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STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

*DIVISION OF PUBLIC HEALTH SERVICES*

Lori A. Weaver
Commissioner

Iain N. Watt
Director

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May 9, 2025

Her Excellency, Governor Kelly A. Ayotte
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 Amy Kritzer, MD (VC#311338-B001), Groton, MA, in the amount of $36,000 to provide medical and specialty consultation services to the Newborn Screening Program, with the option to renew for up to two (2) additional years, effective July 1, 2025, upon Governor and Council approval through June 30, 2027. 100% Other Funds (Newborn Screening Revolving Fund).

Funds are anticipated to be available in the following account for State Fiscal Years 2026 and 2027, 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 FAMILY HEALTH & NUTRITION, NEWBORN SCREENING REVOL FUNDS 100% OTHER FUNDS**

| State Fiscal Year | Class / Account | Class Title | Job Number | Total Amount |
|---|---|---|---|---|
| 2026 | 046-500462 | Consultants | 90080013 | $18,000 |
| 2027 | 046-500462 | Consultants | 90080013 | $18,000 |
| | | | **Total** | **$36,000** |

## EXPLANATION

The purpose of this request is to ensure specialty physician consultant services are available to the Department's Newborn Screening Program and the New Hampshire medical community on a case-by-case, as needed basis. The Department and medical providers require specialty physician consultant services in instances where newborn screening results indicate clinically significant abnormalities that require specific and prompt family follow-up and treatment. The vendor has expertise in the treatment of rare metabolic conditions; the Department does not have any existing expertise in this specialty.

Using data for State Fiscal Year 2026, the Department estimates approximately 25 newborns and their families each year will require support from services provided through this vendor.

The Department's Newborn Screening Program supports screening for all newborns for potentially life threatening, complicated medical disorders through a blood test shortly after birth. This screening is required for all newborns under RSA 132:10a. Given the rarity of conditions identified by the Newborn Screening panel, Pediatricians and General Practice physicians are often unfamiliar with treatment needs and rely on the vendor for timely expertise in cases where screening results show clinically significant abnormal results. These services are critical in enabling immediate clinical response to families' needs and the prevention of unnecessary death and illness among newborns identified with these rare conditions.

The Department will monitor services by:

- Ensuring Contractor completes encounter forms within thirty (30) days of consultation.
- Reviewing quarterly case reviews and classifications submitted by Contractor.
- Ensuring participation in all Newborn Screening Advisory Committee meetings when there are new updates or medical developments pertaining to the Newborn Screening Program.

The Department selected the Contractor through a competitive bid process using a Request for Applications (RFA) that was posted on the Department's website from March 14, 2025, through March 31, 2025. 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 two (2) additional years, contingent upon satisfactory delivery of services, available funding, agreement of the parties, and Governor and Council approval.

Should the Governor and Council not authorize this request, the Department will not have access to specialty medical consultation services to support physicians and families in pursuing timely medical care and mitigating negative health outcomes for New Hampshire newborns.

Area served: Statewide

Respectfully submitted,

Lori A. Weaver
Commissioner

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

**Project ID #** RFA-2026-DPHS-02-NEWBO-01

**Project Title** Newborn Screening Physician Consultant

| | Maximum Points Available | Kritzer |
|---|---|---|
| **Technical** | | |
| Ability (Q1) | 350 | 350 |
| Experience (Q2) | 350 | 300 |
| Knowledge (Q3) | 300 | 225 |
| **TOTAL POINTS** | **1000** | **875** |

| | |
|---|---|
| **TOTAL PROPOSED VENDOR COST** | *Not Applicable - No Cost Proposal for RFA* |

| | Reviewer Name | Title |
|---|---|---|
| 1 | Courtney Keane | Interim Bureau Chief |
| 2 | Sara Beauchemin | Newborn Screening Program Nurse |
| 3 | Lisa Lampron | Finance Administrator |

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<br>New Hampshire Department of Health and Human Services | | 1.2 State Agency Address<br>129 Pleasant Street<br>Concord, NH 03301-3857 | |
| 1.3 Contractor Name<br>Amy Kritzer, MD | | 1.4 Contractor Address<br>[redacted] | |
| 1.5 Contractor Phone Number<br>[redacted] | 1.6 Account Unit and Class<br>TBD | 1.7 Completion Date<br>June 30, 2027 | 1.8 Price Limitation<br>$36,000 |
| 1.9 Contracting Officer for State Agency<br>Robert W. Moore, Director | | 1.10 State Agency Telephone Number<br>(603) 271-9631 | |
| 1.11 Contractor Signature<br>DocuSigned by: Amy Kritzer, MD<br>Date: 5/7/2025 | | 1.12 Name and Title of Contractor Signatory<br>Amy Kritzer, MD MD | |
| 1.13 State Agency Signature<br>DocuSigned by: Iain Watt<br>Date: 5/7/2025 | | 1.14 Name and Title of State Agency Signatory<br>Iain Watt Director - DPHS | |
| 1.15 Approval by the N.H. Department of Administration, Division of Personnel *(if applicable)*<br>By: Director, On: | | | |
| 1.16 Approval by the Attorney General (Form, Substance and Execution) *(if applicable)*<br>By: DocuSigned by: Robyn Guarino On: 5/13/2025 | | | |
| 1.17 Approval by the Governor and Executive Council *(if applicable)*<br>G&C Item number: G&C Meeting Date: | | | |



Contractor Initials DS AKM
Date 5/7/2025

**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, 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.

3.3 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. 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 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, 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 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. 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.

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 The State's liability under this Agreement shall be limited to monetary damages not to exceed the total fees paid. The Contractor agrees that it has an adequate remedy at law for any breach of this Agreement by the State and hereby waives any right to specific performance or other equitable remedies against the State.

**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 and the Governor's order on Respect and Civility in the Workplace, Executive order 2020-01. 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 age, sex, sexual orientation, race, color, marital status, physical or mental disability, religious creed, national origin, gender identity, or gender expression, and will take affirmative action to prevent such discrimination, unless exempt by state or federal law. The Contractor shall ensure any subcontractors comply with these nondiscrimination requirements.

6.3 No payments or transfers of value by Contractor or its representatives in connection with this Agreement have or shall be made which have the purpose or effect of public or commercial bribery, or acceptance of or acquiescence in extortion, kickbacks, or other unlawful or improper means of obtaining business.

6.4. 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 this Agreement and all rules, regulations and orders pertaining to 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 The Contracting Officer specified in block 1.9, or any successor, shall be the State's point of contact pertaining to this Agreement.



Contractor Initials AKM
Date 5/7/2025

**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) calendar days from the date of the notice; and if the Event of Default is not timely cured, terminate this Agreement, effective two (2) calendar 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.

**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) calendar 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) calendar 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. In addition, at the State's discretion, the Contractor shall, within fifteen (15) calendar days of notice of early termination, develop and submit to the State a transition plan for Services under the Agreement.

**10. PROPERTY OWNERSHIP/DISCLOSURE.**

10.1 As used in this Agreement, the word "Property" shall mean all data, 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 Disclosure of data, information and other records shall be governed by N.H. RSA chapter 91-A and/or other applicable law. Disclosure 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 Contractor shall provide the State written notice at least fifteen (15) calendar days before any proposed assignment, delegation, or other transfer of any interest in this Agreement. No such assignment, delegation, or other transfer shall be effective without the written consent of the State.

