graduate Studies, Boston Campus, Boston, Massachusetts,

**Matthew L. Meyer**, Associate Vice Provost for Research and Director of the Office of Research & Sponsored Programs, Boston Campus, Boston, Massachusetts,

**Shala A. Bonyun**, Assistant Director for the Office of Research and Sponsored Programs, Boston Campus, Boston, Massachusetts,

### **Dartmouth Campus**

**Mark Fuller** Chancellor, Dartmouth Campus, Dartmouth, Massachusetts,

**Michael Goodman**, Acting Provost & Vice Chancellor for Academic Affairs, Dartmouth Campus, Dartmouth, Massachusetts,

**Michelle M. Plaud**, Manager of Pre and Post Award Administration, Dartmouth Campus, Dartmouth, Massachusetts,

**Megan Hennessey-Greene**, Director, Office of Research Administration, Dartmouth Campus, Dartmouth Massachusetts,

**Ramprasad Balasubramanian**, Vice Provost for Research and Academic Affairs, Dartmouth Campus, Dartmouth, Massachusetts,

### **Lowell Campus**

**Jacqueline F. Moloney**, Chancellor, Lowell Campus, Lowell, Massachusetts,

**Joseph Hartman**, Provost, Lowell Campus, Lowell, Massachusetts,

**Steven O'Riordan**, Vice Chancellor for Finance and Operations, Lowell Campus, Lowell, Massachusetts,

**Susan Puryear**, Assistant Vice Chancellor for Research Administration, Development & Support Services, Lowell Campus, Lowell, Massachusetts,

**Julie Chen**, Vice Chancellor for Research & Innovation, Lowell Campus, Lowell, Massachusetts,

**Anne Maglia**, Associate Vice Chancellor, Research Administration, Lowell Campus, Lowell, Massachusetts,

**Jacqueline Black**, Director, Grants & Contracts Administration, Lowell Campus, Lowell, Massachusetts,

### **President's Office**

**Eric Heller**, Executive Director of the University of Massachusetts Donahue Institute

### **Worcester**

**Michael F. Collins**, M.D., Chancellor, University of Massachusetts Chan Medical School, Worcester, Massachusetts

**Terence R. Flotte**, M.D., Executive Deputy Chancellor, Provost, and Dean, T.H. Chan School of Medicine, University of Massachusetts Chan Medical School, Worcester, Massachusetts

**John C. Lindstedt**, Executive Vice Chancellor for Administration & Finance, University of Massachusetts Chan Medical School, Worcester, Massachusetts

**Marcy Culvenvell**, Associate Vice Chancellor for Administration & Finance, University of Massachusetts Chan Medical School, Worcester, Massachusetts

**Parth Chakrabarti**, Executive Vice Chancellor, Office of Innovation & Business Development, University of Massachusetts Chan Medical School, Worcester, Massachusetts

**George Xixis**, Associate Vice Chancellor, Head of Transactions, Office of Innovation and

Business Development, University of Massachusetts Chan Medical School, Worcester, Massachusetts

**Lisa M. Colombo**, Executive Vice Chancellor for Commonwealth Medicine at University of Massachusetts Chan Medical School, Worcester, Massachusetts

**Patti Onorato**, Deputy Executive Vice Chancellor of Operations for Commonwealth Medicine at University of Massachusetts Chan Medical School, Worcester, Massachusetts

**Mireli Fino**, Executive Vice Chancellor for MassBiologics at University of Massachusetts Chan Medical School, Worcester, Massachusetts

**Frank Fazio**, Deputy Executive Vice Chancellor for MassBiologics at University of Massachusetts Chan Medical School, Worcester, Massachusetts

**Katherine Luzuriaga**, M.D., Vice Provost for Clinical and Translational Research, University of Massachusetts Chan Medical School, Worcester, Massachusetts

**Danielle Howard**, Director Clinical Research Operations, University of Massachusetts Chan Medical School, Worcester, Massachusetts

**Amy Miarecki**, Associate Vice Chancellor, Grants and Contracts Administration, University of Massachusetts Chan Medical School, Worcester, Massachusetts

**Janice Lagace**, Associate Director Research Funding Services, University of Massachusetts Chan Medical School; Worcester, Massachusetts

**Elizabeth Giehl**, Director of Grant Accounting and Compliance, University of Massachusetts Chan Medical School, Worcester, Massachusetts

**James G. Healy**, JD, Deputy Executive Vice Chancellor for Management, University of Massachusetts Chan Medical School, Worcester, Massachusetts

I further certify that Lisa A. Calise, Andrew W. Russell, Kumble R. Subbaswamy, Michael F. Malone, Jennifer A. Donais, Marcia Day, Laura J. Howard, Steven D. Goodwin, John Fillio, Alene Denson, Marcelo Suárez-Orozco, Kathleen Kirleis, Joseph Berger, Bala Sundaram, Matthew L. Meyer, Shala A. Bonyun, Mark Fuller, Michael Goodman, Megan Hennessey- Greene, Ramprasad Balasubramanian, Michelle M. Plaud, Jacqueline F. Moloney, Steven O'Riordan, Julie Chen, Joseph Hartman, Anne Maglia, Susan Puryear, Jacqueline Black, Eric Heller, Michael F. Collins, Terence R. Flotte, John C. Lindstedt, Marcy Culvenvell, Parth Chakrabarti, George Xixis, Lisa M. Colombo, Patti Onorato, Mireli Fino, Frank Fazio, Katherine Luzuriaga, Danielle Howard, Amy Miarecki, Janice Lagace, Elizabeth Giehl, and James G. Healy, are members of the University Administration with its principal office located at 333 South Street, Shrewsbury, County of Worcester, in the Commonwealth of Massachusetts.

Date: June 7, 2022

  
\_\_\_\_\_  
Zunilka Barrett, Secretary to the Board of Trustees



# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)  
6/10/2022

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

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

<b>PRODUCER</b> Arthur J. Gallagher Risk Management Services, Inc. 470 Atlantic Avenue Boston MA 02210  License#: BR-724491 UNIVOFM-21	<b>CONTACT NAME:</b> PHONE (A/C, No., Ext): 617-261-6700      FAX (A/C, No.): 617-646-0400 E-MAIL ADDRESS:	
	<b>INSURER(S) AFFORDING COVERAGE</b> NAIC #	
<b>INSURED</b> University of Mass System 333 South Street Suite 400 Shrewsbury MA 01545	<b>INSURER A:</b> United Educators Ins, a Reciprocal Risk Retention      10020	
	<b>INSURER B:</b>	
	<b>INSURER C:</b>	
	<b>INSURER D:</b>	
	<b>INSURER E:</b>	
<b>INSURER F:</b>		

**COVERAGES**      **CERTIFICATE NUMBER:** 360762126      **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR  GEN'L AGGREGATE LIMIT APPLIES PER: <input checked="" type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC OTHER:	Y		U40-75A	5/1/2022	5/1/2023	EACH OCCURRENCE	\$ 750,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	\$ 750,000
							MED EXP (Any one person)	\$
							PERSONAL & ADV INJURY	\$ Included
							GENERAL AGGREGATE	\$ 3,000,000
							PRODUCTS - COMP/OP AGG	\$ Included
							Self Insured Retent	\$ 250,000
	<input type="checkbox"/> AUTOMOBILE LIABILITY <input type="checkbox"/> ANY AUTO <input type="checkbox"/> OWNED AUTOS ONLY <input type="checkbox"/> SCHEDULED AUTOS <input type="checkbox"/> HIRED AUTOS ONLY <input type="checkbox"/> NON-OWNED AUTOS ONLY <input type="checkbox"/> AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident)	\$
							BODILY INJURY (Per person)	\$
							BODILY INJURY (Per accident)	\$
							PROPERTY DAMAGE (Per accident)	\$
								\$
	<input type="checkbox"/> UMBRELLA LIAB <input type="checkbox"/> OCCUR <input type="checkbox"/> EXCESS LIAB <input type="checkbox"/> CLAIMS-MADE  DED    RETENTION \$						EACH OCCURRENCE	\$
							AGGREGATE	\$
								\$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y/N	N/A				PER STATUTE	OTH-ER
							E.L. EACH ACCIDENT	\$
							E.L. DISEASE - EA EMPLOYEE	\$
							E.L. DISEASE - POLICY LIMIT	\$

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

State of NH  
 Department of Health and Human Services  
 129 Pleasant Street  
 Concord, NH 03301-3857  
 is additional insured as per policy provisions and exclusions.

