



## STATE OF NEW HAMPSHIRE DEPARTMENT OF HEALTH AND HUMAN SERVICES

### DIVISION OF PUBLIC HEALTH SERVICES

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

September 27, 2019

Jeffrey A. Meyers Commissioner Lisa M. Morris Director

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

### **REQUESTED ACTION**

- 1. Authorize the Department of Health and Human Services, Division of Public Health Services, to retroactively amend an existing agreement with Trustees of Dartmouth College, (Vendor #177157), One Medical Center Drive, Lebanon, New Hampshire 03756, to provide the use of an estimated 130 infant Dried Blood Spot Specimen cards per year to conduct research on the impact of environmental contaminants on children's health, by increasing the price limitation by \$9,600 from \$9,600 to \$19,200 and by extending the completion date from June 30,2019 to June 30, 2023. The vendor will pay the Department \$2,400 per State Fiscal Year for the use of Dried Blood Spot Specimen cards, up to \$9,600 for the term of this agreement, effective retroactive to July 1, 2019, upon Governor and Executive Council approval. The funds for SFY 2022 and SFY 2023 will be included in future operating budgets. 100% Other funds.
- 2. Subject to approval of Item #1 above, authorize the Department of Health and Human Services, Division of Public Health Services, Bureau of Population Health and Community Services, Newborn Screening Program, to accept and expend Other Funds in an amount not to exceed \$4,800 from the Trustees of Dartmouth College, effective retroactive to July 1, 2019 through June 30, 2021 and further authorize the funds to be allocated as follows:

The original agreement was originally approved by the Governor and Executive Council on December 16, 2015 (Item #25).

Funds received to support this request will be deposited into the following account for State Fiscal Year 2020 through State Fiscal Year 2023 to fund the Newborn Screening Revolving Fund..

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

2020 Class/Object	Class Title	Current Modified Budget	Increase (Decrease) Amount	Revised Modified Amount
003-403177	Other-Revolving Fund Filter Paper Fee	\$2,001,043	\$0	\$2,001,043
005-403318	Other-Dartmouth Newborn Screening	\$0	\$2,400	\$2,400
Total Revenue		\$2,001,043	\$2,400	\$2,003,443
010-500100	Personal Serv - Perm	\$66,249	\$0	\$66,249

026-500251	Organizational Dues	\$500 \$100,675	\$0 \$0	\$500 \$100,675
037-500173	Technology - Hardware	\$2,500	\$0	\$2,500
038-500175	Technology – Software	\$500	\$0	\$500
039-500188	Telecommunications	\$100	\$0	\$100
046-500462	Consultants	\$20,000	\$0	\$20,000
050-500109	Personal Serv - Temp	\$36,479	\$0	\$36,479
060-500602	Benefits	\$24,856	\$0	\$24,856
066-500545	Employee Training	\$100	\$1,200	\$1,300
080-500710	Out of State Travel	\$5,000	\$0	\$5,000
102-500731	Contracts for Program Services	\$1,729,855	\$0	\$1,729,855
Total Expenses		\$2,001,043	\$2,400	\$2,003,443

2021		Current Modified	Increase (Decrease)	Revised Modified
Class/Object	Class Title	Budget	Amount	Amount
003-403177	Other-Revolvina Fund Filter Paper Fee	\$1,663,865	\$0	\$1,663,865
005-403318	Other-Dartmouth Newborn Screening	\$0	\$2,400	\$2,400
Total Revenue		\$1,663,865	\$2,400	\$1,666,265
010-500100	Personal Serv - Perm	\$66,249	\$0	\$66,249
020-500200	Current Expense	\$13,350	\$1,200	\$14,550
026-500251	Organizational Dues	\$500	\$0	\$500
030-500310	Equipment	\$100,675	\$0	\$100,675
037-500173	Technology - Hardware	\$2,500	\$0	\$2,500
038-500175	Technology – Software	\$250	\$0	\$250
039-500188	Telecommunications	\$100	\$0	\$100
046-500462	Consultants	\$20,000	\$0	\$20,000
050-500109	Personal Serv - Temp	\$31,870	\$0	\$31,870
060-500602	Benefits	\$25,021	\$0	\$25,021
066-500545	Employee Trainina	\$100	\$1,200	\$1,300
080-500710	Out of State Travel	\$5,000	. \$0	\$5,000
102-500731	Contracts for Program Services	\$1,398,250	\$0	\$1,398,250
Total Expenses		\$1,663,865	\$2,400	\$1,666,265

### **EXPLANATION**

This request is **retroactive** because more time was needed to negotiate and finalize the scope of the work prior to the vendor accepting the terms of the agreement.

The purpose of this agreement is to allow Trustees of Dartmouth College's Geisel School of Medicine at Dartmouth, to research the impact of environmental contaminants, specifically arsenic, on children's health.

To enable the research on children's health, the Trustees of Dartmouth College is provided Dried Blood Spot Cards of infants born in New Hampshire. The Dried Blood Spot

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This agreement advances the understanding of the impact of the environmental contaminants on children's health. The partnership between the Division on Public Health Services (DPHS) and Dartmouth Medical School provides data onthe presence and impact of toxins, specifically arsenic, in drinking water on our very youngest residents, which may impact lifelong health. Funds from this agreement helps fund the daily activities of the Newborn Screening Program.

The Department will monitor the effectiveness of the Contractor and the delivery of services required under this agreement using the following performance measures:

- The vendor will provide the Department with published reports.
- The vendor will provide the Department with articles or written proceedings resulting from activities of the New England Newborn screening program.

Should the Governor and Executive Council not authorize this request, the State will lose the opportunity, and additional funds, to better understand the impact of environmental exposures, such as arsenic, on the incidence of birth defects and newborn metabolic conditions throughout the State.

Respectfully submitted.

Jeffrey A. Meyers Commissioner



### CONTRACT AND DATA USE AGREEMENT AMENDMENT #1

This 1<sup>st</sup> Amendment to the Dried Blood Spot (DBS) Specimen Card Contract and Data Use Agreement ("Amendment #1") is made and entered into by and between the New Hampshire Department of Health and Human Services, Division of Public Health Services (the "Department"), and the Trustees of Dartmouth College on behalf of the Geisel School of Medicine at Dartmouth, Section of Biostatistics and Epidemiology, Children's Center for Environmental Health and Disease Prevention ("Data Recipient").

