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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
<b>Total Revenue</b>		<b>\$1,574,067.00</b>	<b>\$2,400.00</b>	<b>\$1,576,467.00</b>
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

026-500251	Organizational Dues	\$650.00	\$0.00	\$650.00
030-500310	Equipment	\$5,615.00	\$0.00	\$5,615.00
039-500188	Telecommunications	\$565.00	\$0.00	\$565.00
046-500462	Consultants	\$18,500.00	\$0.00	\$18,500.00
050-500109	Personal Serv - Temp	\$48,253.00	\$0.00	\$48,253.00
060-500602	Benefits	\$57,879.00	\$0.00	\$57,879.00
066-500545	Employee Training	\$400.00	\$1,200.00	\$1,600.00
070-500704	In State Travel	\$1,631.00	\$0.00	\$1,631.00
080-500710	Out of State Travel	\$8,591.00	\$0.00	\$8,591.00
102-500731	Contracts for Program Services	\$1,345,690.00	\$0.00	\$1,345,690.00
<b>Total Expenses</b>		<b>\$1,574,067.00</b>	<b>\$2,400.00</b>	<b>\$1,576,467.00</b>

**SFY17**

<b>Class/Object</b>	<b>Class Title</b>	<b>Current Modified Budget</b>	<b>Increase (Decrease) Amount</b>	<b>Revised Modified Amount</b>
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
<b>Total Revenue</b>		<b>\$993,154.00</b>	<b>\$2,400.00</b>	<b>\$995,554.00</b>
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
<b>Total Expenses</b>		<b>\$993,154.00</b>	<b>\$2,400.00</b>	<b>\$995,554.00</b>

**EXPLANATION**

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

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.

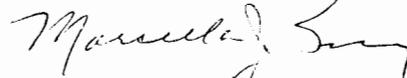
These funds will not change the program eligibility levels. No new program will be established with the acceptance of these funds.

Area served: statewide.

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

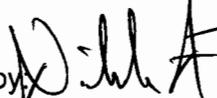
In the event that the Other Funds become no longer available, General Funds will not be requested to support this program.

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 26 day of October, 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. Individual 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.
2. 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. Protected Health Information or PHI 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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10/26/15

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**

1. 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**

1. 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](mailto: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: [cliane@dhhs.state.nh.us](mailto:cliane@dhhs.state.nh.us)

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.

7. 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.

9. 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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*10/26/15*

10. Data Recipient agrees not to identify the information contained in the Dried Blood Spot (DBS) Specimen Card.
11. 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**

1. 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.
2. 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.
3. 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**

1. 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.
2. 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

1. 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](mailto: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](mailto: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.
9. 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

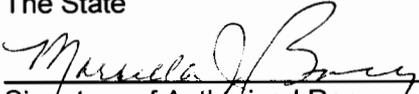
**TRUSTEES OF DARTMOUTH COLLEGE**

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 Center

**THE STATE**

**Department of Health and Human Services**

The State

  
 Signature of Authorized Representative

**Marcella J. Bobinsky, MPH**

Name of Authorized Representative

**Acting Director**

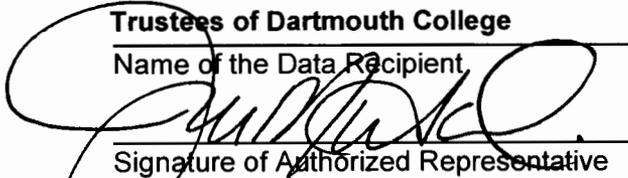
Title of Authorized Representative

11/3/15  
 Date

**DATA RECIPIENT**

**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

10/26/15  
 Date

**Acknowledgement:**

State of New Hampshire County of Grafton on 10/26/2015, before the undersigned officer, personally appeared the person identified 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.