### CERTIFICATE HOLDER

### CANCELLATION

UMass Medical School  
 Biotech 4, 2nd Flr; 377 Plantation Street  
 Worcester MA, Massachusetts. 01605

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

AUTHORIZED REPRESENTATIVE

*Patrick J. Keane*

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# University of Massachusetts

Amherst • Boston • Dartmouth • Lowell • Medical School • UMassOnline

To Whom It May Concern:

The University of Massachusetts, as an entity of the Commonwealth of Massachusetts, is self-insured for Worker's Compensation in accordance with Chapter 152 of the Massachusetts General Laws.

If you have any questions or concerns, please contact me at 774-455-7616. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joshua Tucker', written over a horizontal line.

Joshua Tucker  
Insurance Risk Analyst

# Roger B. Eaton, PhD

Director, New England Newborn Screening Program



## Education

State University of New York at  
Buffalo, Buffalo, NY:  
PhD, Philosophy

MS

University of Vermont,  
Burlington, VT:  
BA

## Awards

Association of Public Health  
Laboratories:  
The Harry Hannon Newborn  
Screening Laboratory  
Improvement Award (2021)

Dr. Eaton has served as the Director of the New England Newborn Screening Program since 1998 and has been with the program since 1991. He is responsible for leading all aspects of the program, including policies, long-range goals, laboratory QA/QC activities, implementation and use of new technologies, data system development and determining research and development priorities. Under Dr. Eaton's direction, Massachusetts became one of the first states to apply tandem mass spectrometry their newborn screening tests.

Dr. Eaton is an associate professor in the department of pediatrics at the UMass Chan Medical School. He received his master's and PhD from the State University of New York. He has authored or co-authored more than twenty articles in the last ten years on a number of subjects relevant to newborn screening, such as long-term follow-up for individuals diagnosed with newborn screening conditions, or the effects of expanded newborn screening for biochemical genetic disorders.

Dr. Eaton is a member of the Association of Public Health Laboratories (APHL) and the International Society of Newborn Screening (ISNS) and serves on a number of workgroups and committees. In 2021, APHL honored him with the prestigious Harry Hannon Newborn Screening Laboratory Improvements Award. He also participates on the Health Information Technology Workgroup for the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

## Experience

Commonwealth Medicine, UMass Chan Medical School, Shrewsbury, MA (the New England Newborn Screening Program began operating under the UMass Medical School on July 1, 1997.) ..... 1997 – Present  
 Director, New England Newborn Screening Program ..... 1998 – Present  
 Associate Professor, Department of Pediatrics ..... 1998 – Present  
 Chief of Laboratory – Serology ..... 1991 – Present  
 Brigham and Women's Hospital, Boston, MA ..... 1987 – 1991  
 Associate in Rheumatology and Immunology  
 Harvard Medical School, Boston, MA ..... 1981 – 1991  
 Instructor in Medicine, Department of Rheumatology  
 and Immunology ..... 1984 – 1991  
 Postdoctoral Fellow and Research Fellow (joint appointment);  
 Brigham and Women's Hospital ..... 1981 – 1984

## Additional Professional Experience (since 2015)

- Member, Commonwealth Medicine's Commit to Excellence Workgroup of its Strategic Plan initiative, 2019 - present

- Invited expert, Quality Indicator Working Group, NewSTEPS, Association of Public Health Laboratories. National workgroup conference. Feb. 10, 2016, Silver Spring, MD. Association of Public Health Laboratories, 2016
- Member, Steering Committee for the Newborn Screening Technical assistance, and Evaluation Program (NewSTEPS), Association of Public Health Laboratories, 2014–2018
- Member, Association of Public Health Laboratories, Health Information Technology Workgroup, 2014–Present
- Advisory Board Member, HRSA-grant Sickle Cell Disease Newborn Screening Program Advisory Board. (Barry Zuckerman, M.D., Boston Medical Center, Principal Investigator), 2013–2015
- Member, UMass Medical School Commonwealth Medicine Division Strategic Planning Goal #1 (Quality Improvement) Workgroup, 2010-2016
- Member, UMass Medical School Commonwealth Medicine Division Strategic Planning Goal #1 (Quality Improvement) Workgroup, 2010-2016
- Member, Leadership Forum, Commonwealth Medicine Division, University of Massachusetts Medical School, 2006-2018
- Expert Consultant and Presenter, Newborn Screening Advisory Committee to the State of New Hampshire Department of Public Health, 2005-Present
- Expert Consultant and Presenter, Newborn Screening Technical Advisory Committee to the Commonwealth of Pennsylvania Department of Public Health, 2004-2015
- Member, International Society of Newborn Screening, 2000-Present
- Expert Consultant and Presenter, Newborn Screening Advisory Committee to the Commissioner of the Massachusetts Department of Public Health, 1998-Present
- Participant, Strategic Planning Workshop Series for Strategic Planning and Development of Commonwealth Medicine Division, University of Massachusetts Medical School, 2006, 2016, and 2019.

#### Recent Publications and Presentations (since 2003)

Waisbren SE, Albers S, Amato S, Ampola M, Brewster TG, Demmer L, Eaton RB, Greenstein R, Korson M, Larson C, Marsden D, Msall M, Naylor EW, Pueschel S, Seashore M, Shih VE, Levy HL. Effect of expanded newborn screening for biochemical genetic disorders on child outcomes and parental stress. *JAMA*. 2003 Nov 19;290(19):2564-72.

Comeau AM, Larson C, Eaton RB. Integration of new genetic diseases into statewide newborn screening: New England experience. *Am J Med Genet C Semin Med Genet*. 2004 Feb 15;125(1):35-41.

Comeau AM, Parad RB, Dorkin HL, Dovey M, Gerstle R, Haver K, Lapey A, O'Sullivan BP, Waltz DA, Zwerdling RG, Eaton RB. Population-based newborn screening for genetic disorders when multiple mutation DNA testing is incorporated: a cystic fibrosis newborn screening model demonstrating increased sensitivity but more carrier detections. *Pediatrics*. 2004 Jun;113(6):1573-81.

Comeau AM, Parad R, Gerstle R, O'Sullivan BP, Dorkin HL, Dovey M, Haver K, Martin T, Eaton RB. Communications systems and their models: Massachusetts parent

compliance with recommended specialty care after positive cystic fibrosis newborn screening result. *J Pediatr*. 2005 Sep;147(3 Suppl):S98-100.

Comeau AM, Parad R, Gerstle R, O'Sullivan BP, Dorkin HL, Dovey M, Haver K, Martin T, **Eaton RB**. Challenges in implementing a successful newborn cystic fibrosis screening program. *J Pediatr*. 2005 Sep;147(3 Suppl):S89-93. Review.