WHEREAS, pursuant to a Contract and Data Use Agreement (the "Contract") approved by the Governor and Executive Council on December 16, 2015, (Item #25), the Contractor agreed to perform certain services based upon the terms and conditions specified in the Contract and in consideration of certain sums specified; and

WHEREAS, pursuant to Form P-37, General Provisions, Paragraph 18, the Contract may be amended upon written agreement of the parties and approval from the Governor and Executive Council; and

WHEREAS, the parties agree to extend the term of the agreement, modify the scope, and increase the price limitation by \$9,600, from \$9,600 (\$2,400 per State Fiscal Year) to \$19,200, to support continued delivery of these services for an additional four (4) years upon Governor and Executive Council approval through June 30, 2023; and

NOW THEREFORE, in consideration of the foregoing and the mutual covenants and conditions contained in the Contract and set forth herein, the parties hereto agree to amend the Contract as follows:

1. Delete the last sentence of paragraph #3 of Section C, OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT, and replace with:

This research has been approved by the Dartmouth Committee for the Protection of Human Subjects (see attached letter dated May 3, 2019.)

- 2. Delete paragraph #d Payment, of Section C, OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT, and replace with:
  - 1) Payment shall be made by the Data Recipient within 30 days of receipt of acceptable invoice.
  - 2) Payment shall be made payable to Treasurer, State of NH and sent to the attention of:

Data Recipient Initials: Date: 47.130119



Ellen Chase-Lucard Contracts & Finance Section Bureau of Public Health Systems, Policy and Performance Division of Public Health Services New Hampshire Department of Health and Human Services 29 Hazen Drive Concord, NH 03301-6504 Phone: 603-271-4780

Email: ellen.chase-lucard@dhhs.nh.gov

- 3. Delete paragraph #1, of Section E, TERM AND TERMINATION, and replace with:
  - The provisions of this Agreement shall be effective on the date of 1. Governor and Council approval and shall terminate on June 30, 2093 2924 or sooner. When the study has concluded and all of the Dried Blood Spot (DBS) Specimen Cards provided by the Department to Data Recipient are destroyed or returned to the Department, or, if it is Infeasible to return or destroy the Dried Blood Spot (DBS) Specimen Cards, protections are extended to such information, in accordance with the termination provisions in this Section.
- 4. Delete the third paragraph of paragraph #2, Section F, MISCELLANEOUS, and replace with:

Any notices from the Data Recipient to the Department should be sent to the attention of: Rhonda Siegel, MS Ed Administrator New Hampshire Department of Health and Human Services Division of Public Health Services 29 Hazen Drive Concord, New Hampshire 03301-6504 Phone: 603-271-4526

Email: rhonda.siegel@dhhs.nh.gov

- This agreement is further amended by adding Exhibit K "DHHS INFORMATION SECURITY REQUIREMENTS" (Dartmouth Hitchcock only) dated October 2018.
- This agreement is further amended by attaching the CPHS Approval of Submission letter dated May 3, 2019, as Attachment A.

Data Recipient Initials: Date: 30/19

Data Use Agreement - Amendment #1 Page 2 of 5



- 7. This agreement is further amended by amending the Data Use agreement "B. Scope and Purpose" 2. to read "Except as otherwise specified herein, Data Recipient may make all legal uses and disclosures of the Dried Blood Spot (DBS) Specimen Cards necessary to conduct its research of how environmental contaminants, specifically the presence of arsenic in the mother's drinking water, impacts children's health.
- 8. Section C "Obligations and Activities of Data Recipient" will be amended to include, "Data Recipient and all End Users of the DHHS Data on or related to the DBS specimen shall sign and agree to the terms of the "End User Agreement" attached here to as Attachment B. Data Recipient agrees to ensure all users of DHHS data sign the "End User Agreement" prior to gaining access to the data. Data Recipient agrees to maintain a copy of each agreement signed."

All terms and conditions of the Agreement not inconsistent with this Amendment #1 remain in full force and effect.

Data Recipient Initials Date: 13011



This amendment shall be effective upon the date of Governor and Executive Council approval. IN WITNESS WHEREOF, the parties have set their hands as of the date written below,

State of New Hampshire

Department of Health and Human Services Division of Public Health Services Name: LISA MORRIS Title: DIRECTOR, DIVISION OF PUBLICHETH. SPUCE. TRUSTEES OF DARTMOUTH COLLEGE on behalf of the Geisel School of Medicine at Dartmouth Section of Biostatistics and Epidemiology Children's Center for Environmental Health and Disease Prevention Research Center Director, Office of Sponsned Projects Acknowledgement of Contractor's signature: State of Naw Hampshire, County of Graffon on 8/30/19, before the undersigned officer, personally appeared the person identified directly above, or satisfactorily proven to be the person whose name is signed above, and acknowledged that s/he executed this document in the capacity indicated above. Signature of Notary Public or Justice of the Peace HEATHER A. ARNOLD, Notary Public My Commission Expires August 24, 2021 Name and Title of Notary or Justice of the Peace My Commission Expires:



The preceding Amendment, having been reviewed by this office, is approved as to form, substance, and execution.

OFFICE OF THE ATTORNEY GENERAL

Name: CATHERINE PINOS
Title: Afformat

I hereby certify that the foregoing Amendment was approved by the Governor and Executive Council of the State of New Hampshire at the Meeting on: \_\_\_\_\_\_ (date of meeting)

OFFICE OF THE SECRETARY OF STATE

Name: Title:



Exhibit K

#### 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," "Confidential Data," or "Data" (as defined in Exhibit K), 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'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 a security policy, which includes successful attempts) 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

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storage of data; and changes to system hardware, firmware, or software characteristics without the owner's knowledge, instruction, or consent. Incidents include the loss of data through theft or device misplacement, loss or misplacement of hardcopy documents, and misrouting of physical or electronic documents or mail.

- 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

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except as required or permitted under this Contract or required by law. 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.

- 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. 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.

### II. METHODS OF SECURE TRANSMISSION OF DATA

- 1. Application Encryption. If Contractor 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. Contractor may not use computer disks or portable storage devices, such as a thumb drive, as a method of transmitting DHHS Data.
- 3. Encrypted Email. Contractor 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 Contractor 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. Contractor may not use file hosting services, such as Dropbox or Google Cloud Storage, to transmit Confidential Data.
- 6. Ground Mail Service. Contractor 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 Contractor is employing portable devices to transmit Confidential Data said devices must be encrypted and password-protected.
- 8. Open Wireless Networks. Contractor 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 Contractor is employing remote communication to

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access or transmit Confidential Data, a secure method of transmission or remote access, which complies with the terms and conditions of Exhibit K, must be used.