12.2 For purposes of paragraph 12, 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.

12.3 None of the Services shall be subcontracted by the Contractor without prior written notice and consent of the State.

12.4 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.** The Contractor shall indemnify, defend, and hold harmless the State, its officers, and employees from and against all actions, claims, damages, demands, judgments, fines, liabilities, losses, and other expenses, including, without limitation, reasonable attorneys' fees, arising out of or relating to this Agreement directly or indirectly arising from death, personal injury, property damage, intellectual property infringement, or other claims asserted against the State, its officers, or employees caused by the acts or omissions of negligence, reckless or willful misconduct, or fraud by the Contractor, its employees, agents, or subcontractors. 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 State's sovereign immunity, which immunity is hereby reserved to the State. This covenant in paragraph 13 shall survive the termination of this Agreement.



Contractor Initials AKM

Date 5/7/2025

**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 any successor, a certificate(s) of insurance for all insurance required under this Agreement. At the request of the Contracting Officer, or any successor, the Contractor shall provide certificate(s) of insurance for all renewal(s) of insurance required under this Agreement. 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 any successor, proof of Workers' Compensation in the manner described in N.H. RSA chapter 281-A and any applicable renewal(s) thereof, which shall be attached and are incorporated herein by reference. The State shall not be responsible for payment of any Workers' Compensation premiums or for any other claim or benefit for Contractor, or any subcontractor or employee of Contractor, which might arise under applicable State of New Hampshire Workers' Compensation laws in connection with the performance of the Services under this Agreement.

**16. WAIVER OF BREACH.** A State's failure to enforce its rights with respect to any single or continuing breach of this Agreement shall not act as a waiver of the right of the State to later enforce any such rights or to enforce any other or any subsequent breach.

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

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

**19. CHOICE OF LAW AND FORUM.**
19.1 This Agreement shall be governed, interpreted and construed in accordance with the laws of the State of New Hampshire except where the Federal supremacy clause requires otherwise. 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.
19.2 Any actions arising out of this Agreement, including the breach or alleged breach thereof, may not be submitted to binding arbitration, but must, instead, be brought and maintained in the Merrimack County Superior Court of New Hampshire which shall have exclusive jurisdiction thereof.

**20. CONFLICTING TERMS.** In the event of a conflict between the terms of this P-37 form (as modified in EXHIBIT A) and any other portion of this Agreement including any attachments thereto, the terms of the P-37 (as modified in EXHIBIT A) shall control.

**21. THIRD PARTIES.** This Agreement is being entered into for the sole benefit of the parties hereto, and nothing herein, express or implied, is intended to or will confer any legal or equitable right, benefit, or remedy of any nature upon any other person.

**22. 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.

**23. SPECIAL PROVISIONS.** Additional or modifying provisions set forth in the attached EXHIBIT A are incorporated herein by reference.

**24. FURTHER ASSURANCES.** The Contractor, along with its agents and affiliates, shall, at its own cost and expense, execute any additional documents and take such further actions as may be reasonably required to carry out the provisions of this Agreement and give effect to the transactions contemplated hereby.

**25. 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.

**26. 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.



Contractor Initials AKM
Date 5/7/2025

**New Hampshire Department of Health and Human Services**
**Newborn Screening Physician Consultant**

# 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, this Agreement, and all obligations of the parties hereunder, shall become effective on July 1, 2025. ("Effective Date").

   1.2. Paragraph 3, Effective Date/Completion of Services, is amended by deleting subparagraph 3.3., in its entirety and replacing it as follows:

   3.3. Contractor must complete all Services by the Completion Date specified in block 1.7. The parties may extend the Agreement for up to two (2) 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 12.5., as follows:

   12.5. 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 if applicable, a Business Associate Agreement in accordance with the Health Insurance Portability and Accountability Act. Written agreements shall specify how corrective action shall be managed. 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.

# EXHIBIT B

## Scope of Services

### 1. Statement of Work

1.1. The Contractor must provide medical and specialty consultation services when New Hampshire's newborn screen panel indicates abnormal results for metabolic screening disorders, requiring time-sensitive medical follow-up and treatment.

1.2. The Contractor must provide consultation services to the New Hampshire Newborn Screening Program (NSP), the NSP's screening laboratory, and the New Hampshire medical community regarding the diagnosis and management of abnormal metabolic screening disorder results. The Contractor must:

1.2.1. Must provide services approximately 5 hours per month.

1.2.2. Be available by phone and secure email Monday through Friday, from 8:00 AM to 4:30 PM EST, as approved by the Department.

1.2.3. Provide consultation services to the Department regarding newborn screening and condition specific standards within one (1) business day of request.

1.2.4. Provide the Department with at least a five (5) business day notice of any upcoming unavailability.

1.2.5. Assist the Department in the development and review of condition- specific standards and protocols to guide the daily operations of the NSP, as requested by the Department.

1.2.6. Participate in a periodic review of newly added screenings within the NBS panel, in conjunction with the staff of the NSP and the screening laboratory, as requested by the Department.

1.2.7. Attend all Newborn Screening Advisory Committee meetings and provide the Department with updates of new medical developments pertaining to newborn screening program operations.

1.3. The Contractor must participate in meetings with the Department on a quarterly basis, or as otherwise requested by the Department.

### 2. Reporting

2.1. The Contractor must complete the Department's medical consultation encounter form for each consultation within thirty (30) days of the consultation.

2.2. The Contractor must submit a quarterly case review and classification of metabolic disorders according to national case definitions for NSP.

2.3. The Contractor may be required to provide other data and metrics to the Department in a format specified by the Department.

## 3. Contract End-of-Life Transition Services

3.1. General Requirements

3.1.1. If applicable, upon early termination or expiration of the Agreement the parties agree to cooperate in good faith to effectuate a secure transition of the services ("Transition Services") from the Contractor to the Department and, if applicable, the new Contractor ("Recipient") engaged by the Department to assume the services. Ninety (90) days prior to the end-of the contract or unless otherwise specified by the Department, the Contractor must begin working with the Department and if applicable, the Recipient to develop a Data Transition Plan (DTP). The Department shall provide the DTP template to the Contractor.

3.1.2. The Contractor must assist the Recipient, in connection with the transition from the performance of Services by the Contractor and its End Users to the performance of such Services. This may include assistance with the secure transfer of records (electronic and hard copy),transition of historical data (electronic and hard copy), 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 the Recipient and cooperation with and assistance to any third-party consultants engaged by Recipient in connection with the Transition Services.

3.1.3. If a system, database, hardware, software, and/or software licenses (Tools) was purchased or created to manage, track, and/or store Department Data in relationship to this contract said Tools will be inventoried and returned to the Department, along with the inventory document, once transition of Department data is complete.

3.1.4. The internal planning of the Transition Services by the Contractor and its End Users shall be provided to the Department and if applicable the

Recipient in a timely manner. Any such Transition Services shall be deemed to be Services for purposes of this Agreement.

3.1.5. In the event the data Transition extend beyond the end of the Agreement, the Contractor agrees that the Information Security Requirements, and if applicable, the Department's Business Associate Agreement terms and conditions remain in effect until the Data Transition is accepted as complete by the Department.

3.1.6. In the event the Contractor has comingled Department Data and the destruction or Transition of said data is not feasible, the Department and Contractor will jointly evaluate regulatory and professional standards for retention requirements prior to destruction, refer to the terms and conditions of the Department's DHHS Information Security Requirements Exhibit.