The SYROCOT (Systematic Review on Congenital Toxoplasmosis) Study Group. Effectiveness of prenatal treatment for congenital toxoplasmosis: a meta-analysis of individual patients' data. *The Lancet*. 2007;369:115-22.

B Therrell, F Lorey, R **Eaton**, D Frazier, G Hoffman, C Boyle, D Green, O Devine, H Hannon. Impact of Expanded Newborn Screening --- United States, 2006. *MMWR*, September 19, 2008 / 57(37);1012-1015.

Hsu HW, Zytovicz TH, Comeau AM, Strauss AW, Marsden D, Shih VE, Grady GF, **Eaton RB**. Spectrum of Medium Chain Acyl-CoA Dehydrogenase Deficiency Detected by Newborn Screening. *Pediatrics* (2008) May;121:e1108-e1114.

Cynthia F. Hinton, Katharine B. Harris, Lynette Borgfeld, Margaret Drummond-Borg, **Roger Eaton**, Fred Lorey, Bradford L. Therrell, Jill Wallace, and Kenneth A. Pass, PhD. Trends in Incidence Rates of Congenital Hypothyroidism Related to Select Demographic Factors: Data From the United States, California, Massachusetts, New York, and Texas. *Pediatrics*. 2010;125 Supplement:S37-S47

Thompson JG, Wilkey JF, Baptiste JC, Navas JS, Pai S-Y, Pass KA, **Eaton RB**, Comeau AM. Development of a High Throughput Multiplexed TREC qPCR Assay with Internal Controls for Detection of Severe Combined Immunodeficiency in Population-based Newborn Screening. *Clinical Chemistry* 2010 Sep;56(9):1466-74.

Comeau AM, Hale JE, Pai S-Y, Bonilla FA, Notarangelo LD, Pasternack MS, Meissner HC, Cooper, ER, DeMaria A, Sahai I, **Eaton RB**. Guidelines for Implementation of Population-based newborn screening for severe combined immunodeficiency. *Journal of Inherited Metabolic Disease*. 2010, October;33 (Supplement 2): 273-281.

Sahai I, **Eaton RB**, Hale JE, Mulcahy EA, Comeau AM. Long-term follow-up to ensure quality care of individuals diagnosed with newborn screening conditions: early experience in New England. *Genetics in Medicine*. 2010 Dec; 12(12):S220-S227.

Sahai I, Bailey JC, **Eaton RB**, Zytovicz T, Harris DJ. A near-miss: very long chain acyl-CoA dehydrogenase deficiency with normal primary markers in the initial well-timed newborn screening specimen. *J Pediatr*. 2010 Nov 11.

Sahai I, Zytkowicz T, Rao Kotthuri S, Lakshmi Kotthuri A, **Eaton RB**, Akella RR. Neonatal Screening for Inborn Errors of Metabolism Using Tandem Mass Spectrometry: Experience of the Pilot Study in Andhra Pradesh, India, *Indian J Pediatr*. 2011 Mar 17.

Marquardt G, Currier R, McHugh DMS, Gavrilov D, Magera MJ, Matern D, Oglesbee D, Raymond K, Rinaldo P, Smith EH, Tortorelli S, Turgeon CT, Lorey F, Wilcken B, Wiley V, Greed LC, Lewis B, Boemer F, Schoos R Sandrine Marie S, Vincent MF, Cleverthon Sica Y, Torquado Domingos M, Al-Thihli K, Sinclair G, Al-Dirbashi OY, Chakraborty P, Dymerski M, Porter C, Manning A, Seashore MR, Quesada J, Reuben A, Petr Christina P, Hornik P, Atef Mandour I, Atty Sharaf SA, Bodamer O, Dy B, Torres J, Zori R, Cheillan D, Vianey-Saban C, Ludvigson D, Stembridge A, Bonham J, Downing M, Dotsikas Y, Loukas YL, Papakonstantinou V, Zacharioudakis GSA, Baráth A, Karg E, Franzson L, Jonsson JJ, Breen NN, Lesko BG, Berberich SL, Turner K, Ruoppolo M, Scolamiero E, Antonozzi I, Carducci C, Caruso U, Cassanello M, la Marca G, Pasquini E, Di Gangi IM, Giordano G, Camilot M, Teofoli F, Manos SM, Peterson CK, Mayfield Gibson SK, Sevier DW, Lee SY, Park HD, Khneisser I, Browning

P, Gulamali-Majid F, Watson MS, **Eaton RB**, Sahai I, Ruiz C, Torres R, Seeterlin MA, Stanley EL, Hietala A, McCann M, Campbell C, Hopkins PV, de Sain-Van der Velden MG, Elvers B, Morrissey MA, Sunny S, Knoll D, Webster D, Frazier DM, McClure JD, Sesser DE, Willis SA, Rocha H, Vilarinho L, John C, Lim J, Caldwell SG, Tomashitis K, Castiñeiras Ramos DE, Cocho de Juan JA, Rueda Fernández I, Yahyaoui Macías R, Egea Mellado JM, González Gallego I, Delgado Pecellin C, García-Valdecasas Bermejo MS, Chien YH, Hwu WL, Childs T, McKeever CD, Tanyalcin T, Abdulrahman M, Queijo C, Lemes A, Davis T, Hoffman W, Baker M, Hoffman GL. (2012) Enhanced interpretation of newborn screening results without analyte cutoff values. Enhanced interpretation of newborn screening results without analyte cutoff values. *Genet in Med* 2012(7);14:648-655.

Zytkovicz TH, Sahai I, Rush A, Odewale A, Johnson D, Fitzgerald E, Britton D, **Eaton RB**. Newborn screening for hepatorenal tyrosinemia-I by tandem mass spectrometry using pooled samples: a four-year summary by the New England newborn screening program. *Clin Biochem*. 2013 May;46(7-8):681-4.

Sahai I, Garganta CL, Bailey J, James P, Levy HL, Martin M, Neilan E, Phornphutkul C, Sweetser DA, Zytkovicz TH, **Eaton RB**. Newborn Screening for Glutaric Aciduria-II: The New England Experience. *JIMD Rep*. 2014 Nov; 13: 1-14.

Hale JE, Platt CD, Bonilla FA, Hay BN, Sullivan JL, Johnston AM, Pasternack MS, Hesterberg PE, Meissner HC, Cooper ER, Barmettler S, Farmer JR, Fisher D, Walter JE, Yang N, Sahai I, **Eaton RB**, DeMaria A, Notarangelo LD, Pai S-Y, Comeau AM. Ten Years of Newborn Screening for Severe Combined Immunodeficiency (SCID) in Massachusetts. *Journal of Allergy and Clinical Immunology*: 2021 May;9(5):2060-2067.

Hale JE, Abbott MA, Chen JY, Counihan AM, Darras BT, **Eaton RB**, Estrella E, Gerstel-Thompson J, Hay BN, Kumar B, Sahai I, Swaboda KJ, Comeau AM. Massachusetts' Findings from Statewide Newborn Screening for SMA. *IJNS* 2021 May 23;7(2):26.

Kumar B, Barton S, Kordowska J, **Eaton RB**, Counihan AM, Hale JE, Comeau AM. Novel modification of a confirmatory SMA sequencing assay that can be used to determine SMN2 copy number 2021 Jul 21;7(3):47.