Heather A. Arnold

Signature of Notary Public or Justice of the Peace

HEATHER A. ARNOLD

Notary Public - New Hampshire

My Commission Expires August 10, 2016

\_\_\_\_\_  
Name and Title of Notary or Justice of the Peace

My Commission Expires: \_\_\_\_\_

Approved as to form, execution and substance:

OFFICE OF THE ATTORNEY GENERAL

By: [Signature]  
Assistant Attorney General

Date: 11/25/15

I hereby certify that the foregoing contract was approved by the Governor and Council of the State of New Hampshire at the Meeting on: \_\_\_\_\_.

OFFICE OF THE SECRETARY OF STATE

By: \_\_\_\_\_

Title: \_\_\_\_\_



BOARD OF TRUSTEES

CERTIFICATE

I, Marcia J. Kelly, 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 9<sup>th</sup> 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, and November 8, 2014. The document is available on Dartmouth website at: <http://www.dartmouth.edu/~control/policies/signature-authority.html>.

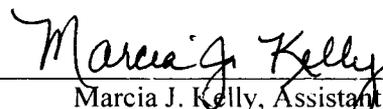
I further certify that said vote remains in full force and effect as of the date hereof and is not contrary to any provision of the Charter of said corporation.

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:

Jill Mortali	Director, Office of Sponsored Projects	September 15, 2008
Martin N. Wybourne	Vice Provost for Research	July 1, 2004
Christine Bothe	Associate Director, Office of Sponsored Projects	December 1, 2011
Aarron Clough	Assistant Director, Office of Sponsored Projects	January 1, 2013
Heather A. Arnold	Assistant Director, Office of Sponsored Projects	December 1, 2011

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of the corporation this 26<sup>th</sup> day of October, 2015.



Marcia J. Kelly, Assistant Clerk  
Trustees of Dartmouth College

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 our records show that a special corporate charter was granted to the TRUSTEES OF DARTMOUTH COLLEGE by the British Crown on December 13, 1769. I further certify that no fees are required to be paid to this office by this corporation.



IN TESTIMONY WHEREOF, I hereto set my hand and cause to be affixed the Seal of the State of New Hampshire, this 20<sup>th</sup> day of April, A.D. 2015

A handwritten signature in cursive script, appearing to read "Wm Gardner".

William M. Gardner  
Secretary of State

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

**Howard Hughes, PhD, Chair CPHS A  
Daniel O'Rourke, MD, Chair CPHS B and D  
Jack van Hoff, MD, Chair CPHS C**

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

**APPROVAL OF SUBMISSION**

May 4, 2015

Margaret Karagas  
Epidemiology

CPHS #:	STUDY00020844	Action:	Approved
Principal Investigator:	Margaret Karagas	Action Date:	5/4/2015
Submission Type:	Modification and Continuing Review	Expiration Date:	5/13/2016
Review Type	Full Committee		
Funding:	<ul style="list-style-type: none"><li>• Environmental Protection Agency (EPA)</li><li>• National Institute of Diabetes &amp; Digest &amp; Kidney Disease (NIDDK)</li><li>• National Institute of Environmental Health Sciences (NIEHS)</li><li>• National Institutes of Health (NIH)</li><li>• Harvard University</li></ul>		
Title of Study:	New Hampshire Birth Cohort Study		
Notes:	<ul style="list-style-type: none"><li>• 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 46.204.18</li><li>• CPHS previously determined that this study involving minors continues to be research not involving greater than minimal risk [45 CFR 46.404].</li></ul>		
Modification Description:	Addition of a new questionnaire (BASC 6-11) for parents of children age 6 and over. Minor revisions to current newsletters and a new newsletter, new study letters and postcards to be mailed to participants to obtain permission to review medical records, and a new lab information sheet for participants in the Concord area.		
Documents Reviewed:	<ul style="list-style-type: none"><li>• 20844Karagas_MainConsent_04302015 (5).pdf</li><li>• ReConsenting_Postcard_medrec_4.9.15.pdf</li><li>• 5 Year Blood Draw Consent_02.19.15.pdf</li><li>• 20844_Indoor_Air_Study_Consent_Form_cphs_08282014.pdf</li><li>• 20844Karagas_FocusGroup_Consent_cphs_08082013.pdf</li><li>• 5 Year Visit Consent Form_MedRecs_1.6.15.pdf</li><li>• 5 Year Visit Videotaping Consent Form__02.19.15.pdf</li></ul>		