3.2. Completion of Transition Services

3.2.1. Each service or transition phase shall be deemed completed (and the transition process finalized) at the end of fifteen (15) business days after the product, resulting from the Service, is delivered to the Department and/or the Recipient in accordance with the mutually agreed upon Transition plan, unless within said fifteen (15) business day term the Contractor notifies the Department of an issue requiring additional time to complete said product.

3.2.2. Once all parties agree the data has been migrated the Contractor will have thirty (30) days to destroy the data per the terms and conditions of the Department's Information Security Requirements Exhibit.

3.3. Disagreement over Transition Services Results

3.3.1. In the event the Department is not satisfied with the results of the Transition Service, the Department shall notify the Contractor, in writing, stating the reason for the lack of satisfaction within fifteen (15) business days of the final product or at any time during the data Transition process. The Parties shall discuss the actions to be taken to resolve the disagreement or issue. If an agreement is not reached, at any time the Department shall be entitled to initiate actions in accordance with the Agreement.

**4. Exhibits Incorporated**

4.1. The Contractor must manage all confidential data related to this Agreement in

accordance with the terms of Exhibit D, DHHS Information Security Requirements.

4.2. The Contractor must 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 E Business Associate Agreement, which has been executed by the parties.

**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

**5.2. Credits and Copyright Ownership**

5.2.1. All documents, notices, press releases, research reports and other materials prepared during or resulting from the performance of the services of the Agreement must 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."

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

5.2.3. The Department must retain copyright ownership for any and all original materials produced, including, but not limited to reports, protocols, guidelines, brochures, posters, and resource directories.

5.2.4. The Contractor must not reproduce any materials produced under the Agreement without prior written approval from the Department.

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

5.3.1. In the operation of any facilities for providing services, the Contractor must 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 must 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 must be required for the operation of the said facility or the performance of the said services, the Contractor will procure said license or permit, and will at all times comply with the terms and conditions of each such license or permit. In connection with the foregoing requirements, the Contractor hereby covenants and agrees that, during the term of this Agreement the facilities must comply with all rules, orders, regulations, and requirements of the State Office of the Fire Marshal and the local fire protection agency, and must be in conformance with local building and zoning codes, by-laws and regulations.

**6. Records**

6.1. The Contractor must 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. 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 must have access to all reports and records maintained pursuant to the Agreement for purposes of audit, examination, excerpts and transcripts.

6.3. If, upon further review, the Department must disallow any expenses claimed by the Contractor as costs hereunder, the Department retains the right, at its discretion, to deduct the amount of such expenses as are disallowed or to recover such sums from the Contractor.

**New Hampshire Department of Health and Human Services**
**Newborn Screening Physician Consultant**

# EXHIBIT C

## Payment Terms

1. This Agreement is funded by:
   1.1. 100% Other Funds Newborn Screening Revolving Funds
2. For the purposes of this Agreement the Department has identified:
   2.1. The Contractor as a Contractor, based on criteria specified in 2 CFR 200.331.
   2.2. The Indirect Cost Rate for this Agreement as 0%.
3. Payment shall be made based on an all-inclusive hourly rate of $300, including travel and mileage, not to exceed price limitation, for services provided in the fulfillment of this Agreement, as specified in Exhibit B Scope of Work.
4. The Contractor will be paid only for the actual number of hours services are provided.
5. The Contractor shall submit an invoice to the Department no later than the fifteenth (15th) working day of the month following the month in which the services were provided. The Contractor shall ensure each invoice:
   5.1. Includes the Contractor's Vendor Number issued upon registering with New Hampshire Department of Administrative Services.
   5.2. Is submitted in a format as provided by or otherwise acceptable to the Department.
   5.3. Identifies and requests payment in accordance with Section 3, above.
   5.4. Includes supporting documentation with each invoice, including, but not limited to, proof of expenditures, itemized receipts for purchases, time sheets, and payroll records with position or staff detail, as applicable.
   5.5. Is completed, dated and returned to the Department to initiate payment.
   5.6. Is assigned an electronic signature and is emailed to DHHS.DPHS.Contract@dhhs.nh.gov or mailed to:

      Financial Manager
      Department of Health and Human Services
      129 Pleasant Street
      Concord, NH 03301
6. The Department shall make payments to the Contractor within thirty (30) calendar days only upon receipt and approval of the submitted invoice and required supporting documentation.
7. The final invoice and any required supporting documentation shall be due to the Department no later than forty (40) calendar days after the contract

completion date specified in Form P-37, General Provisions Block 1.7.,Completion Date.

8. Notwithstanding Paragraph 18 of the General Provisions Form P-37, changes limited to adjusting direct and indirect cost amounts within the price limitation between budget class lines, as well as adjusting encumbrances between State Fiscal Years 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.

9. Audits

9.1. The Contractor must email an annual audit to dhhs.act@dhhs.nh.gov if any of the following conditions exist:

9.1.1. Condition A - The Contractor is subject to a Single Audit pursuant to 2 CFR 200.501 Audit Requirements.

9.1.2. Condition B - The Contractor is subject to audit pursuant to the requirements of NH RSA 7:28, III-b.

9.1.3. Condition C - The Contractor is a public company and required by Security and Exchange Commission (SEC) regulations to submit an annual financial audit.

9.2. If Condition A exists, the Contractor shall submit an annual Single Audit performed by an independent Certified Public Accountant (CPA) to dhhs.act@dhhs.nh.gov 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.

9.2.1. The Contractor shall submit a copy of any Single Audit findings and any associated corrective action plans. The Contractor shall submit quarterly progress reports on the status of implementation of the corrective action plan.

9.3. 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.

9.4. The Contractor, regardless of the funding source and/or whether Conditions A, B, or C exist, may be required to submit annual financial audits performed by an independent CPA upon request by the Department.

9.5. In addition to, and not in any way in limitation of obligations of the Agreement, 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 Agreement to which exception has been taken, or which have been disallowed because of such an exception, within sixty (60) days.

10. If applicable, the Contractor must request disposition instructions from the Department for any equipment, as defined in 2 CFR 200.313, purchased using funds provided under this Agreement, including information technology systems.

# New Hampshire Department of Health and Human Services

Exhibit D

## 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

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or misplacement of hardcopy documents, and misrouting of physical or electronic 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 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.

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8. Open Wireless Networks. End User may not transmit Confidential Data via an open 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. SFTP folders and sub-folders used for transmitting Confidential Data will be coded for 24-hour 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, antihacker, anti-spam, anti-spyware, and anti-malware utilities. The environment, as a whole, must have aggressive intrusion-detection and firewall protection.

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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.).

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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

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.

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

The Contractor must notify the State's Privacy Officer and Security Officer of any Security Incidents and Breaches immediately, at the email addresses provided in Section VI.

The Contractor must further handle and report Incidents and Breaches involving PHI in accordance with the agency's documented Incident Handling and Breach Notification procedures and in accordance with 42 C.F.R. §§ 431.300 - 306. In addition to, and notwithstanding, Contractor's compliance with all applicable obligations and procedures, Contractor's procedures must also address how the Contractor will:

1. Identify Incidents;
2. Determine if personally identifiable information is involved in Incidents;
3. Report suspected or confirmed Incidents as required in this Exhibit or P-37;

4. Identify and convene a core response group to determine the risk level of Incidents and determine risk-based responses to Incidents; and
5. Determine whether Breach notification is required, and, if so, identify appropriate Breach notification methods, timing, source, and contents from among different options, and bear costs associated with the Breach notice as well as any mitigation measures.