# Anne Marie Comeau, PhD

Deputy Director, New England Newborn Screening Program



## Education

*Harvard School of Public Health, Boston, MA:*  
Fellowship

*Brandeis University, Waltham, MA:*  
PhD, Biology

*College of the Holy Cross, Worcester, MA:*  
BA, Biology

## Certification and Licensure

*Clinical Laboratory Improvements Amendments (CLIA):*  
License-eligible Laboratory Director (NENSP CLIA License)

## Awards and Honors

*Association of Public Health Laboratories:*  
The Harry Hannon Newborn Screening Laboratory Improvement Award (2013)

*Commonwealth of Massachusetts:*  
Citation for Outstanding Performance (1999)

*National Institute of Allergy and Infectious Disease:*  
Individual National Research Service Award (1985 - 1988)

## Professional Memberships and Activities

*American College of Medical Genetics:*  
Affiliate Specialist Member

*Council of State and Laboratory Epidemiologists:*  
Member

*Association of Public Health Laboratories:*  
Member

*International Society of Newborn Screening:*  
Member

Anne Marie Comeau is an avid advocate of interdisciplinary evidence-based development and evaluation of newborn screening protocols. She has promoted policies and developed protocols that facilitate Massachusetts' expansion of newborn screening services while respecting human subjects' protections. Her publication topics include evaluations of molecular applications in newborn screening, implications of expanded newborn screening on the health care community, recommendations for successful implementation of newborn screening programs and considerations for research use of data held under public health stewardship.

## Experience

Commonwealth Medicine, UMass Chan Medical School  
Shrewsbury, MA .....2021 – present

*Professor, Department of Pediatrics* .....2021 – Present

*Deputy Director, New England Newborn Screening Program* .....2021 – Present

*Director, Molecular Development and Diagnostics Laboratory*.....1990 – Present

Commonwealth Medicine, University of Massachusetts Medical School,  
Shrewsbury, MA .....1997 – 2021

*Professor, Department of Pediatrics* .....2012 – 2021

*Associate Professor, Department of Pediatrics* .....2005 – 2012

*Assistant Professor, Department of Pediatrics* .....1997 – 2005

*Deputy Director, New England Newborn Screening Program* .....1998 – 2021

New England Regional Newborn Screening Program.....1988 – 1997

*Assistant Director, New England Newborn Screening Program*.....1991 – 1997

*Director, Molecular Development and Diagnostics Laboratory*.....1990 – 2021

*Senior Research Associate, Theobald Smith Research Institute*.....1988 – 1990

Harvard School of Public Health, Boston, MA .....1985 – 1988

*Postdoctoral Research Fellow*

E.K. Shriver Center, Waltham, MA .....1986 – 1987

*Clinical Human Genetic Counselor*

## Grants and Contracts (Five recent examples of completed work)

- **NICHD HHSN2752015000091.** Newborn Screening Pilot Studies. Comeau (PI), 2015–2020. An NICHD IDIQ contract award allowing eligibility to compete for funds to implement newborn screening pilot studies. Minimum Award: \$5,000 annually for PI consultation Maximum Award: up to \$9,000,000 for specified implementations.
- **CDC RFA-EH18-1804** Newborn Screening New Condition Implementation: Capacity Building and Quality Improvement through Data Harmonization Comeau (PI). 2018-20. To enhance the infrastructure in the molecular laboratory with additional equipment and to continue networking with the CDC and its partners to improve analytic and post-analytic protocols such that

- optimum harmonization is achieved nationally. Total Award \$458,164 (Direct \$427,794; Indirect \$30,370) Principal Investigator (10% FTE)
- **UMMS Center for Clinical and Translational Science Life Moment Fund 2012 Comeau (PI), 2012.** A retrospective study with prospective potential: evaluating specimens of children diagnosed with conditions that may be identifiable in the newborn period by molecular testing for measures of T and B cell development. To determine whether children with non-SCID immune conditions are likely to be reliably identified by SCID newborn screening and whether quality improvements using additional tests in SCID newborn screening might provide useful data for interpretation of clinical status.
- **CDC IV01-EH000362-01 Comeau (PI), 2008–2011** Implementing SCID Newborn Screening with Multiplexed Assays in an Integrated Program Approach. To develop, validate and implement SCID NBS tests and algorithm(s) for identifying infants with SCID and to make the assay/algorithm(s) available to public health NBS laboratories for implementation of SCID NBS Total Award \$1,464,519 (Direct \$1,368,836; Indirect \$95,683) Principal Investigator (15% FTE)
- **HRSA U22MC03959 New England Genetics Collaborative (NEGC) , John Moeschler (PI), 2007–2012.** Building upon the Foundation of Six New England States' Comprehensive Newborn Screening Programs for Sustainable Follow-up (Independent national competitive bid for project support (Subcontract for Long Term Follow Up; competitive application independent of award to NEGC). To establish a sustainable systematic public health approach to Long-Term Follow-Up, based upon the success of comprehensive NBS systems and compatible with national endeavors. Total Award \$1,131,847 (Direct \$984,215; Indirect \$147,632). Project Leader, Comeau (15% FTE, in kind contribution)

#### Peer-Reviewed Publications (2015 forward)

- Dobbs K, Dominguez Conde C, Zhang SY, Parolini S, Audry M, Chou J, Haapaniemi E, Keles S, Bilic I, Okada S, Massaad MJ, Rounioja S, Alwahadneh AM, Serwas NK, Capuder K, Çiftçi E, Felgentreff K, Ohsumi TK, Pedergrana V, Boisson B, Haskoloğlu Ş, Ensari A, Schuster M, Moretta A, Itan Y, Patrizi O, Rozenberg F, Lebon P, Saarela J, Knip M, Petrovski S, Goldstein DB, Parrott RE, Savas B, Schambach A, Tabellini G, Bock C, Chatila TA, **Comeau AM**, Geha RS, Abel L, Buckley RH, İkinçioğulları A, Al-Herz W, Helminen M, Doğu F, Casanova JL, Boztuğ K, Notarangelo LD.. Inherited DOCK2 Deficiency in Patients with Early-Onset Invasive Infections. *N Engl J Med.* 2015 Jun 18;372(25):2409-22.
- Goldenberg AJ, **Comeau AM**, Grosse SD, Tanksley S, Prosser LA, Ojodu J, Botkin JR, Kemper AR, Green NS. Evaluating Harms in the Assessment of Net Benefit: A Framework for Newborn Screening Condition Review. *Matern Child Health J.* 2016 Mar;20(3):693-700.
- Hinton CF, Homer CJ, Thompson AA, Williams A, Hassell KL, Feuchtbaum L, Berry SA, **Comeau AM**, Therrell BL, Brower A, Harris KB, Brown C, Monaco J, Ostrander RJ, Zuckerman AE, Kaye C, Dougherty D, Greene C, Green NS; Follow-up and Treatment Sub-committee of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC). A framework for assessing outcomes from newborn screening: on the road to measuring its promise. *Mol Genet Metab.* 2016 Aug;118(4):221-9. PMC4970906