- 10. SSH File Transfer Protocol (SFTP), also known as Secure File Transfer Protocol. If Contractor 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 Contractor 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 DHHS Data and any derivative of the data for the duration of this Contract. After such time, the Contractor will have thirty (30) days to destroy the data and any derivative in whatever form it may exist, unless, otherwise required by law or, if it is infeasible to return or destroy DHHS Data, protections are extended to such information, in accordance with the termination provisions in this Section. To this end, the parties must:

### A. Retention

- 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.
- 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 accessed or utilized for purposes of carrying out this contract.
- The Contractor agrees to provide security awareness and education for its End Users in support of protecting DHHS Confidential information.
- The Contractor agrees to retain all electronic and hard copies of Confidential Data in a secure location and identified in section IV. A.2
- 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, current, updated, and

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maintained anti-malware (e.g. anti-viral, anti-hacker, anti-spam, anti-spyware) utilities. The environment, as a whole, must have aggressive intrusion-detection and firewall protection.

 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

If the Contractor maintains any Confidential Information on its systems (or its sub-contractor systems) and it has not done so previously, the Contractor will implement policies and procedures to ensure that any storage media on which such data maybe recorded will be rendered unreadable and that the data will be un-recoverable when the storage media is disposed of. Upon request, the Contractor will provide the Department with copies of these policies and with written documentation demonstrating compliance with the policies. The written documentation will include all details necessary to demonstrate data contained in the storage media has been rendered unreadable and un-recoverable. Where applicable, regulatory and professional standards for retention requirements may be jointly evaluated by the State and Contractor prior to destruction.

- 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.
- 2. 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:
  - 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

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used to store the data (i.e., tape, disk, paper, etc.).

- 3. The Contractor will maintain appropriate authentication and access controls to contractor systems that collect, transmit, or store Department confidential information where applicable.
- 4. If the Contractor will be sub-contracting any core functions of the engagement supporting the services for State of New Hampshire, the Contractor will ensure End-User will maintain 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.
- 5. 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.
- 6. 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.
- 7. The Contractor will not store 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.
- 8. Data Security Breach Liability. In the event of any computer security incident, incident, or 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.
- 9. 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, HIPAA Privacy and Security Rules (45 C.F.R. Parts 160 and 164) and 42 C.F.R. Part 2 that govern protections for individually identifiable

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health information and as applicable under State law.

- 10. 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.
- 11. Contractor agrees to maintain a documented breach notification and incident response process. The Contractor will notify the State's Privacy Officer, and additional email addresses provided in Section VI, of any security breach within 24-hours of the time that the Contractor learns of its occurrence. 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.
- 12. 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.
- 13. The Contractor is responsible for End User oversight and compliance with the terms and conditions of the contract and Exhibit K.

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.

### LOSS REPORTING

The Contractor must notify the State's Privacy Officer, Information Security Office and Program Manager of any Security Incidents and Breaches within 24- hours of the time that the Contractor learns of their occurrence.

The Contractor must further handle and report Incidents and Breaches involving PHI in accordance with DHHS's documented Incident Handling and Breach Notification procedures and in accordance with- the HIPAA, Privacy and Security Rules. In addition to, and notwithstanding, Contractor's compliance with all applicable obligations and procedures, Contractor's procedures must also address how the Contractor will:

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- 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
- 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 contact for Data Management or Data Exchange issues: DHHSInformationSecurityOffice@dhhs.nh.gov
- B. DHHS contacts for Privacy issues: DHHSPrivacyOfficer@dhhs.nh.gov
- C. DHHS contact for Information Security issues: DHHSInformationSecurityOffice@dhhs.nh.gov
- D. DHHS contact for Breach notifications:

DHHSInformationSecurityOffice@dhhs.nh.gov DHHSPrivacyOfficer@dhhs.nh.gov

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### Trustees of Dartmouth College • Dartmouth-Hitchcock Medical Center COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

63 South Main Street • HB 6254 • Hanover, NH 03755 Telephone (603) 646-6482 • Fax (603) 646-9141

CPHS APPROVAL OF SUBMISSION

Margaret Karagas Epidemiology May 3, 2019

CPHS #: Principal Investigator: Submission Type:

Margaret Karagas Modification and Continuing Review Full Committee

STUDY00020844

Action: Approved
Approval Date: 5/2/2019
Expiration Date: 5/13/2020
Committee Review: 5/2/2019

Study Type: Funding:

• National Institute of Environmental Health Sciences (NIEHS) - Sponsor's Funding

ID: PO1ES022832; ID: P42ES007373

• National Institute of General Medical Sciences (NIGMS) - Sponsor's Funding ID: P20GM104416

• Environmental Protection Agency (EPA) - Sponsor's Funding ID: RD-8354420

• University of Southern California

• Office of the Director, NIH - Sponsor's Funding ID:

UH3OD023275/UG3OD023275

46.204.18

• Emory University - Sponsor's Funding ID: T720029

• Emory University School of Medicine - Sponsor's Funding ID: T701316

Title of Study:

### **New Hampshire Birth Cohort Study**

Notes:

+ CPHS previously determined that this research involving pregnant women presents only minimal risk to the study participants and that the study design has minimized the risks of study participation to the extent possible. The testing of the participants' drinking water for arsenic content and promptly notifying participants about those test results may provide a direct benefit to some study participants. This research does not encompass any medical decisions about an individual's pregnancy. The CPHS approved the involvement of pregnant women in this study in accordance with 45 CFR

+ CPHS previously determined that this study involving minors continues to be research not involving greater than minimal risk [45 CFR 46.404].

+ Consent elements altered per 45 CFR 46.116(d), signed parental permission and assent is not required when electronically indicated.

+Dartmouth CPHS provides reviews for Children's Hospital of Boston for the Indoor Air Quality Sub-Study and Maine Medical Center.

+ WIRB will review the related ECHO-Wide Data Protocol, CPHS#00031259

Modifications/Update:

+ Consent forms and Multiple study forms updated; New subject letter for the middle

childhood visit; Updates to study's annual newsletter; Updated study team.