- 5 Year Visit Consent Form\_12.30.14.pdf
- 20844Karagas\_VideotapingConsent\_cphs06172013.pdf
- 20844Karagas\_InfantBlood\_Consent\_cphs\_11282012.pdf
- Rapport\_ChildrenForm\_01202014.docx
- pregnant\_women\_form\_4\_11\_14.docx
- SocBehavNonclinical\_Research\_Plan\_4.24.15.docx
- NHBCS re-consent letter\_medrec\_4\_9\_15.docx
- NHBCS\_InitialConsentLetter\_medrec\_4\_13\_15.docx
- Patient Directions\_Concord Lab locations\_4.8.2015.docx
- NHBCS\_Newsletter\_4.8.15.pdf
- ReConsenting\_ReminderPostcard\_medrec\_4.8.15.docx
- NHBCS Newsletter for 1 year olds\_4.13.15.docx

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 and a study design in which risks to subjects are minimized.

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 5/13/2016. 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](mailto:CPHS.Tasks@Dartmouth.edu).

Sincerely,



Ann O'Hara, Assistant Director  
Committee for the Protection of Human Subjects

cc: Vicki Sayarath



8/25/2015 0:00:00

David Conway, MD  
Family Health Center  
250 Pleasant St  
Concord NH 03301

**RE: Our Study #** HIC 08-5                      **At:** Concord Hospital

Dear Dr. Conway:

**Full Board Meeting Date:** 8/25/2015    **At:** Concord Hospital

**Protocol Title:**

New Hampshire Birth Cohort Study (NHBCS)

This is to advise you that the above referenced Study has been presented at the Human Investigation Committee meeting dated above and the following action taken:

**Internal #:** 2183  
**Expiration Date:** 8/24/2016  
**On Agenda For:** Renewal  
**Reason 1:** Progress Report  
**Description:** This study is due for a 12 Month Review. The study is now closed to new enrollment. The Status Report is copied below.

**NUMBER OF SUBJECTS SCREENED:** As of 7/24/15

Local: 2737

National: 6640

**NUMBER OF SUBJECTS ENROLLED**

Local: 413 (Mothers) 415 (Children)  
National: 1014 (Mothers) 930 (Children)

**NUMBER OF WITHDRAWALS FROM THE RESEARCH:**

Local: 0                      National: 1

Reasons for withdrawals:

One subject decided to withdraw from the research study, stating that she did not want to explain her reasons for discontinuing participation.

**NUMBER AND EXPLANATION OF ANY COMPLAINTS:**

None

**SUMMARY DESCRIPTION OF SUBJECT EXPERIENCES:**

We continue to receive positive feedback from the participants regarding the study. The subjects are comfortable with the design of the study, the samples that are collected and the ongoing follow up of their children. They express interest in the fact that the research is designed to better the overall health care of both themselves and their children. We feel the subjects are pleased with their overall experience as participants in the study.

NEW INFORMATION SINCE LAST HIC REVIEW, AMENDMENTS OR UPDATES (include changes in Economic Considerations):

In this review period we met our enrollment goals for the Concord area for the New Hampshire Birth Cohort Study in January 2015. We continued to follow the enrolled women and collect samples from these women and their infants through delivery and are continuing to follow enrolled infants/children for updated information per our study protocol. We also continue activities with the Concord Hospital laboratories for collection of samples for enrolled children.

In May we opened a study office near the Concord hospital and clinics. Our trained staff are conducting neurodevelopmental, anthropometric and other assessments of study children who are turning 5 years of age.

New study staff include: Meagan Durso, Laurent Perreard and Jessica Buckey.