**Notes:**

*\*Supervisor and mentor of first author.*

- Brauer PM, Pessach IM, Clarke E, Rowe JH, Ott de Bruin L, Lee YN, Dominguez-Brauer C, Comeau AM, Awong G, Felgentreff K, Zhang YH, Bredemeyer A, Al-Herz W, Du L, Ververs F, Kennedy M, Gilliani S, Keller G, Sleckman BP, Schatz DG, Bushman FD, Notarangelo LD, Zúñiga-Pflücker JC. Modeling altered T-cell development with human induced pluripotent stem cells from patients with RAG1 mutations and distinct immunological phenotypes. *Blood*. 2016 Aug 11;128(6):783-93. PMC4982452
- Kemper AR, Brosco J, Comeau AM, Green NS, Grosse SD, Jones E, Kwon JM, Lam WK, Ojodu J, Prosser LA, Tanksley S. Newborn screening for X-linked adrenoleukodystrophy: evidence summary and advisory committee recommendation. *Genet Med*. 2017 Jan;19(1):121-126. PMC5182180
- Kumar B, Barton S, Kordowska J, Eaton RB, Counihan AM, Hale JE, Comeau AM, Kemper AR, Brosco J, Comeau AM, Green NS, Grosse SD, Jones E, Kwon JM, Lam WK, Ojodu J, Prosser LA, Tanksley S. Newborn screening for X-linked adrenoleukodystrophy: evidence summary and advisory committee recommendation. *Genet Med*. 2017 Jan;19(1):121-126. PMC5182180.
- Delmonte OM, Biggs CM, Hayward A, Comeau AM, Kuehn HS, Rosenzweig SD, Notarangelo LD. First case of X-linked Moesin deficiency identified after newborn screening for SCID. *J Clin Immunol. J Clin Immunol*. 2017 May;37(4):336-338.
- Goda V, Malik A, Kalmar T, Maroti Z, Patel B, Ujhazi B, Csomos K, Hale JE, Chen K, Bleesing J, Palma P, Cancrini C, Comeau AM, Krivan G, Walter JE. Partial RAG deficiency in a patient with varicella infection, autoimmune cytopenia, and anticytokine antibodies. *J Allergy Clin Immunol Pract*. 2018 Feb 2. pii: S2213-2198(18)30042-4.
- Sontag MK, Sarkar D, Comeau AM, Hassell K, Botto L, Parad R, Rose SR, Wintergerst KA, Smith-Whitley K, Singh S, usuf C, Ojodu J, Copeland S, Hinton, CF. Case definitions for conditions identified by newborn screening public health surveillance. *International Journal of Neonatal Screening. Int. J. Neonatal Screen*. 2018, 4, 16; doi:10.3390/ijns4020016. PMC5978752
- Verheijen J, Wong SY, Rowe JH, Raymond K, Calzoni E, Pai SY, Delmonte OM, Choi U, Yamazaki Y, Comeau AM, Janssen E, Henderson L, Hazen M, Berry G, Aldhekri He M, Notarangelo LD. Defining a new immune deficiency syndrome: MAN2B2-CDG. *J Allergy Clin Immunol* 2020 March 145 (3): 1008-1011.
- \*Hale JE, Platt CD, Bonilla FA, Hay BN, Sullivan JL, Johnston AM, Pasternack MS, Hesterberg PE, Meissner HC, Cooper ER, Barmettler S, Farmer JR, Fisher D, Walter JE, Yang N, Sahai I, Eaton RB, DeMaria A, Notarangelo LD, Pai S-Y, Comeau AM. Ten Years of Newborn Screening for Severe Combined Immunodeficiency (SCID) in Massachusetts. *J Allergy Clin Immunol Pract*. 2021 May;9(5):2060-2067.e2
- \*Hale JE, Darras BT, Swaboda KJ, Estrella E, Chen JY, Abbott MA, Hay BN, Kumar B, Counihan AM, Gerstel-Thompson J, Sahai I, Eaton RB, Comeau AM. Massachusetts' Findings from Statewide Newborn Screening for SMA. IJNS submission April 30, 2021. *Int. J. Neonatal Screen*. 2021, 7, 26. <https://doi.org/10.3390/ijns7020026>.
- Novel modification of a confirmatory SMA sequencing assay that can be used to determine SMN2 copy number. *Int. J. Neonatal Screen*. 2021, 7, 47. <https://doi.org/10.3390/ijns7030047>



**Commonwealth  
Medicine**

# Devinder Kaur, PhD

Manager, Newborn Screening Program

## Education

*Post Graduate Institute of  
Medical Education & Research  
(PGIMER), Chandigarh, India:*

PhD, Philosophy  
MS, Biochemistry  
BS, Medical Laboratory  
Technology

*University of Massachusetts,  
Amherst, Amherst, MA:*  
Introductory Biostatistics,  
Application of Social and  
Behavioral Theories in Public  
Health Interventions, and  
Introduction to US Health Care.

## Professional Affiliations

*International Union Against  
Tuberculosis and Lung Disease*

*American Society of  
Microbiology*

*Green Light Committee (gGLC)  
of the WHO and the Stop TB  
Partnership*  
Technical Advisor

Devinder Kaur is a Manager at Commonwealth Medicine with over 20 years of experience in medical research.

## Experience

Commonwealth Medicine, UMass Chan Medical School  
Boston/Shrewsbury, MA.....2010 – Present  
*Manager, New England Newborn Screening Program  
Commonwealth Medicine.....2017 – Present*  
*Assistant Professor, Department of Pediatrics .....2021–Present*  
*Research Assistant Professor, Dept of Internal Medicine .....2017 – 2021*  
*Interim Director, MA Supranational TB Reference Lab (MSRL) &  
Research Assistant Professor, Dept of Internal Medicine .....2015 – 2017*  
*Assistant Director, MA Supranational TB Reference Lab (MSRL) &  
Research Assistant Professor, Dept of Internal Medicine .....2010 – 2015*  
Colorado State University, Fort Collins, CO .....2000 – 2010  
*Research Scientist III.....2009 – 2010*  
*Research Scientist II.....2008 – 2009*  
*Research Scientist I.....2005 – 2008*  
*Postdoctoral Research Fellow.....2000 – 2005*  
Post Graduate Institute of Medical Education & Research  
(PGIMER) Chandigarh, India .....1992 – 2000  
*Senior Research Fellow.....1999 – 2000*  
*Junior Research Fellow.....1995 – 1999*  
*Post graduate Dissertation.....1993 – 1995*  
*Laboratory Technologist.....1992 – 1993*

## Recent Invited Speaker (2010 - )

- Kaur D. "MSRL Activities: 2012-2014" Presentation at the PAHO/WHO TB Laboratory Working Group meeting of the Americas, Mexico City, Mexico, May 23rd to 26th, 2014
- Kaur D. and Onesky A. "Improving TB control in high burden settings: country engagement and support model for diagnosis, testing, surveillance, and program development – Presentation at Ministry of Health and Social Welfare, Monrovia, Liberia, West Africa, 31st July 2013
- Kaur, D. "Conventional and molecular diagnostics for detection of drug-resistant pulmonary tuberculosis" Seminar delivered to medical consultants and physicians from HIV clinics of Ecuador, 16th April 2012
- Kaur, D. "Structure, Function and Biosynthesis of the M. tuberculosis Lipoglycan: potential for developing new drug targets and vaccine candidates." Emerging Pathogens Institute, University of Florida, Gainesville, Florida, 3rd August 2010

- Kaur, D. "Structure, Function and Biosynthesis of the M. tuberculosis Lipoglycan: potential for developing new drug targets and vaccine candidates." University of Massachusetts Medical School, Jamaica Plain Campus, Boston, Massachusetts, 21st June 2010

#### Recent Presentations (2010 - )

- Maha Farhat, Karen R. Jacobson, Devinder Kaur, Alex Sloutsky, Molly F. Franke, Carole D. Mitnick, and Megan Murray (2014). Comparison of quantitative and qualitative fluoroquinolone susceptibility test results in M. tuberculosis. Poster presented at the Harvard University CFAR Annual Symposium, Cambridge, MA
- Kulkarni Medha, R.R. Yu, S.C. Zaner, P.P. Banada, Robert Blakemore and Devinder Kaur (2013). Analytical performance of the Xpert® MTB/RIF Assay. Poster presented at the 8th National Conference on Laboratory Aspects of Tuberculosis organized by Association of Public Health Laboratories, San Diego, CA.