Incidents and/or Breaches that implicate PI must be addressed and reported, as applicable, in accordance with NH RSA 359-C:20.

## VI. PERSONS TO CONTACT

A. DHHS Privacy Officer:

DHHSPrivacyOfficer@dhhs.nh.gov B.

DHHS Security Officer:

DHHSInformationSecurityOffice@dhhs.nh.gov

## BUSINESS ASSOCIATE AGREEMENT

The Contractor identified in Section 1.3 of the General Provisions of the Agreement (Form P-37) ("Agreement"), and any of its agents who receive use or have access to protected health information (PHI), as defined herein, shall be referred to as the "Business Associate." The State of New Hampshire, Department of Health and Human Services, "Department" shall be referred to as the "Covered Entity," The Contractor and the Department are collectively referred to as "the parties."

The parties agree, to comply with the Health Insurance Portability and Accountability Act, Public Law 104-191, the Standards for Privacy and Security of Individually Identifiable Health Information, 45 CFR Parts 160, 162, and 164 (HIPAA), provisions of the HITECH Act, Title XIII, Subtitle D, Parts 1&2 of the American Recovery and Reinvestment Act of 2009, 42 USC 17934, et sec., applicable to business associates, and as applicable, to be bound by the provisions of the Confidentiality of Substance Use Disorder Patient Records, 42 USC s. 290 dd-2, 42 CFR Part 2, (Part 2), as any of these laws and regulations may be amended from time to time.

(1) Definitions

a. The following terms shall have the same meaning as defined in HIPAA, the HITECH Act, and Part 2, as they may be amended from time to time:

"Breach," "Designated Record Set," "Data Aggregation," Designated Record Set," "Health Care Operations," "HITECH Act," "Individual," "Privacy Rule," "Required by law," "Security Rule," and "Secretary."

b. Business Associate Agreement, (BAA) means the Business Associate Agreement that includes privacy and confidentiality requirements of the Business Associate working with PHI and as applicable, Part 2 record(s) on behalf of the Covered Entity under the Agreement.

c. "Constructively Identifiable," means there is a reasonable basis to believe that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information.

d. "Protected Health Information" ("PHI") as used in the Agreement and the BAA, means protected health information defined in HIPAA 45 CFR 160.103, limited to the information created, received, or used by Business Associate from or on behalf of Covered Entity, and includes any Part 2 records, if applicable, as defined below.

e. "Part 2 record" means any patient "Record," relating to a "Patient," and "Patient Identifying Information," as defined in 42 CFR Part 2.11.

f. "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.

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

a. Business Associate shall not use, disclose, maintain, store, or transmit Protected Health Information (PHI) except as reasonably necessary to provide the services outlined under the Agreement. Further, Business Associate, including but not

limited to all its directors, officers, employees, and agents, shall protect any PHI as required by HIPPA and 42 CFR Part 2, and not use, disclose, maintain, store, or transmit PHI in any manner that would constitute a violation of HIPAA or 42 CFR Part 2.

b. Business Associate may use or disclose PHI, as applicable:

I. For the proper management and administration of the Business Associate;

II. As required by law, according to the terms set forth in paragraph c. and d. below;

III. According to the HIPAA minimum necessary standard;

IV. For data aggregation purposes for the health care operations of the Covered Entity; and

V. Data that is de-identified or aggregated and remains constructively identifiable may not be used for any purpose outside the performance of the Agreement.

c. To the extent Business Associate is permitted under the BAA or the Agreement to disclose PHI to any third party or subcontractor prior to making any disclosure, the Business Associate must obtain, a business associate agreement or other agreement with the third party or subcontractor, that complies with HIPAA and ensures that all requirements and restrictions placed on the Business Associate as part of this BAA with the Covered Entity, are included in those business associate agreements with the third party or subcontractor.

d. The Business Associate shall not, disclose any PHI in response to a request or demand for disclosure, such as by a subpoena or court order, on the basis that it is required by law, without first notifying Covered Entity so that Covered Entity can determine how to best protect the PHI. If Covered Entity objects to the disclosure, the Business Associate agrees to refrain from disclosing the PHI and shall cooperate with the Covered Entity in any effort the Covered Entity undertakes to contest the request for disclosure, subpoena, or other legal process. If applicable relating to Part 2 records, the Business Associate shall resist any efforts to access part 2 records in any judicial proceeding.

(3) Obligations and Activities of Business Associate

a. Business Associate shall implement appropriate safeguards to prevent unauthorized use or disclosure of all PHI in accordance with HIPAA Privacy Rule and Security Rule with regard to electronic PHI, and Part 2, as applicable.

b. The Business Associate shall immediately notify the Covered Entity's Privacy Officer at the following email address, DHHSPrivacyOfficer@dhhs.nh.gov after the Business Associate has determined that any use or disclosure not provided for by its contract, including any known or suspected privacy or security incident or breach has occurred potentially exposing or compromising the PHI. This includes inadvertent or accidental uses or disclosures or breaches of unsecured protected health information.

c. In the event of a breach, the Business Associate shall comply with the terms of this Business Associate Agreement, all applicable state and federal laws and regulations and any additional requirements of the Agreement.

d. The Business Associate shall perform a risk assessment, based on the information available at the time it becomes aware of any known or suspected privacy or

security breach as described above and communicate the risk assessment to the Covered Entity. The risk assessment shall include, but not be limited to:

I. The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification;

II. The unauthorized person who accessed, used, disclosed, or received the protected health information;

III. Whether the protected health information was actually acquired or viewed; and

IV. How the risk of loss of confidentiality to the protected health information has been mitigated.

e. The Business Associate shall complete a risk assessment report at the conclusion of its incident or breach investigation and provide the findings in a written report to the Covered Entity as soon as practicable after the conclusion of the Business Associate's investigation.

f. 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 US Secretary of Health and Human Services for purposes of determining the Business Associate's and the Covered Entity's compliance with HIPAA and the Privacy and Security Rule, and Part 2, if applicable.

g. Business Associate shall require all of its business associates that receive, use or have access to PHI under the BAA to agree in writing to adhere to the same restrictions and conditions on the use and disclosure of PHI contained herein.

h. Within ten (10) 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 BAA and the Agreement.

i. 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.

j. 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.

k. Business Associate shall document any disclosures of PHI and information related to any 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.

l. 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.

m. In the event any individual requests access to, amendment of, or accounting of PHI directly from the Business Associate, the Business Associate shall within five (5) 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.

n. Within thirty (30) 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-ups of such PHI in any form or platform.

VI. If return or destruction is not feasible, or the disposition of the PHI has been otherwise agreed to in the Agreement, or if retention is governed by state or federal law, 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 as long as the Business Associate maintains such PHI. If Covered Entity, in its sole discretion, requires that the Business Associate destroy any or all PHI, the Business Associate shall certify to Covered Entity that the PHI has been destroyed.

(4) Obligations of Covered Entity

a. Covered Entity shall post a current version of the Notice of the Privacy Practices on the Covered Entity's website:

https://www.dhhs.nh.gov/oos/hipaa/publications.htm in accordance with 45 CFR Section 164.520.

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 BAA, 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 of Agreement for Cause

a. In addition to the General Provisions (P-37) of the Agreement, the Covered Entity may immediately terminate the Agreement upon Covered Entity's knowledge of a material breach by Business Associate of the Business Associate Agreement. 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.