Approved: • Consent forms:

-20844Karagas\_MainConsent\_3.25.19 -Consent Form\_EC Visit \_v.04.02.19 -Consent Form\_MedRecs\_03.07.19

-EC and MC Videotaping Consent Form\_\_04.01.19

-MC-blood-draw-consent\_04.01.19
-MC\_assent-form\_pulmonary\_v3.26.19
-MC\_expedited-consent\_pulmonary\_v3.26.19
-20844\_Indoor\_Air\_Study\_Consent\_Form\_04302018
-20844Karagas\_FocusGroup\_Consent\_cphs\_08082013
-20844Karagas\_InfantBlood\_Consent\_01.04.16
-20844Karagas\_VideotapingConsent\_cphs06172013
• SocBehavNonclinical\_Research\_Plan\_04.01.19

- Subject Letter Additional Tooth Kit Mailing v.2.27.2019
- Subject Instructions for Tooth Collection-v.2.25.2019
- 1-year food checklist v2.19.19
- Subject Letter ECVisit Mailing IntroductoryLetter \_3.18.19
- Study Document--Acknowledgment of EC visit Payments v.4.2.19
- Early Childhood Reminder Card 3.18.19
- EC visit Letter Recruitment Non-Responder\_4.1.19
- EC food checklist 3.26.19
- Subject Instructions Activity and Air Quality Monitor 03222019
- Subject Instructions Activity and Air Quality Monitors\_childcareproviders\_3.22.19
- ECHO Invite and Reminders 04.01.19
- ECHO 3WK Reminder Letter 04.01.19
- MC Subject Letter IntroductoryLetter 0312819
- MC food checklist 3.26.19
- Study Document--Acknowledgment of MC visit Payments v.3.21.19
- Subject Instructions for Nail Collection--Child at 7.5 Year Follow-up\_v.02.25.19
- Newsletter New Hampshire Birth Cohort Study 2019-5-Final\_wCHText

The Committee for the Protection of Human Subjects has approved this submission. Approval by CPHS is based on the study's appropriate balance of risk and benefit to subjects, a study design in which risks to subjects are minimized, and a determination that the criteria for approval at 45 CFR 46.111 and 21 CFR 56.111 are satisfied as appropriate.

Informed consent is a process beginning with a description of the research and including an evaluation of comprehension by the researcher. Once the consent form has been signed, each participant should receive a copy. Assessment of each participant's consent by the researcher should continue throughout a research study.

Go to the documents tab in this study in Rapport to download the stamped approved consent form.

CPHS approval of this study expires on 5/13/2020. It is your responsibility as Principal Investigator to ensure that all other appropriate institutional approvals are obtained.

You are required to submit a continuing review at least 30 days before expiration or study closure. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR.

Any modification to previously approved materials must be approved by the CPHS prior to initiation. You can submit a modification by navigating to the active study and clicking Create Modification / CR.

Navigate to the active study and click "Report New Information" to report unanticipated problems involving risks to subjects or others, as well as certain adverse drug events and medical device effects. In addition, please promptly report any known instances of noncompliance and complaints.

If you have any questions, please direct them to CPHS. Tasks@Dartmouth.edu.

Sincerely,

Kimberly A. Lyford, CIP Senior Research Analyst

Committee for the Protection of Human Subjects

cc: Vicki Sayarath

## ATTACHMENT B END USER AGREEMENT

Please send signed EUA as an email attachment to: DHHSInformationSecurityOffice@dhhs.nh.gov

By requesting and receiving approval to access the DHHS Data:

- I understand that I will have direct and indirect access to protected health and confidential information in the course of performing my work activities.
- I agree to protect the confidential nature of all information to which I have access.
- I understand that there are state and federal laws and regulations that ensure the privacy and confidentiality of an individual's information.
- I understand that there are DHHS policies and agency procedures with which I am required to comply related to the protection of individually identifiable information.
- I understand that the information I will have direct and indirect access to shall not be shared
  outside the DHHS Scope of Work or related signed Contract, Memorandum of Understanding
  and/or Information Exchange Agreement/Data Sharing Agreement agreed upon.
- I understand that my SFTP or any information security credentials (Dartmouth name and password) should not be shared with anyone. This applies to credentials used to access the site directly or indirectly through a third party application.
- I will not disclose or make use of the identity, financial or health information of any person or establishment discovered inadvertently. I will report such discoveries within two (2) hours to **DHHSInformationSecurityOffice@dhhs.nh.gov** and **DHHSPrivacyOffice@dhhs.nh.gov** and the DHHS Program Manager contact.
- I will not imply or state, either in written or oral form, that interpretations based on the
  data are those of the original data sources or the State of NH unless the data Dartmouth
  and DHHS are formally collaborating.
- I will acknowledge, in all reports or presentations based on these data, the original source of the data.
- I understand how I am expected to ensure the protection of individually identifiable information. Should questions arise in the future about how to protect information to which I have access, I will immediately notify my supervisor.
- I have been informed that this signed agreement will be retained on file for future reference.

Signature	_	Date	
Printed Name	<u>.</u>	Title	
Business Name			

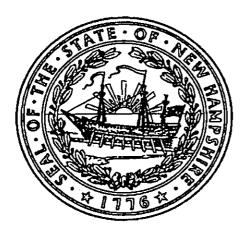
# State of New Hampshire Department of State

### **CERTIFICATE**

I, William M. Gardner, Secretary of State of the State of New Hampshire, do hereby certify that TRUSTEES OF DARTMOUTH COLLEGE a New Hampshire State Chartered (Legislative) formed to transact business in New Hampshire on December 13, 1769. I further certify that it has paid the fees required by law and has not dissolved.

Business ID: 66740

, Certificate Number: 0004575593



IN TESTIMONY WHEREOF,

I hereto set my hand and cause to be affixed the Seal of the State of New Hampshire, this 4th day of September A.D. 2019.

William M. Gardner

Secretary of State



### CERTIFICATE

l, Laura H. Hercod, hereby certify that I am Assistant Clerk of Trustees of Dartmouth College, a corporation created by Royal Charter and existing under the laws of the State of New Hampshire; that as Assistant Clerk I have custody of the records of meetings of the Board of Trustees of said corporation; and that at a meeting of said Board duly called and held on the 9th day of April, 2011 at which a quorum was present and acting throughout, the following vote was adopted:

VOTED: To approve the Signature and Requisition Authority Policy, effective July 1, 2011 or such earlier date as the Executive Vice President/Chief Financial Officer shall determine. The provisions of the Signature and Requisition Authority Policy shall take precedence over any previous inconsistent vote of the Board of Trustees.

I further certify that said Board voted to adopt amendments to the Signature and Requisition Authority Policy on March 3, 2012 (effective January 1, 2012), September 22, 2013, January 2, 2014, March 8, 2014, November 8, 2014, and September 17, 2016, March 4, 2017, and November 4, 2017, and that pursuant to authority granted in the policy, amendments by the Executive Vice President and the Provost were made August 7, 2015 (effective July 1, 2015), as amended on September 17, 2016, March 4, 2017 and as further amended on November 6, 2017. The document is available on Dartmouth's website at: <a href="http://www.dartmouth.edu/~control/policies/signature-authority.html">http://www.dartmouth.edu/~control/policies/signature-authority.html</a>.