#### Recent Publications (2010 - )

- Farhat MR, Freschi L, Calderon R, Loerger T, Snyder M, Meehan CJ, Jong B, Rigouts L, Sloutsky A, Kaur D, Sunyaev S, van Soolingen D, Shendure J, Sacchettini J and Murray MG. GWAS for quantitative resistance phenotypes in *Mycobacterium tuberculosis* reveals resistance genes and regulatory regions. *Nat Commun.* 10 (1), 2128 (2019).
- Decout A, Silva-Gomes S, Drocourt D, Blattes E, Rivière M, Prandi J, Larrouy-Maumus G, Caminade AM, Hamasur B, Källenius G, Kaur D, Dobos KM, Lucas M, Sutcliffe IC, Besra GS, Appelmelk BJ, Gilleron M1, Jackson M, Vercellone A, Tiraby G, Nigou J. Deciphering the molecular bases of mycobacteria and lipoglycan recognition by the C-type lectin Dectin-2. *Sci Rep.* Nov 15;8(1):16840. 35393-5 (2018).
- Farhat MR, Jacobson KR, Franke MF, Kaur D, Murray M, and Mitnick CD. Fluoroquinolone resistance mutation detection is non-inferior to culture-based drug sensitivity testing for predicting MDR TB treatment outcome: A retrospective cohort study. *Clinical Infectious Diseases*, Volume 65, Issue 8, 15 October 2017, Pages 1364–1370.
- Dharan NJ, Blakemore R, Sloutsky A, Kaur D, Alexander RC, Ghajar M, Musser KA, Escuyer VE, Rowlinson MC, Crowe S, Laniado-Laborin R, Valli E, Nabeta P, Johnson P, Alland D. Performance of the G4 Xpert® MTB/RIF assay for the detection of *Mycobacterium tuberculosis* and rifampin resistance: a retrospective case-control study of analytical and clinical samples from high- and low-tuberculosis prevalence settings. *BMC Infect Dis.* 2016 Dec 20;16(1):764.
- Kaniga K, Cirillo DM, Hoffner S, Ismail NA, Kaur D, Lounis N, Metchock B, Pfyffer GE, Venter A. A multilaboratory, multicountry study to determine MIC quality control ranges for phenotypic drug susceptibility testing of selected first-line antituberculosis drugs, second-line injectables, fluoroquinolones, clofazimine, and linezolid. *Journal of Clinical Microbiology.* 2016 Dec;54(12):2963-2968.

- Kaniga K, Cirillo DM, Hoffner S, Ismail NA, Kaur D, Lounis N, Metchock B, Pfyffer GE, Venter A. A multilaboratory, multicountry study to determine bedaquiline MIC quality control ranges for phenotypic drug susceptibility testing. *Journal of Clinical Microbiology*. 2016 Dec;54(12):2956-2962.
- Farhat MR, Razvan S, Iartchouk O, Bozeman S, Galagan J, Sisk P, Stolte C, Nebenzahl-Guimaraes H, Jacobson K, Sloutsky A, Kaur D, Posey J, Kreiswirth BN, Kurepina N, Rigouts L, Streicher EM, Victor TC, Warren RM, van Soolingen D, and Murray M. Genetic determinants of drug resistance in *Mycobacterium tuberculosis* and their diagnostic value. *American J. Respir. Crit. Care Med*. 2016 Sep 1;194(5):621 Feb 24
- Farhat MR, Jacobson KR, Franke MF, Kaur D, Sloutsky A, Mitnick CD, Murray M. Gyrase Mutations are associated with variable levels of fluoroquinolone resistance in *Mycobacterium tuberculosis*. *Journal of Clinical Microbiology*. 2016 Mar;54(3):727-33
- Salvatore PP, Becerra MC, Abel Zur Wiesch P, Hinkley T, Kaur D, Sloutsky A, Cohen T. Fitness costs of drug resistance mutations in multidrug-resistant *Mycobacterium tuberculosis*: A household-based case-control study. *J Infect Dis*. 2016 Jan 1;213(1):149-55.
- Farhat MR, Mitnick CD, Franke MF, Kaur D, Sloutsky A, Murray M, and Jacobson KR. Concordance of *Mycobacterium tuberculosis* fluoroquinolone resistance testing: implications for treatment. *The International Journal of Tuberculosis and Lung Disease*. 2015 Mar;19(3):339-41.
- Kaur D, Angala SK, Wu SW, Khoo KH, Chatterjee D, Brennan PJ, Jackson M, McNeil MR. A single arabinan chain is attached to the phosphatidylinositol mannosyl core of the major immunomodulatory mycobacterial cell envelope glycoconjugate, lipoarabinomannan. *J. Biol. Chem*. 2014 Oct 31;289(44):30249-56.
- Farhat MR, Shapiro BJ, Sultana R, Jacobson K, Victor TC, Warren RM, Streicher EM, Calver A, Sloutsky A, Kaur D, Posey JE, Plikaytis B, Oggiono MR, Gardy JL, Johnston JC, Rodrigues M, Tang PKC, Kato-Maeda M, Kreiswirth B, Kurepina N, Borowski M, Muddukrishan B, Galagan J, Birren B, Sabeti P, Murray M. Genomic analysis identifies targets of convergent positive selection in drug-resistant *Mycobacterium tuberculosis*. *Nature Genetics*. 2013 Oct;45(10):1183-9.
- Urresti S, Albesa-Jové D, Schaeffer F, Pham HT, Kaur D, Gest P, van der Woerd MJ, Carreras-González A, López-Fernández S, Alzari PM, Brennan PJ, Jackson M, Guerin ME. Mechanistic insights into the retaining glucosyl-3-phosphoglycerate synthase from mycobacteria. *J. Biol. Chem*. 2012 Jul 13;287(29):24649-61.
- Barczak AK, Gomez JE, Kaufmann BB, Hinson ER, Cosimi L, Borowsky ML, Onderdonk A, Stanley SA, Kaur D, Bryant KF, Knipe DM, Sloutsky A, Hung DT. RNA signatures allow rapid identification of pathogens and antibiotic susceptibilities. *Proceedings of National Academy of Sciences, USA*. 2012; Apr 17;109(16):6217-22.
- Dianišková P, Korduláková J, Skovierová H, Kaur D, Jackson M, Brennan PJ, Mikušová K. Investigation of ABC transporter from mycobacterial arabinogalactan biosynthetic cluster. *Gen Physiol Biophys*. 2011 Sep;30(3):239-50.

# Binod Kumar, MS, PhD

Assistant Professor, Newborn Screening and Dept. of Pediatrics



## Education

*Bhabha Atomic Research Center, Mumbai, India:*  
Doctor of Philosophy, Radiation and Cancer Biology

*APS University, Rewa, India:*  
MS, Biotechnology

*Ranchi University, Ranchi, India:*  
BS, Biotechnology

## Academic Journal Reviewer

*Molecular and Cellular Biochemistry*

*Molecular Oncology*

*Cancer Letters*

*Technology in Cancer Research and Advancement*

*Children*

*Nutrients*

## Professional Affiliations

*The RNA Society:*  
Full Member

*American Association for Cancer Research:*  
Associate Member

*American Urological Association:*  
Affiliate Member

*Society of Basic Urological Research:*  
Affiliate Member

Dr. Binod Kumar is a highly skilled biomedical research scientist practiced in cell-based assay development, high throughput screening, molecular biology and oncology, and laboratory management. He is also expert and experienced with small drug discovery platform, drafting corresponding technical and research documents. Dr. Kumar has more than 13 years of research experience; he has established and led successful research teams and has organized complex studies involving multiple scientists and institutes. Dr. Kumar is adept at facilitating internal as well as external networks and at training research fellows, clinical fellows, and interns/summer students. He leads his team with a high level of initiative to achieve the objectives of the Newborn Screening Program—for instance he helped implement screening for four new disorders on the screening panel through development of cost-efficient new DNA sequencing assays. Dr. Kumar currently provides clinical guidelines, services, and consulting for DNA sequencing, molecular genetic testing, and classification of variants in newborn settings.