(6) Miscellaneous

a. Definitions, Laws, and Regulatory References. All laws and regulations used,

herein, shall refer to those laws and regulations as amended from time to time. A reference in the Agreement, as amended to include this Business Associate Agreement, to a Section in HIPAA or 42 Part 2, means the Section as in effect or as amended.

b. **Change in law** - Covered Entity and Business Associate agree to take such action as is necessary from time to time for the Covered Entity and/or Business Associate to comply with the changes in the requirements of HIPAA, 42 CFR Part 2 other 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 BAA and the Agreement shall be resolved to permit Covered Entity and the Business Associate to comply with HIPAA and 42 CFR Part 2.

e. **Segregation** - If any term or condition of this BAA 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 BAA are declared severable.

f. **Survival** - Provisions in this BAA regarding the use and disclosure of PHI, return or destruction of PHI, extensions of the protections of the BAA in section (3) g. and (3) n.l., and the defense and indemnification provisions of the General Provisions (P-37) of the Agreement, shall survive the termination of the BAA.

IN WITNESS WHEREOF, the parties hereto have duly executed this Business Associate Agreement.

| | |
|---|---|
| Department of Health and Human Services | Amy Kritzer |
| The State | Name of the Contractor |
| DocuSigned by: Iain Watt D778BBC2F0704C7... | DocuSigned by: Amy Kritzer, MD 09DAA4F010FD4A7... |
| Signature of Authorized Representative | Signature of Authorized Representative |
| Iain Watt | Amy Kritzer, MD |
| Name of Authorized Representative | Name of Authorized Representative |
| Director - DPHS | MD |
| Title of Authorized Representative | Title of Authorized Representative |
| 5/7/2025 | 5/7/2025 |
| Date | Date |



Contractor Initials DS AKM

Date 5/7/2025

Docusign Envelope ID: FCEE54F5-9358-48CB-B772-F0155CFEEA77

**CRICO (A Reciprocal Risk Retention Group)**
Burlington, Vermont

# Confirmation of Coverage for Physicians, Dentists, and Podiatrists

**CHILDREN'S MEDICAL CENTER CORPORATION** **Date:** 03/24/2025

AMY MICHELLE KRITZER MD
THE CHILDREN'S HOSPITAL CORPORATION
Genetics
300 LONGWOOD AVENUE
BOSTON, MA 02115

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

| | | |
|---|---|---|
| **Medical Professional Liability:** * | **Limits of Liability:** | |
| | $5,000,000.00 | each "Claim" |
| | $10,000,000.00 | annual aggregate each insured person, for all claims made and reported during the "Policy Period" |
| **Policy Number:** | CH-CRREC-C-GLPL-2025 | |
| **Policy Period:** | 01/01/2025 - 12/31/2025 | |
| **Physician Specialty:** | GENETICS - NO SURGERY (80001) | |

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

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

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

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

NOTICE

This policy is issued by your risk retention group. Your risk retention group may not be subject to all the insurance laws and regulations of your State. State insurance insolvency guaranty funds are not available for your risk retention group.

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

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

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

CRICO
(A Reciprocal Risk Retention Group)

Duly Authorized Representative

Docusign Envelope ID: FCEE54F5-9358-48CB-B772-F0155CFEEA77

**The Faculty of Medicine**
**Harvard University**
**Curriculum Vitae**

| | |
|---|---|
| **Date Prepared:** | 04/23/25 |
| **Name:** | Amy Michelle Kritzer |
| **Office Address:** | [redacted] |
| **Home Address:** | [redacted] |
| **Work Phone:** | [redacted] |
| **Work Email:** | [redacted] |
| **Place of Birth:** | [redacted] |

**Education:**

| | | | |
|---|---|---|---|
| 09/1994 – 05/1998 | BA | Biology | Barnard College, NY, NY |
| 09/1998 – 09/2003 | MD | Medicine | Albert Einstein College of Medicine, Bronx, NY |

**Postdoctoral Training:**

| | | | |
|---|---|---|---|
| 06/2007 – 06/2008 | Transitional Year | Medicine and Pediatrics | MetroWest Medical Center |
| 07/2010 – 06/2013 | Resident | Pediatrics | The Floating Hospital for Children, Tufts Medical Center |
| 07/2013 – 06/2015 | Fellow | Genetics | Boston Children's Hospital |
| 07/2015 – 06/2016 | Fellow | Medical Biochemical Genetics | Boston Children's Hospital |

**Faculty Academic Appointments:**

| | | | |
|---|---|---|---|
| 07/2010 – 06/2013 | Clinical Instructor | Pediatrics | The Floating Hospital for Children, Tufts Medical Center |
| 07/2016 – 8/2021 | Instructor | Pediatrics | Harvard Medical School |
| 07/2018 – present | Instructor | Pediatrics | Geisel School of Medicine at Dartmouth (non-voting) |
| 09/2021 – present | Assistant Professor | Pediatrics | Harvard Medical School |

**Appointments at Hospitals/Affiliated Institutions:**

| | | | |
|---|---|---|---|
| 07/2016 – present | Attending Physician | Division of Genetics and Genomics | Boston Children's Hospital |
| 11/2016 – present | Consultant | Newborn Medicine | Brigham and Women's Hospital |

| | | | |
|---|---|---|---|
| 11/2017 – present | Staff Physician | Division of Genetics | Children's Hospital at Dartmouth Hitchcock |
| 10/2019 – present | Consultant | Neonatology | Beth Israel Deaconess Medical Center |
| 4/2021 – present | Consultant | Pediatrics | Franciscan Children's |
| 1/2023 – 10/2024 | Consultant | Neonatology | North Central, Baptist Health |
| 1/2023 – 10/2024 | Consultant | Neonatology | St. Luke's Baptist Health |

**Other Professional Positions:**

| | | | |
|---|---|---|---|
| 2016 – 2018 | Speakers Bureau | Sanofi-Genzyme | 2 days per year |
| 2017 – present | Medical Advisory Council | Make-a-Wish of MA and RI | 1 hour per month |
| 2017 – present | Chapter Medical Advisor | Make-a-Wish of MA and RI | 2 hours per month |
| 2019 – present | Medical Consultant | New Hampshire Newborn Screening Program | 1 hour per month |
| 2020 – present | Co-Director | New England Consortium of Metabolic Programs | 1 hour per month |
| 2021 – present | Board of Directors | The Genesis Foundation for Children | 1 hour per month |
| 2022- present | National Medical Advisory Council | Make-a-Wish of America | 2 hours per month |
| 2022 – present | Rare New England | Medical Scientific Advisory Board | 1 hour per month |
| 2025 – present | Smith Lemli Opiz Foundation | Medical Scientific Advisory Board | 1 hour per month |

**Major Administrative Leadership Positions:**

**Local**

| | | |
|---|---|---|
| 2023 – present | Clinical Chief, Division of Genetics and Genomics | Boston Children's Hospital |
| 2025 – present | Director, Metabolism Clinical Program | Boston Children's Hospital |
| 2016 – present | Physician Lead, Quality Improvement, Division of Genetics and Genomics | Boston Children's Hospital |

**Committee Service:**

**Local**

| | | |
|---|---|---|
| 2024 - present | Medical Directors Special Interest Group | American College of Medical Genetics |

| | | |
|---|---|---|
| 2022 – present | Equity, Diversity and Inclusion Committee, Member, Division of Genetics and Genomics | Boston Children's Hospital |
| 2022 – present | Process Improvement committee, Division of Genetics and Genomics | Boston Children's Hospital |