I further certify that said vote remains in full force and effect as of the date hereof and is not contrary to any provision of the Charter of said corporation.

I further certify that attached hereto is a true and correct copy of the Introduction and the Sponsored Activities Administration and Intellectual Property Transactions section (Appendix G) of the said Signature and Requisition Authority Policy.

I further certify that the following persons were appointed to the positions opposite their respective names and continue to serve in said positions as of the dates shown:

David F. Kotz	Interim Provost	November 23, 2017
Dean Madden	Vice Provost for Research	July 1, 2017
Gail Goodness	Controller	June 9, 2008
Jill Mortali	Director, Office of Sponsored Projects	September 15, 2008
Nila Bhakuni	Director of Technology Transfer Office	July 1, 2015
Heather A. Arnold	Associate Director, Office of Sponsored	September 1, 2016
	Projects	

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of the corporation this

Laura H. Hercod, Assistant Clerk Trustees of Dartmouth College



### CERTIFICATE OF LIABILITY INSURANCE

08/19/2019

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

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

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		phia, PA 19103-2797			11	E-MAIL ADDRES					
						INSURER(S) AFFORDING COVERAGE				NAIC#	
J092	54-DA	RT-GAWUP-19-20			Į,	INSURER A : Pinnacle Consortium of Higher Ed VT RRRG				11980	
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	TRUSTEES OF DARTMOUTH COLLEGE ATTN: TINA FEENEY			l T	INSURER B: Safety National Casuatty Corporation 15105 INSURER C: Genesis Insurance Company 38962					38962	
5	3 S. M.	AIN STREET, SUITE 212			<b>[-</b>		RD:N/A	, , ,	<del></del>		N/A
Н	ANOV	/ER, NH 03755			Į-		RE: N/A				N/A
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		CLAIMS-MADE X OCCUR							DAMAGE TO RENTED PREMISES (Ea occurrence)	\$	2,000,000
						- 1			MED EXP (Any one person)	5	5,000
1					•				PER\$ONAL & ADV INJURY	<u> </u>	2,000,000
İ	GEN	L'L AGGREGATE LIMIT APPLIES PER:							GENERAL AGGREGATE	\$	5,000,000
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NH DHHS 129 Pleasant Street Concord, NH 03301				SHO THE ACC	ULD ANY OF	DATE THE	ESCRIBED POLICIES BE CA EREOF, NOTICE WILL E LY PROVISIONS.				
		-1					h USA Inc.	· · · · · · · · · · · · · · · ·			
l				Manashi Mukherjee Manashi Mukanate							



### CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 08/19/2019

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

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

Marsh USA Inc.				NAME;					
1717 Arch Street			PHONE   FAX   (A/C, No, Ext):   (A/C, No):						
Philadelphia, PA 19103-2797			E-MAIL ADDRESS:						
			INSURER(S) AFFORDING COVERAGE				NAIC #		
J09254-DART-GAWUP-19-20				INSURER A : N/A					N/A
INSURED OF PARTHOLITH COLLEGE				INSURE	RB: N/A				N/A
TRUSTEES OF DARTMOUTH COLLEGE ATTN: TINA FEENEY					RC: N/A				N/A
53 S. MAIN STREET, SUITE 212					R D : Midwest En	nniovars Casualh	Company		23612
HANOVER, NH 03755				ľ	R E : American C				20427
					R F : Transportat				20494
COVERAGES				INSURE	-R F . Halispoliai	BOIT INSUIANCE CO			120101
THIS IS TO CERTIFY THAT THE POLICIES INDICATED. NOTWITHSTANDING ANY RE CERTIFICATE MAY BE ISSUED OR MAY EXCLUSIONS AND CONDITIONS OF SUCH	QUIRE PERTA POLICI	EMEN UN, 1 IES. I	NT, TERM OR CONDITION THE INSURANCE AFFORDI LIMITS SHOWN MAY HAVE	OF AN'	Y CONTRACT THE POLICIE REDUCED BY	OR OTHER I S DESCRIBEI PAID CLAIMS.	OCUMENT WITH RESPEC	OT TO	WHICH THIS
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EVIDENCE OF INSURANCE									
CERTIFICATE HOLDER				CANO	CELLATION				
NH DHHS 129 Pleasant Street Concord, NH 03301			SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.						
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					♠ 10	99 2016 AC	OPD COPPORATION	All ria	hte recented





Nicholas A. Toumpas Commissioner

Marcella J. Bobinsky Acting Director

#### STATE OF NEW HAMPSHIRE

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

29 HAZEN DRIVE, CONCORD, NH 03301-6527 603-271-4517 1-800-852-3345 Ext. 4517 Fax: 603-271-4519 TDD Access: 1-800-735-2964



October 29, 2015

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

### REQUESTED ACTION

- 1) Authorize the Department of Health and Human Services, Division of Public Health Services, Bureau of Population Health and Community Services, Newborn Screening Program, to enter into a Contract Data Use Agreement with Trustees of Dartmouth College (vendor #177157-B013), One Medical Center Drive, Lebanon, New Hampshire 03756, for the use of an estimated 960 infant Dried Blood Spot Specimen cards to conduct research on the impact of environmental contaminants on children's health, effective the date of Governor and Council approval through June 30, 2019. The vendor will pay the Department \$2,400 per State Fiscal Year for the use of Dried Blood Spot Specimen cards, up to \$9,600 for the term of this agreement. Vendor payments will fund the Newborn Screening Revolving Fund. There is no cost to the State associated with this agreement. 100% Other Funds.
- 2) Subject to approval of Item #1 above, authorize the Department of Health and Human Services, Division of Public Health Services, Bureau of Population Health and Community Services, Newborn Screening Program, to accept and expend Other Funds in an amount not to exceed \$4,800 from the Trustees of Dartmouth College, effective the date of Governor and Council approval through June 30, 2017 and further authorize the funds to be allocated as follows:

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

### SFY 2016

Class/Object	Class Title	Current Modified Budget	Increase (Decrease) Amount	Revised Modified Amount
003-403177	Other-Revolving Fund Filter Paper Fee	\$1,574,067.00	\$0.00	\$1,574,067.00
005-403318	Other-Dartmouth Newborn Screening	\$0.00	\$2,400.00	\$2,400.00
Total Revenue		\$1,574,067.00	\$2,400.00	\$1,576,467.00
010-500100	Personal Serv - Perm	\$63,526.00	\$0.00	\$63,526.00
018-500106	Overtime	\$1.00	\$0.00	\$1.00
020-500200	Current Expense	\$22,766.00	\$1,200.00	\$23,966.00

Contracts for Program Services	\$8,591.00 \$1,345,690.00	\$0.00 \$0.00	\$8,591.00 \$1,345,690.00
Out of State Traver	\$8,591.00	\$0.00	\$8.591.00
Out of State Terret	00 504 00		
In State Travel	\$1,631.00	\$0.00	\$1,631.00
Employee Training	\$400.00	\$1,200.00	\$1,600.00
<del></del>	\$57,879.00	\$0.00	\$57,879.00
	\$48,253.00	\$0.00	\$48,253.00
	\$18,500.00	\$0.00	\$18,500.00
	\$565.00	\$0.00	\$565.00
<del> </del>	\$5,615.00	\$0.00	\$5,615.00
	\$650.00	\$0.00	\$650.00
	Organizational Dues Equipment Telecommunications Consultants Personal Serv - Temp Benefits Employee Training In State Travel Out of State Travel	Equipment       \$5,615.00         Telecommunications       \$565.00         Consultants       \$18,500.00         Personal Serv - Temp       \$48,253.00         Benefits       \$57,879.00         Employee Training       \$400.00         In State Travel       \$1,631.00	Equipment         \$5,615.00         \$0.00           Telecommunications         \$565.00         \$0.00           Consultants         \$18,500.00         \$0.00           Personal Serv - Temp         \$48,253.00         \$0.00           Benefits         \$57,879.00         \$0.00           Employee Training         \$400.00         \$1,200.00           In State Travel         \$1,631.00         \$0.00

### SFY17

Class/Object	Class Title	Current Modified Budget	Increase (Decrease) Amount	Revised Modified Amount
003-403177	Other-Revolving Fund Filter Paper Fee	\$993,154.00	\$0.00	\$993,154.00
005-403318	Other-Dartmouth Newborn Screening	\$0.00	\$2,400.00	\$2,400.00
Total Revenue		\$993,154.00	\$2,400:00	\$995,554.00
010-500100	Personal Serv - Perm	\$58,909.00	\$0.00	\$58,909.00
018-500106	Overtime	\$1.00	\$0.00	\$1.00
020-500200	Current Expense	\$12,349.00	\$1,200.00	\$13,549.00
026-500251	Organizational Dues	\$500.00	\$0.00	\$500.00
030-500310	Equipment	\$480.00	\$0.00	\$480.00
039-500188	Telecommunications	\$550.00	\$0.00	\$550.00
046-500462	Consultants	\$18,500.00	\$0.00	\$18,500.00
050-500109	Personal Serv - Temp	\$28,608.00	\$0.00	\$28,608.00
060-500602	Benefits	\$22,520.00	\$0.00	\$22,520.00
066-500545	Employee Training	\$100.00	\$1,200.00	\$1,300.00
070-500704	In State Travel	\$637.00	\$0.00	\$637.00
080-500710	Out of State Travel	\$5,000.00	\$0.00	\$5,000.00
102-500731	Contracts for Program Services	\$845,000.00	\$0.00	\$845,000.00
Total Expenses		\$993,154.00	\$2,400.00	\$995,554.00

### **EXPLANATION**

Other Funds received after State Fiscal Year 2017 will be included in the Operating Budgets for State Fiscal Years 2018 and 2019.

Her Excellency, Governor Margaret Wood Hassan and the Honorable Council Page 3

The purpose of this agreement is to allow Trustees of Dartmouth College's Geisel School of Medicine at Dartmouth, Section of Biostatistics and Epidemiology, Children's Center for Environmental Health and Disease Prevention to research the impact of environmental contaminants on children's health. To enable the research, the Trustees of Dartmouth College will be provided Dried Blood Spot Cards (also known as Guthrie Cards) of infants born in New Hampshire. The Guthrie Cards will be provided only after parental consent is granted and in such a manner as to ensure that all health, personal, confidential and other identifying information of each infant is protected.

Since the 1965 establishment of RSA 132:10a, Protection For Maternity and Infancy, Newborn Screening Tests Required; Newborn Screening Advisory Committee, the State has been responsible for screening of all infants born in New Hampshire. The goal of newborn screening is the prevention of disability and untimely death of newborns from undiagnosed genetic disorders. New Hampshire is currently screening all infants born in the State for a panel of thirty-four (34) disorders. Although some of these disorders are relatively rare, they need to be identified and intervention initiated before the disorder presents clinically. In some cases the critical timeline for a positive outcome may be as short as one week. In 2014, the New Hampshire Newborn Screening Program identified eighteen (18) infants with disorders requiring treatment and ongoing specialty evaluation. In 2013 the program identified twenty-five (25) infants with disorders. Newborn screening results in early identification of disorders for which timely diagnosis and treatment can mean a life without disability. The Program has had a very positive impact on infants and their families.

This agreement will advance the understanding of the impact of environmental contaminants on children's health. The partnership between the Division of Public Health Services and the Children's Center for Environmental Health and Disease Prevention will provide data about the presence and impact of toxicants, such as arsenic, in food and drinking water on our very youngest residents that may impact lifelong health.

Should Governor and Council not approve this request the State will lose the opportunity to better understand the impact of environmental exposures, such as arsenic, on the incidence of birth defects and newborn metabolic conditions throughout the State.

The performance measure for this agreement is that upon completion of this study Trustees of Dartmouth College will provide the Division with any published reports, articles or written proceedings resulting from activities of the New England Newborn Screening Program.

Funds under this agreement are intended to offset expenditures in Class 020 (Current Expense) for Newborn Screening expenses related to this project, and Class 066 (Employee Training) will be used for conferences and workshops awarding CEU's for employee licensure requirements.

These funds may not be used to offset General Funds as they are specifically granted to the State for the Newborn Screening Program for the purpose of providing the services described above.

These funds will not change the program eligibility levels. No new program will be established with the acceptance of these funds.

Area served: statewide.

Her Excellency, Governor Margaret Wood Hassan and the Honorable Council Page 4

Source of Funds: 100% Other Funds (Dried Blood Spot Specimen Card Fees), from Trustees of Dartmouth College.