## Experience

Commonwealth Medicine, UMass Chan Medical School  
Shrewsbury, MA .....2017 – Present  
Assistant Professor.....2020 – Present

- Health Care Service - Lead the team of research staff and interns to achieve key program milestones, including point-of-care clinical service/research (molecular genetic screening and diagnostic services in regulated environment).
- Clinical protocol development - Engaged in clinical protocol development consistent with the regulatory requirements for implementation/submission and licensing. Serve as a scientific advisor and am accountable for design and interpretation of clinical studies.
- Developing quality assurance program for improvement of the clinical genetic testing (screening and diagnosis) protocols.
- Active member of various work groups/ task forces including Bioinformatics, Next Generation Sequencing, Variant interpretation, Automated variant assessment software development work group, etc.
- Develop concept, study design (plan and execution), drafting and reviewing study protocols, data analysis and modeling (biostatistical analysis, writing study reports). Also manage the status of the project, budget, and schedules to meet productivity, quality, and client/contract satisfaction goals.
- Data presentation and scientific interactions/talks/lectures in small groups as well as international or national meetings.
- Developing new research program and technologies with other program members related to pediatric disease including new rare genetic disorders and pediatric cancers.

- Published scientific abstracts, posters, case reports, and manuscripts for submission to scientific congresses or peer-reviewed journals
- Involved in making public health policy and recommendation for private or government agencies for the pediatric diseases related to newborn screening.
- Demonstrate creativity, innovation, planning and execution of product/s that improve program-wide productivity or improvements in cost-effective manner. Focuses on conscientiousness and continued learning for implementation of new technology or policy for better outcomes.
- Skilled at strategic thinking, budget planning, and recommending new operational activity.
- Supervises research staff in the group.

*Laboratory Staff Scientist.....2017 – 2019*

- Successfully developed, validated, and implemented the novel sequencing and real time-PCR based technology for high throughput screening of rare genetic disorders in minimal record time.
- Played central role in successful launch of pilot screen program for Massachusetts for new disorders from January 2018
- Lab provides genetic testing for POMPE, MPS1, SMA, and X-ALD in CLIA environment for Massachusetts and neighboring states.
- Developed streamline workflow system from “Lab Data to follow up Reporting” to the physicians, healthcare organizations, and individuals.
- Expertise in clinical genetics and ability to collaborate with diverse experts for annotation and classification of novel variants.
- Conducts human identification testing (HID) for sample mix-up, parent testing (carrier screening) for the pre-condition of the genetic diseases, etc.
- Consult as expert in genetic testing to others states and agencies.
- Co-developer of large Molecular Research Program to solve the common problem in newborn screening in collaboration with UMASS Information Technology and Center for Disease Control and Prevention.
- Co-developer of extensive research program related to the “Public Health Issues of the Newborn” through multiple molecular approaches including NGS, array platform, etc.
- Partner with software programmer to develop software for automation of “Genetic Variant Classification Process”.
- Supervise research staff in the group.

*The Johns Hopkins Medical Institute Baltimore, MD.....2011 – 2017*

*Senior Post-Doctoral Research Scientist*

- Successfully developed novel therapeutics (patent) as well as biomarkers for prostate cancer.
- Extended high throughput cell- based RNAi screening for novel targets and biomarkers in prostate cancer.
- Designed and optimized assays, Digital Droplet PCR for validation studies using clinical specimen.
- Conducted basic and applied research on cancer and non-coding RNA and managed the sampling and characterization of clinical specimens.

- Next generation sequencing (Illumina) for novel biomarker for early disease detection.
- Data analysis (bioinformatics data, GWAS/omics data).
- Mentored undergraduate/graduate students for scientific techniques and research.

### Select Publications

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- **Kumar\*** et al. Development of novel method for SMA sequencing and SMN2 copy number for SMA disease. International Journal of Neonatal Screening, 2021,7(3),47. \*(Corresponding Author)
- Jaime Hale, **Binod Kumar**, Anne Comeau et al. Massachusetts findings from statewide newborn screening for SMA. International Journal of Neonatal Screening, 2021,7(2),26.
- **Kumar**, et al. Cell-type specific expression of oncogenic and tumor suppressive microRNAs in the human prostate and prostate cancer. Nature-Scientific Reports, Volume 8(May), PP 7189, 2018
- **Kumar**, et al. Identification of miR-30 family members as Androgen Receptor regulating miRNAs and correlation with AR activity in castrate resistant metastatic prostate cancer. Oncotarget, September 2016
- Amarnath Mukherjee, **Binod Kumar** et al. Evaluation of Active vs passive targeting in prostate Cancer model by using PSMA Targeting Antibody. Molecular Cancer Therapeutics, 2016
- Koji Hatano, **Binod Kumar**, et al. Functional screening identifies microRNAs, which alter prostate cancer sensitivity to radiation therapy. Nucleic Acid Research, 2015
- **Kumar**, et al. p38 MAP kinase driven MAPKAPK2 regulates invasion of bladder cancer by modulation of MMP-2 and MMP-9 activity. Cancer Research, 2010 (Highlighted on the Cover page of Cancer Research issue)
- **Kumar**, et al. Reactive Oxygen Species is Inherent in Prostate Cancer and is necessary for Aggressive Phenotype. Cancer Research, 2008
- Thomas R. Johnson, Lakshmi pathi Khandrika, **Binod Kumar**, et al. Focal Adhesion Kinase controls aggressive phenotype of androgen independent prostate cancer; Molecular Cancer Research, 2008
- Hazra B, **Binod Kumar**, et al. Enhancement of the tumor inhibitory activity, in vivo, of diospyrin, a plant-derived quinonoid, through liposomal encapsulation. Toxicology Letters, 2005



# Inderneel Sahai, MD, FACMG

Chief Medical Officer, Newborn Screening

## Education

University of Pune, Armed Forces Medical College, Pune, India:  
MD

Kendriya Vidyalaya, Premedical Sciences, Bangalore, India:  
AISSC

## Certifications

American Board of Medical Genetics:  
Diplomat, Clinical Genetics

Diplomat, Clinical Biochemical Genetics

American Board of Internal Medicine:  
Diplomat, Internal Medicine

Licensure:  
Massachusetts  
Virginia (active)

Dr. Inderneel Sahai is the Chief Medical Officer for the Newborn Screening Program at Commonwealth Medicine and has over 30 years of experience in the medical field.