**Regional**

| | | |
|---|---|---|
| 2017 – present | Lysosomal Storage Disease newborn screening workgroup | Massachusetts Newborn Screening Program |

**National**

| | | |
|---|---|---|
| 2022- 2024 | Co-Chair, Telehealth Work-group | NORD, Centers of Excellence |
| 2022 – present | National Medical Advisory Council | Make-a-Wish of America |

**Professional Societies:**

| | | |
|---|---|---|
| 2010 – present | American Academy of Pediatrics | member |
| 2013 – present | American College of Medical Genetics | member |
| 2015 – present | Society of Inborn Metabolic Disease | member |
| 2020 – present | Society for the Study of Inborn Errors of Metabolism | member |

**Honors and Prizes:**

| | | | |
|---|---|---|---|
| 1998 | Howard Hughes Intern | Barnard College | Research |
| 1998 | Constance Van Waal Prize | Barnard College | For Excellence in Biology |
| 1998 | Barbara Ann Liskin Memorial Prize | Barnard College | For Dedication to Humanistic Care for the Pediatric and Adolescent Populations |
| 1998 | Summa Cum Laude | Barnard College | |
| 1998 | Phi Beta Kappa | Barnard College | |
| 1999 | David E. Rogers Fellowship | New York Academy of Medicine | Research |
| 2003 | Degree with Distinction in Child Psychiatry | Albert Einstein College of Medicine | |
| 2015 | Fellowship for Biochemical Genetics | Genzyme/American College of Medical Genetics Foundation | Academic Training and Research |
| 2015 – 2018 | Scholar Member | BCH Academy | |
| 2018 | Quality Improvement Scholar Development Grant | Boston Children's Hospital | Research and leadership training |
| 2018 | Best in Care Nomination | Boston Children's Hospital | Clinical care |

| | | | |
|---|---|---|---|
| 2019 | Excellence in Clinical Teaching Award nomination | BCH Academy | Teaching |
| 2019 – 2020 | Intermediate Improvement Science Series | Anderson Center, Cincinnati Children's Hospital | Leadership training course |

## Report of Funded and Unfunded Projects

### Current

| | |
|---|---|
| 2014 – projected end 2034 | Lysomal Storage Disease Registry<br>Genzyme-Santofi<br>Site PI ($25,000 per year)<br>Multicenter, longitudinal, observational registry to collect data on patients with Gaucher disease, Fabry disease, Pompe disease and MPS I. Objectives are to enhance the understanding of the variability, progression, and natural history of disease |
| 2016 – 2024 | Morquio A Registry Study (MARS)<br>BioMarin<br>Site PI ($10,000 per year)<br>Multicenter observational Registry for patients diagnosed with MPS IVA. Aims to characterize the spectrum of clinical signs and symptoms of the disease as well as to further characterize the safety profile of Vimizim ERT |
| 2016 – 2024 | Hunter Syndrome Outcome Study (HOS)<br>Shire/Takeda<br>Site Sub-investigator ($5,000 per year)<br>Multicenter observational registry for patients diagnosed with Hunter syndrome (MPS II) who are currently on or have previously been on Elaprase enzyme replacement therapy |
| 2020 – projected end 2029 | Lysosomal Acid Lipase Deficiency (LALD) Registry<br>Alexion<br>Site Investigator ($5000 per year)<br>Multicenter observational registry for patients diagnosed with Lysosomal Acid Lipase deficiency to understand the disease and the long-term effectiveness of therapeutic interventions including sebelipase alfa. |

### Training Grants and Mentored Trainee Grants

| | |
|---|---|
| 2019 – 2020 | **Reducing Time to Diagnosis and Treatment of Lysosomal Storage Diseases Through Automated EMR**<br>Santofi-Genzyme Lysosomal Champion Fellowship<br>PI<br>Mentor of Dr. Joshua Baker |
| 2019 – 2020 | **Patterns of Healthcare Utilization in a Pediatric Genetics Population**<br>Capstone Project for Boston University Genetics Counseling Program |

| | |
|---|---|
| | Mentor of Anna Nagy |
| 2020 – 2022 | **Assessing Barriers to Enzyme Replacement Therapy for Lysosomal Storage Disorders at a Single Pediatric Center**<br>Santofi-Genzyme Biochemical Genetics Fellowship<br>PI<br>Mentor of Dr. Clara Hildebrandt |
| 2020 - present | **Understanding the lived experience of individuals with Smith-Lemli-Opitz Syndrome and their families**<br>Capstone Project for Boston University Genetics Counseling Program<br>Mentor of Riley Schweig |

## Report of Local Teaching and Training

### Formal Teaching of Residents, Clinical Fellows and Research Fellows (post-docs):

| | | |
|---|---|---|
| 2016 | Transport Disorders<br>Clinical and Research fellows in HMS Genetics Training Program | Brigham and Women's Hospital<br>1-hour lecture |
| 2017 | Disorders of Cholesterol Biosynthesis<br>Clinical and Research fellows in HMS Genetics Training Program | Brigham and Women's Hospital<br>1-hour lecture |
| 2018 | Transport and Cholesterol Disorders<br>Clinical and Research fellows in HMS Genetics Training Program | Brigham and Women's Hospital<br>1-hour lecture |
| 2019 | Mucopolysaccharidosis I: clinical presentation and therapy<br>Clinical fellows | Boston Children's Hospital<br>1-hour lecture |
| 2020 | Disorders of Transport Proteins and Cholesterol synthesis<br>Clinical and Research fellows in HMS Genetics Training Program | Brigham and Women's Hospital<br>1-hour lecture |
| 2021 | Disorders of Transport Proteins and Cholesterol synthesis<br>Clinical and Research fellows in HMS Genetics Training Program | Virtual presentation<br>1 hour |
| 2022 | Disorders of Transport Proteins and Cholesterol synthesis<br>Clinical and Research fellows in HMS Genetics Training Program | Virtual presentation<br>1 hour |

### Clinical Supervisory and Training Responsibilities:

| | | |
|---|---|---|
| 2016 – present | Genetics and Metabolism Inpatient Service, Boston Children's Hospital<br>Clinical supervisor | 6 weeks per year<br>30 hours per week |

| | | |
|---|---|---|
| | Clinical genetics fellows and medical biochemical genetics fellows | |
| 2016 – 2018 | Genetics and Metabolism Ambulatory Clinic, Boston Children's Hospital<br>Preceptor for medical students, residents and fellows | 40 weeks per year<br>1 hour per week |
| 2018 – present | Genetics and Metabolism Ambulatory Clinic, Boston Children's Hospital<br>Preceptor for medical students and residents | 40 weeks per year<br>1 hour per week |
| 2020 – present | Genetics Ambulatory Clinic, Children's Hospital at Dartmouth Hitchcock<br>Observation of Genetic counseling students | 10 hours per year |

**Research Supervisory and Training Responsibilities:**

| | | |
|---|---|---|
| 2017 – present | Supervision of clinical 2nd year fellows in quality improvement projects<br>(average 1-2 fellows per year) | Boston Children's Hospital<br>20 hours per year |