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

Respectfully submitted,

Marcella J. Bobinsky, MPH

**Acting Director** 

Approved by \

Nicholas A. Toumpas

Commissioner

### **CONTRACT AND DATA USE AGREEMENT**

This Data Use Agreement ("Agreement") is made and entered into as of this day of day of 2015, by and between the New Hampshire Department of Health and Human Services, Division of Public Health Services (the "Department"), and the Trustees of Dartmouth College on behalf of the Geisel School of Medicine at Dartmouth, Section of Biostatistics and Epidemiology, Children's Center for Environmental Health and Disease Prevention ("Data Recipient").

### **PURPOSE OF THIS AGREEMENT:**

The Data Recipient shall have the right to use all Dried Blood Spot (DBS) Specimen cards provided to it by the Department for the Research, Public Health or Health Care Operations purposes as listed below:

- 1) The purpose of this Agreement is to define the roles and responsibilities of the parties in accordance with the New Hampshire Newborn Screening rules and laws, Administrative Rule He-P 3000 and NH RSA 132:10-a.
- 2) The research of the Data Recipient will advance the understanding of how environmental contaminants impact children's health. The Data Recipient is entering into this Agreement with the Department to obtain certain Newborn Screening Program Guthrie Cards or "Dried Blood Spot" (DBS) cards in accordance with the New Hampshire Administrative Rules and laws.

The Department and Data Recipient are committed to compliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and regulations promulgated there under; and

This Agreement will outline the confidentiality obligations of the parties to ensure the integrity and confidentiality of certain information disclosed or made available to Data Recipient.

In consideration of the foregoing recitals the parties agree as follows:

### A. DEFINITIONS

Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the Privacy Rule.

- 1. <u>Individual</u> shall have the same meaning as the term "individual" in 45 CFR Sect. 164.501 of the Privacy Rule and shall include a person who qualifies as a personal representative in accordance with 45 CFR Sect. 164.502(g) of the Privacy Rule.
- Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.
- 3. <u>Protected Health Information</u> or <u>PHI</u> shall have the same meaning as the term "protected health information" in 45 CFR Sect. 164.501 of the Privacy Rule to the extent such information is created or received by Data Recipient from Covered Entity.

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4. Required by Law shall have the same meaning as the term "required by law" in 45 CFR Sect. 164.501 of the Privacy Rule.

### B. SCOPE AND PURPOSE

- This Agreement sets forth the terms and conditions pursuant to which the Department will disclose certain Dried Blood Spot (DBS) Specimen Cards to the Data Recipient.
- 2. Except as otherwise specified herein, Data Recipient may make all legal uses and disclosures of the Dried Blood Spot (DBS) Specimen Cards necessary to conduct its research of how environmental contaminants impact children's health.

### C. OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT

- The Data Recipient shall obtain informed, written consent from the parent or legal guardian of each infant enrolled in the study in order to obtain that infant's DBS card, which is maintained by the New England Newborn Screening Program, University of Massachusetts Medical School. The consent will allow the Data Recipient to obtain the DBS card prior to the expiration of the 6-month period that the New England Newborn Screening Program, University of Massachusetts Medical School is required to maintain the card. The Data Recipient shall notify the Department within 5 business days if a parent rescinds his/her consent.
- 2. The Data Recipient shall provide the Department with a copy of the signed consent form indicating parental permission to obtain the DBS card, infant unique study identification number, infant name, infant date of birth, hospital of birth, and mother's name, including maiden name. This information, to be provided monthly, in the 5th month following the birth of the infant, will allow the Department to link the participating infant's information to the Guthrie number and make the request for the DBS card from the New England Newborn Screening Program.
- 3. Upon receiving the DBS card from the New England Newborn Screening Program, the Data Recipient shall coordinate with the Department to determine the Guthrie number for each infant. The Data Recipient will conduct analyses, as provided for in the consent form and as approved by Internal Review Board. The Data Recipient shall return the DBS card to the Department within 90 calendar days of receipt of the cards or within 30 calendar days of sample analysis, whichever comes first. This research has been approved by the Dartmouth Committee for the Protection of Human Subjects (see attached approval letter dated May 4, 2015).
- 4. The Data Recipient shall provide the New Hampshire Department of Health and Human Services with an electronic copy or a minimum of five (5) paper copies of any published reports, articles, or written proceedings resulting from activities of the New England Newborn Screening Program.
- 5. The Data Recipient shall provide mutually agreed-upon funds to support activities under this agreement, as follows:
  - a. To reimburse the Department for staff coordination time to: 1) make requests to the New England Newborn Screening Program; 2) link DBS card numbers to infant subjects for the Data Recipient; and 3) to coordinate with Data Recipient

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and the New England Newborn Screening Program the return and disposal of the DBS card; and

- b. It is agreed that reimbursement to the Department for these services shall be at a rate of \$10 per DBS card for the term of this Agreement.
- c. Invoicing

It is agreed that the Department shall submit quarterly billing to the attention of:

Vicki Sayarath, MPH, RD, Research Director Geisel School of Medicine at Dartmouth Section of Biostatistics & Epidemiology Department of Community & Family Medicine One Medical Center Drive, 7927 Rubin Bldg. Lebanon, New Hampshire 03756

Phone: 603-653-9013

Email: vicki.sayarath@dartmouth.edu

#### d. Payment

- 1) Payment shall be made by the Data Recipient within 30 days of receipt of acceptable invoice.
- 2) Payment shall be made payable to Treasurer, State of NH and sent to the attention of:

Cathy Liane
Contracts & Finance Section
Bureau of Public Health Systems, Policy and Performance
Division of Public Health Services
New Hampshire Department of Health and Human Services
29 Hazen Drive
Concord, NH 03301-6504

Phone: 603-271-4541

Email: <a href="mailto:cliane@dhhs.state.nh.us">cliane@dhhs.state.nh.us</a>

- 6. Data Recipient agrees to not Use or Disclose the Dried Blood Spot (DBS) Specimen Card for any purpose other than the Project or as Required by Law.
- Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Dried Blood Spot (DBS) Specimen Card other than as provided for by this Agreement.
- 8. Data Recipient agrees to report to the Department any Use or Disclosure of the Dried Blood Spot (DBS) Specimen Card not provided for by this Agreement, of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor, within ten (10) days of its discovery.
  - Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it
    provides the Dried Blood Spot (DBS) Specimen Card, agrees to the same restrictions
    and conditions that apply through this Agreement to the Data Recipient with respect to
    such information.