## Experience

Commonwealth Medicine, UMass Chan Medical School  
Worcester, MA .....2005 - Present

*Chief Medical Officer, New England Newborn Screening Program*

*Assistant Professor, Pediatrics*

Massachusetts General Hospital, Boston, MA .....2011 – Present

*Attending Physician, Pediatrics – Genetics and Metabolism*

Harvard University, Boston, MA .....2002 – Present

*Lecturer, Pediatrics .....2007 – Present*

*Instructor, Pediatrics .....2002 – 2005*

Buchanan General Hospital, Grundy, VA .....1996 – 2002

*Staff Physician, Internal Medicine*

Army Medical Corps, Orissa, India .....1991 – 1993

*Officer-in-Charge*

Section Hospitals, Army Medical Corps, Clementtown, UP, India....1989 – 1993

*Medical Officer, Captain*

Military Hospital, Army Medical Corps, Clementtown, UP, India....1988 – 1989

*Medical Officer*

## Committee Assignments and Administrative Services

- Metabolic Review Committee (Chair), New England Newborn Screening Program: 2005 - present
- Massachusetts SCID Newborn Screening Working Group (Member), New England Newborn Screening Program: 2008 - present
- Massachusetts SMA Newborn Screening Working Group (Member), New England Newborn Screening Program: 2015 - present
- Clinical Affairs Committee (Member), Commonwealth Medicine, University of Massachusetts Chan Medical School: 2007 - 2017

### External Professional Service

- APHL Newborn Screening Quality Assurance/Quality Control (QA/QC) Subcommittee: 2016 - present
- X-ALD QC /Harmonization Group: 2016 - present
- CDC Biochemical QA/QC Subcommittee: 2012- present
- New England Metabolic Consortium (Member): 2002 - present
- Newborn Screening QI Workgroup (Member), Newborn Screening Technical Assistance and Evaluation Program, (NewSTEPs): 2012 - 2018
- Genomics Medicine Committee (Member), Partners Healthcare, 2011 - 2018

- MS/MS Database Project (Member), Region 4 Genetics Collaborative Advisory Board, 2008 - 2012

### **Invited Presentations**

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#### *International*

- Newborn Screening: X-ALD and LSD All India Institute of Medical Sciences, New Delhi, India, 2019
- Metabolic Myopathies: All India Institute of Medical Sciences, New Delhi, India, 2019
- Newborn Screening: All India Institute of Medical Sciences, Rishikesh, India, 2017
- Case-based management of Inborn Errors of Metabolism, Ganga Ram Hospital, New Delhi, India, 2017
- Newborn Screening: All India Institute of Medical Sciences, Rishikesh, India, 2017
- Expanded Newborn Screening, 4th National Conference on Inborn Errors of Metabolism, Chennai, India, 2017
- The Homocystinuria's, 3rd International Conference on Inborn Errors of Metabolism, Hyderabad, India, 2014
- Newborn Screening: Expert Panel Discussion, 3rd International Conference on Inborn Errors of Metabolism, Hyderabad, India, 2014
- Workshop: Analysis of Tandem Mass Spectrometry, 3rd International Conference on Inborn Errors of Metabolism, Hyderabad, India, 2014
- Newborn Screening for Inborn Errors of Metabolism: New England Experience, 2nd International Conference on Inborn Errors of Metabolism, New Delhi, India, 2013
- Follow-up of Inborn Errors of Metabolism detected by Newborn Screening, 2nd International Conference on Inborn Errors of Metabolism, New Delhi, India, 2013
- The Long and Short of Newborn Screening for Glutaric Aciduria-Type II: The New England Experience. The 2013 Joint Meeting of the Newborn Screening and Genetic Testing Symposium and the International Society for Neonatal Screening, May 7, Atlanta, GA, 2013

#### *National*

- Newborn Screening for X-ALD-NENSP: Massachusetts Experience, Newborn Screening and Genetic Testing Symposium, Online, 2020
- Low Citrulline in Newborn Screening Specimens: The Proximal Urea Cycle Defects and Beyond, The 2014 Newborn Screening and Genetic Testing Symposium, Oct 28, Anaheim, CA, 2014
- The Long and Short of Newborn Screening for LCHAD: The New England Experience, The 2011 Newborn Screening and Genetic Testing Symposium, Nov 9, San Diego, CA, 2011
- Region 1 Quality Control Project: Multicenter Validation of Algorithms to Improve Communication of Results to the Medical Home, Report to the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, May, Washington, DC, 2011

- Newborn Screening Rationale for Screening for SCID & New England Experience, Pan American Forum on Primary Immunodeficiency, Washington, DC, 2011
- Rising Incidence of Congenital Hypothyroidism in Massachusetts, The 2010 Newborn Screening and Genetic Testing Symposium, May 5, Orlando, FL, 2010

## **Publications**

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### *Relevant Peer-reviewed publications*

- Hale JE, Darras BT, Swoboda KJ, Estrella E, Chen JYH, Abbott MA, Hay BN, Kumar B, Counihan AM, Gerstel-Thompson J, Sahai I, Eaton RB, Comeau AM. Massachusetts' Findings from Statewide Newborn Screening for Spinal Muscular Atrophy. *Int J Neonatal Screen*. 2021 May 23;7(2):26. doi: 10.3390/ijns7020026. PMID: 34071063; PMCID: PMC8162354.
- Hale JE, Platt CD, Bonilla FA, Hay BN, Sullivan JL, Johnston AM, Pasternack MS, Hesterberg PE, Meissner HC, Cooper ER, Barmettler S, Farmer JR, Fisher D, Walter JE, Yang NJ, Sahai I, Eaton RB, DeMaria A, Notarangelo LD, Pai SY, Comeau AM. Ten Years of Newborn Screening for Severe Combined Immunodeficiency (SCID) in Massachusetts. *J Allergy Clin Immunol Pract*. 2021 May;9(5):2060-2067.e2. doi: 10.1016/j.jaip.2021.02.006. Epub 2021 Feb 16. PMID: 33607339; PMCID: PMC8113135
- Sahai I, Garganta CL, Bailey J, James P, Levy HL, Martin M, Neilan E, Phornphutkul C, Sweetser DA, Zytkevich TH, Eaton RB. Newborn Screening for Glutaric Aciduria-II: The New England Experience. *JIMD Rep* 13:1-14 (2014).
- Mitchell ML, Hsu HW, Sahai I. Changing perspectives in screening for congenital hypothyroidism and congenital adrenal hyperplasia. *Curr Opin Endocrinol Diabetes Obes* 21(1):39-44 (2014).
- Mitchell ML, Hsu HW, Sahai I; Massachusetts Pediatric Endocrine Work Group. The increased incidence of congenital hypothyroidism: fact or fancy? *Clin Endocrinol (Oxf)*. 2011;75(6):806-810. doi:10.1111/j.1365-2265.2011.04128.x
- Sahai I, Eaton RB, Hale JE, Mulcahy EA, Comeau AM. Long-term follow-up to ensure quality care of individuals diagnosed with newborn screening conditions: early experience in New England. *Genet Med*. 2010;12(12 Suppl):S220-S227. doi:10.1097/GIM.0b013e3181fe5d37

### *Books & Chapters*

- Sahai I and Levy HL. Newborn Screening. In *Avery's Diseases of the Newborn: Expert Consult 10th Edition* (Eds. Christine A. Gleason and Sandra E. Juul). Sanders (2018)
- Sahai I and Levy HL. Newborn Screening. In *Avery's Diseases of the Newborn: Expert Consult 9th Edition* (Eds. Christine A. Gleason and Sherin U. Devaskar). Sanders (2011)
- Sahai I and Levy HL. Advances in newborn screening for biochemical and genetic disorders. In *Encyclopedia of Genetics, Genomics, Proteomics, and Bioinformatics*. Wiley and Sons (2005)

**CONTRACTOR NAME**Key Personnel

Name	Job Title	Salary	% Paid from this Contract	Amount Paid from this Contract
Roger B. Eaton	Director, NENSP and Assoc. Prof, Pediatrics	\$160,182.62	0%	0
Anne Comeau	Deputy Director, NENSP and Prof. Pediatrics	\$158,201.15	0%	0
Inderneel Sahai	Chief Medical Officer, NENSP and Asst. Prof., Pediatrics	\$150,684.25	0%	0
Binod Kumar	Asst. Prof., Pediatrics	\$96,054.94	0%	0
Devinder Kaur	Asst. Prof, Pediatrics	\$98,494.97	0%	0