**Local Invited Presentations:**

☒ *No presentations below were sponsored by 3rd parties/outside entities*

☐ *Those presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.*

| | |
|---|---|
| 2018 | Transforming Care through Quality Improvement Initiatives<br>Precision Medicine Summit, Boston Children's Hospital |
| 2018 | Psychosocial Issues in Patients with Inborn Errors of Metabolism<br>Division of Genetics, Massachusetts General Hospital |
| 2019 | Care of the acutely ill metabolic patient & hypoglycemia work up<br>Network Emergency Department Lecture Series, Boston Children's Hospital |
| 2019 | Transforming Care through Quality Improvement Initiatives<br>Precision Medicine Summit, Boston Children's Hospital |
| 2019 | A Rare Fatty Acid Oxidation Disorder and an Innovative Nutrition Intervention<br>Longwood Nutrition Seminar Series, Division of Nutrition at Harvard |
| 2020 | Quality Improvement: Tools to Transform Patient Care<br>Division of Genetics and Genomics Scientific Retreat, Boston Children's Hospital |
| 2020 | A Rare Fatty Acid Oxidation Disorder and an Innovative Nutrition Intervention<br>GI Grand Rounds, Division of Gastroenterology and Nutrition, Boston Children's Hospital |
| 2022 | Fabry Disease: a multisystem lysosomal storage disease<br>Nephrology Grand Rounds, Division of Nephrology, Boston Children's Hospital |

**Report of Regional, National and International Invited Teaching and Presentations**

☐ *No presentations below were sponsored by 3rd parties/outside entities*

☒ *Those presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.*

**Regional**

| | |
|---|---|
| 2016 | Presentation of inborn errors of metabolism<br>The Floating Hospital for Children, Tufts Medical Center<br>Boston, MA |
| 2016 | Metabolic emergencies and therapeutic interventions<br>The Floating Hospital for Children, Tufts Medical Center<br>Boston, MA |
| 2017 | Introduction to Lysosomal Storage Disease<br>Brandeis University, Genetic Counselor training program<br>Waltham, MA |
| 2017 | Psychiatric Presentations in Genetic and Metabolic Disorders<br>Tufts Medical Center<br>Boston, MA |
| 2018 | Introduction to Lysosomal Storage Disease<br>Brandeis University, Genetic Counselor training program<br>Waltham, MA |
| 2019 | An Innovative Nutrition Intervention for CACT deficiency<br>New England Consortium of Metabolic Program<br>Boylston, MA |
| 2019 | How Newborn Screening Impacts Families<br>The Genesis Foundation Symposium, "Your DNA: A 21st Century Users Guide"<br>Cambridge, MA |
| 2020 | Managing GSD Ia with medical and nutritional complexities<br>New England Consortium of Metabolic Programs<br>Virtual |

**National**

| | |
|---|---|
| 2019 | Using Quality Improvement Tools to Enhance Patient Care and Training in Genetics<br>American College of Medical Genetics<br>Seattle, WA |
| 2019 | Quality Improvement Research: Advancing Metabolic Care for all of our Patients<br>Society for Inborn Metabolic Disease<br>Bellevue, WA |
| 2024 | Frame Shifting Our Discussions Around Prognosis and End of Life<br>American College of Medical Genetics<br>Toronto, CA |
| 2024 | The Power of Wishing<br>Seattle Children's Hospital, Clinical and Biochemical Genetics Division<br>Seattle, WA (via zoom) |

| | |
|---|---|
| 2025 | Fabry Disease: Pediatric case perspectives<br>Scientific satellite sponsored by Santofi Genzyme<br>American College of Medical Genetics meeting<br>Los Angelas, CA |

**International**

| | |
|---|---|
| 2019 | Presentation of Genetic and Metabolic Disorders across the Lifespan<br>Chinese Pediatric Society<br>Xiamen, China |

## Report of Clinical Activities and Innovations

**Current Licensure and Certification:**

| | |
|---|---|
| 2013 – present | Massachusetts Medical License |
| 2013 - present | Certification, American Academy of Pediatrics |
| 2017 – present | New Hampshire Medical License |
| 2017 – present | Certification, Clinical Genetics, American Board of Genetics and Genomics |
| 2017 – present | Certification, Medical Biochemical Genetics, American Board of Genetics and Genomics |
| 2022 - 2024 | Texas Medical license |

**Practice Activities:**

| | | | |
|---|---|---|---|
| 2016 – present | Ambulatory Clinic | Division of Genetics and Genomics, Boston Children's Hospital | 2-5 sessions per week |
| 2016 – present | Inpatient Service Consult Attending | Division of Genetics and Genomics, Boston Children's Hospital | 6 weeks per year |
| 2018 – present | Ambulatory Clinic | Division of Genetics, Children's Hospital at Dartmouth | 1-2 sessions per week (through BCH) |

**Clinical Innovations:**

| | |
|---|---|
| 2019 – 2020 | **Emergency Use of UX007 (IND)**<br>Created compassionate use protocol for use of Triheptanoin as primary therapy with innovative first-time use of skimmed breast milk as primary and preventive therapy for a child with Carnitine Acylcarnitine Translocase Deficiency; published in JIMD Reports |
| 2016 – present | **EMR documentation of Critical Contingency Plans at Boston Children's Hospital**<br>Creation of EMR embedded emergency plans for patients at risk of acute metabolic decompensation due to inborn errors of metabolism. ED disease specific ordersets for emergency labs were also created to facilitate complete and timely ordering of labs. (Available on internal share drive) |
| 2016 – 2020 | **Improving Phenylalanine Levels in Patients with PKU: A QI initiative**<br>Multiple initiatives to improve care for patients with Phenylketonuria (PKU). Projects focused on creating standardized follow-up tiered by phenylalanine level, increase percentage of patients with follow-up within past year and decreasing time to follow-up in patients with sub-optimal metabolic control. |
| 2018 – 2020 | **Adapting the iPASS system for subspecialty specific sign-out**<br>Modified the iPASS standardized handoff bundle that was created for inpatient services to be used by a subspecialty consultation service. |
| 2020 – present | **Improving care for patients with hyperammonemia: A QI initiative**<br>Establishing benchmark data on time to medication and diet interventions for patients at risk of severe metabolic decompensation and implementation of care bundles to improve care |
| 2022 – present | **Improving Equity in Clinical Care: A QI initiative**<br>Evaluating new systems to decreased missed opportunities for clinical care for patients whose primary language is Spanish |
| 2022 - present | **Clinical Care pathway for Patients with Hyperammonemia**<br>Developing an evidence based guideline for patients admitted to the hospital with high ammonia levels |

**Report of Teaching and Education Innovations**

| | |
|---|---|
| 2016 – present | **Designed and implemented a QI curriculum for clinical fellows in Genetics**<br>Introduced basic principles of QI to fellows. Discussed standard measurement tools in QI and the subset of measurement tools most suitable for QI work in rare disease. Taught fellows how to design surveys and other instruments for obtaining quantitative and qualitative data useful for QI projects. Also, taught fellows how to implement evidence-based QI projects in rare disease, a non-traditional area for QI. |
| 2016 – present | Served as the primary advisor for all QI projects designed and implemented by clinical fellows. This involved a large amount of direct and personalized advising, since all clinical fellows must design and implement a QI project as part of the training program. |
| 2017-2019 | Lectured to undergraduate pre-medical students at Tufts University about the patient experience in Genetics and Metabolism, and about connections between basic chemistry and biochemistry and inborn errors of metabolism. |

| | |
|---|---|
| 2018 – 2019 | Introduced principles of QI and how they can be adapted for rare disease in the Precision Medicine Summit. |
| 2018 – 2019 | Lectured to students in Brandeis University's Genetic Counselor program on lysosomal storage diseases. |
| 2018 – present | Revised curriculum for units on inborn errors of metabolism for Advanced Human Genetics course, which serves both clinical and laboratory fellows. |
| 2018 – present | Recruited external speakers for the Advanced Human Genetics course. |
| 2019 – present | Partnered with non-profit organization Rare New England to ensure careers related to Genetics and Metabolism, including Genetic Counseling, Nutrition, and Physician specializing in pediatric genetics and metabolism, were represented. Discussed careers in Genetics and Metabolism with undergraduates and graduate students. |
| 2019 | Excellence in Clinical Teaching Award nomination, BCH Academy. |
| 2021 | Direct outreach and advising to undergraduate pre-medical students at Tufts University interested in Genetics and Metabolism, focusing on BIPOC and first-generation students. |