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- 10. Data Recipient agrees not to identify the information contained in the Dried Blood Spot (DBS) Specimen Card.
- Data Recipient will indemnify, defend and hold harmless the Department and any of the Department's affiliates, and their respective trustees, officers, directors, employees and agents from and against any claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney's fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Disclosure of the Dried Blood Spot (DBS) Specimen Card or any other breach of this Agreement by Data Recipient or any subcontractor, agent or person under Data Recipient's control.

### D. OBLIGATIONS AND ACTIVITIES OF THE DEPARTMENT

- The Department shall facilitate the requests for DBS cards for the Data Recipient upon receipt of a copy of the signed consent form and list of infant's unique study identification number, infant's name, infant date of birth, hospital of birth, and mother's name, including maiden name. The Department's coordinator will link this information to the appropriate Guthrie number.
- The Department will send a list of the Guthrie numbers to the New England Newborn Screening Program authorizing release of the cards to the Data Recipient prior to expiration of the 6-month retention period required by the New Hampshire Administrative Rules and law.
- The Department coordinator will assist the Data Recipient with linking the DBS card to the correct infant, by sending a list of Infant unique study identification numbers and the associated Guthrie numbers to the Data Recipient's point of contact for this study.
- 4. The Department's coordinator will be responsible for receiving the DBS cards from the Data Recipient and ensuring that the returned cards are destroyed according to the New Hampshire Administrative Rules and law.

### E. TERM AND TERMINATION

- The provisions of this Agreement shall be effective on the date of Governor and Council approval and shall terminate on June 30, 2019 or sooner when the study has concluded and all of the Dried Blood Spot (DBS) Specimen Cards provided by the Department to Data Recipient are destroyed or returned to the Department, or, if it is infeasible to return or destroy the Dried Blood Spot (DBS) Specimen Cards, protections are extended to such information, in accordance with the termination provisions in this Section.
- In the event that the Data Recipient determines that returning or destroying the PHI is infeasible, the Data Recipient shall provide to the Department notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of PHI is infeasible, the Data Recipient shall extend the protections of this Data Use Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Recipient maintains PHI.

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3. This Agreement may be canceled or terminated without cause at any time, subject to the restrictions and prohibits set forth herein, by providing not less than thirty (30) days prior written notice thereof to the Parties.

### F. MISCELLANEOUS

- A reference in this Agreement to a section in the Privacy Rule means the section as amended or as renumbered.
- 2. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for the Department to comply with the requirements of the Privacy Rule and any and all uses and disclosures of data not presently addressed herein.

Any notices from the Department to the Data Recipient should be sent to the attention of:

Vicki Sayarath, MPH, RD, Research Director Geisel School of Medicine at Dartmouth Section of Biostatistics & Epidemiology Department of Community & Family Medicine One Medical Center Drive, 7927 Rubin Bldg. Lebanon, New Hampshire 03756

Phone: 603-653-9013

Email: vicki.sayarath@dartmouth.edu

Any notices from the Data Recipient to the Department should be sent to the attention of:

Rhonda Siegel, MS Ed

Administrator

New Hampshire Department of Health and Human Services

Division of Public Health Services

29 Hazen Drive

Concord, New Hampshire 03301-6504

Phone: 603-271-4516

Email: rsiegel@dhhs.state.nh.us

- 3. The respective rights and obligations of Data Recipient under Section C of this Agreement shall survive termination of this Agreement.
- 4. Any ambiguity in this Agreement shall be resolved to permit the Department to comply with the Privacy Rule.
- 5. There are no intended third party beneficiaries to this Agreement. Without in any way limiting the foregoing, it is the parties' specific intent that nothing contained in this Agreement gives rise to any right or cause of action, contractual or otherwise, in or on behalf of the individuals whose PHI is Used or Disclosed pursuant to this Agreement.
- 6. No provision of this Agreement may be waived or modified except by an agreement in writing signed by the waiving or modifying party. A waiver of any term or provision shall not be construed as a waiver or modification of any other term or provision.

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- 7. The persons signing below have the right and authority to execute this Agreement and no further approvals are necessary to create a binding agreement.
- 8. In the event of any conflict between the terms and conditions stated within this Agreement and those contained within any other agreement or understanding between the parties, written, oral or implied, the terms of this Agreement shall govern. Without limiting the foregoing, no provision of any other agreement or understanding between the parties limiting the liability of Data Recipient to the Department shall apply to the breach of any covenant in this Agreement by Data Recipient.
- This Agreement shall be construed in accordance with and governed by the laws of the State of New Hampshire.
- 10. No party shall be deemed the legal representative of the other. Each party agrees to assume complete responsibility for its own employees with regard to federal or state employers liability and withholding tax, workers' compensation, social security, unemployment insurance, and Occupational Safety and Health Administration requirements and other federal, State and local laws.
- 11. In the event that any New Hampshire, or federal law hereinafter enacted (including applicable rulings of a State or federal regulatory agency) or any current law prohibits the Department from providing certain or all of the data requested by Data Recipient, then the Department shall be relieved of its obligation to provide same.

IN WITNESS WHEREOF, the parties have executed this Agreement effective upon the Effective Date set forth above.

### NH DEPARTMENT OF HEALTH AND HUMAN SERVICES

Division of Public Health Services

TRUSTEES OF DARTMOUTH COLLEGE on behalf of the Geisel School of Medicine at Dartmouth
Section of Biostatistics and Epidemiology
Children's Center for Environmental
Health and Disease Prevention Research

THE STATE

Department of Health and Human Services

The State

Signature of Authorized Representative

Marcella J. Bobinsky, MPH

Name of Authorized Representative

**Acting Director** 

Title of Authorized Representative

Date

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Center

Trustees of Dartmouth College

Name of the Data Recipient.

Signature of Authorized Representative

√Jill Mortali

Name of Authorized Representative

Director, Office of Sponsored Projects

Title of Authorized Representative

Date

Acknowledgement:	
State of New Hampshire County of Gundersigned officer, personally appeared the person whose name is signed above, and a capacity indicated above.	on 10/26/2015, before the ne person identified above, or satisfactorily proven to be the acknowledged that s/he executed this document in the
Signature of Notary Public or Justice of the HEATHER A. ARNOLD Notary Public - New Hampshire My Commission Expires Guguet 16	o, 2016
My Commission Expires:	
Approved as to form, execution and substa	nce:
	OFFICE OF THE ATTORNEY GENERAL
	By:Assistant Attorney General  Date:
I hereby certify that the foregoing constate of New Hampshire at the Meeting on:	
	OFFICE OF THE SECRETARY OF STATE
	By:
	Title:

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