**Report of Education of Patients and Service to the Community**

☐ *No presentations below were sponsored by 3rd parties/outside entities*

☒ *Those presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.*

**Activities**

| | |
|---|---|
| 2019 | Biotech Week Boston<br>"Fireside Chat" Selections from Disorder: A Rare Disease Film Festival<br>Sponsored by Takeda |
| 2020 | Genesis Foundation for Children<br>Created a video on the importance of connections and care during the pandemic for the Celebration of Care: A virtual spring event<br>Sponsored by The Genesis Foundation for Children |

## Report of Scholarship

### Peer-Reviewed Scholarship in print or other media:

### Research Investigations

1. Hickey CL, Sherman JC, Goldenberg P, **Kritzer A**, Caruso P, Schmahmann JD, Colvin MK. Cerebellar cognitive affective syndrome: insights from Joubert syndrome. *Cerebellum Ataxias*. 2018;5(5). PMID: 29568536.
2. Murry JB, Machini K, Ceyhan-Birsoy O, **Kritzer A**, Krier JB, Lebo MS, Fayer S, Genetti CA, VanNoy GE, Yu TW, Agrawal PB, Parad RB, Holm IA, McGuire AL, Green RC, Beggs AH, Rehm HL. Reconciling newborn screening and a novel splice variant in *BTD* associated with partial biotinidase deficiency: a BabySeq Project case report. *Cold Spring Harb Mol Case Stud*. 2018;4(4):a002873. PMID: 29728376.
3. Gold NB,Blumenthal JA, Wessel AE, Stein DR, Scott A, Fox VL, Turner A, **Kritzer A,** Rajabi F, Peeler K, Tan WH. Acute Pancreatitis in a Patient with Maple Syrup Urine Disease: A Management Paradox. *J Pediatr*. 2018;198:313-316. PMID: 29681447.
4. Mullikin D, Pillai N, Sanchez R, **Kritzer A**, Tal L, Almannai M, Berry GT, Gambello MJ, Li H, Graham B, Srivaths L, Sutton VR, Grimes A. Megaloblastic Anemia Progressing to Severe Thrombotic Microangiopathy in Patients with Disordered Vitamin $B_{12}$ Metabolism: Case Reports and Literature Review *J Pediatr*. 2018;202:315-319.E2. PMID: 30057141
5. **Kritzer A**, Siddharth, Leestma K, Bodamer O. Early initiation of enzyme replacement therapy in classical Fabry disease normalizes biomarkers in clinically asymptomatic pediatric patients. *Mol Genet Metab Rep*. 2019;21:100530. PMID: 31660293
6. Gold NB**, **Kritzer A**, Weiner DL, Michelson KA. Emergency Laboratory Evaluations for Patients With Inborn Errors of Metabolism. *Pediatr Emerg Care*. 2019. PMID: 31738301.
7. D'Gama AM, Brucker W, J Zhang T, Gubbels CS,,Ferdinandusse S, Shi J, Grant PE, VanNoy G, Genetti CA, Juusola J, Yu TW, **Kritzer A**, Agrawal PB. A phenotypically severe, biochemically "silent" case of HIBCH deficiency in a newborn diagnosed by rapid whole exome sequencing and enzymatic testing. *Am J Med Genet A*. 2020;182(4):780-784. PMID: 32022391.
8. Sacharow S, Papaleo C, Almeida K, Goodlett B, **Kritzer A,** Levy H, Martell L, Wessel A, Viau K. First 1.5 years of pegvaliase clinic: Experiences and outcomes. *Mol Genet Metab Rep*. 2020;24:100603. PMID: 32489881.
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1. Weiner DL and **Kritzer A.** "Reye Syndrome" In *Clinical Infectious Disease 3rd edition,* Schlossberg ed. Oxford University Press, NY, NY (2019).
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**Professional Educational Materials or Reports, in print or other media**

**Abstracts, Poster Presentations and Exhibits Presented at Professional Meetings**

1. 2016 International Network for Fatty Acid Oxidation Research and Management (INFORM)
   Poster presentation
   The use of massive anabolic therapy to rescue an infant with heart failure and VLCAD deficiency
   **Kritzer A**, Neilan E, O'Donnell A, Wojick M, Rohr R, Tarrant S, Tan WH, Berry G

2. 2016 Society for Inborn Metabolic Disease
   Poster presentation
   The use of pentosane polysulfate as adjunct therapy in Mucopolysaccharidosis I
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3. 2018 American College of Medical Genetics
   Poster presentation
   Rapid turnaround whole exome sequencing for critically ill neonates
   Gubbels CS, VanNoy G, Wojcik M,Comrie, C,Genetti C,Gold N,, Brucker W, **Kritzer A**, Stoler J,Beggs A,Bodamer O, Juusola J, Agrawal PB, Yu TW

4. 2018 Institute for Healthcare Improvement Scientific Symposium
   Poster presentation
   Creation and Implementation of Critical Contingency Plans for Patients with Inborn Errors of Metabolism
   Lenz C, Brucker W, Kerr J,Banerjee T, Hecht L, **Kritzer A**

5. 2021 American College of Medical Genetics Virtual meeting
   Post presentation
   Patterns of Healthcare Utilization in a Pediatric Genetic Cohort
   Nagy A, Dies K, Brewster S, and **Kritzer A**,

6. 2021 American College of Medical Genetics Virtual meeting
   Poster presentation
   Standard Operating Procedure for Genetic and Metabolic Consults for Possible Non-Accidental Trauma
   Hildebrandt C, Wilson, C and **Kritzer A**

7. 2025 American College of Medical Genetics

Poster Presentation
Improving Care for Patients with Hyperammonemia: Use of Quality and Safety Frameworks and Creation of a Clinical Care Pathway
Holtz A, Michl E, Horlbeck M, Kelly D, Currier D, Russ C, Cheng A, Durney J and **Kritzer A**

8. 2025 American College of Medical Genetics
   Poster Presentation
   Mitochondrial Dysfunction in Propionic Acidemia: A Case-Report and Review of the Literature
   Walther B, Murray B, Pandiyan P, Ray R, Yeoh L, and **Kritzer A**

9. 2025 American College of Medical Genetics
   Poster Presentation
   Use of Cholic Acid in Smith-Lemli-Opitz Syndrome (SLOS): Real-World Patient Outcomes
   Ferren EC, Hillman PR, **Kritzer A**, Ray J, Serrano AH, Northrup H, Roberts P, Dutta R, Pramparo T, Terner-Rosenthal J, Vig P, Steiner RD