New medical students include: Bridget Curley and Megan Januska

Staff no longer with the study include: Stephanie Matos Jackson, Shaleen Theiler and Sarah Crist

**IRB ACTION:** Full Board Approval

The committee requires that you submit a final/termination report if the protocol is terminated prior to its Expiration Date. If you require an extension beyond the Expiration Date, you must request an extension at least one month prior to that time. In the interim, any revisions, amendments and/or updates to the protocol, or accrual closure must be reported to the HIC promptly. Unanticipated events must be reported in accordance with the "UNANTICIPATED PROBLEMS, SERIOUS ADVERSE EVENTS (SAE) & SERIOUS ADVERSE DRUG REACTIONS (SADR)". Failure to comply will be handled as investigator non-compliance. Please feel free to contact me at any time with questions or concerns.

Sincerely yours,

*Lisa A. Rocheford*

Lisa A. Rocheford, MBA, CIM  
Research & Education Coordinator  
Medical Staff Services - HIC

250 Pleasant Street Concord, New Hampshire 03301 (603)225-2711 [www.concordhospital.org](http://www.concordhospital.org)



# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)  
07/08/2015

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

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

<b>PRODUCER</b> Marsh USA Inc. 1717 Arch Street Philadelphia, PA 19103-2797  J09254-DART-CASPR-15-16	<b>CONTACT NAME:</b> PHONE (A/C, No, Ext): E-MAIL ADDRESS:	FAX (A/C, No):													
	<table border="1"> <thead> <tr> <th>INSURER(S) AFFORDING COVERAGE</th> <th>NAIC #</th> </tr> </thead> <tbody> <tr> <td>INSURER A : Pinnacle Consortium of Higher Ed VT RRRG</td> <td>11980</td> </tr> <tr> <td>INSURER B : Zurich American Insurance Company</td> <td>16535</td> </tr> <tr> <td>INSURER C : N/A</td> <td>N/A</td> </tr> <tr> <td>INSURER D :</td> <td></td> </tr> <tr> <td>INSURER E :</td> <td></td> </tr> <tr> <td>INSURER F :</td> <td></td> </tr> </tbody> </table>		INSURER(S) AFFORDING COVERAGE	NAIC #	INSURER A : Pinnacle Consortium of Higher Ed VT RRRG	11980	INSURER B : Zurich American Insurance Company	16535	INSURER C : N/A	N/A	INSURER D :		INSURER E :		INSURER F :
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INSURER D :															
INSURER E :															
INSURER F :															
<b>INSURED</b> THE TRUSTEES OF DARTMOUTH COLLEGE ATTN: CATHERINE LARK 53 S. MAIN STREET, SUITE 212 HANOVER, NH 03755															

## COVERAGES

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	<input checked="" type="checkbox"/> <b>COMMERCIAL GENERAL LIABILITY</b> <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR  GEN'L AGGREGATE LIMIT APPLIES PER: <input checked="" type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC OTHER:			PCHE2015-03	07/01/2015	07/01/2016	EACH OCCURRENCE	\$ 2,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	\$ 2,000,000
							MED EXP (Any one person)	\$ 5,000
							PERSONAL & ADV INJURY	\$ 2,000,000
							GENERAL AGGREGATE	\$ 5,000,000
							PRODUCTS - COMP/OP AGG	\$ 2,000,000
								\$
B	<input checked="" type="checkbox"/> <b>AUTOMOBILE LIABILITY</b> <input type="checkbox"/> ANY AUTO <input type="checkbox"/> ALL OWNED AUTOS <input type="checkbox"/> HIRED AUTOS <input type="checkbox"/> SCHEDULED AUTOS <input type="checkbox"/> NON-OWNED AUTOS			BAP 9267272-05 SELF-INSURED FOR PHYSICAL DAMAGE	07/01/2015	07/01/2016	COMBINED SINGLE LIMIT (Ea accident)	\$ 2,000,000
							BODILY INJURY (Per person)	\$
							BODILY INJURY (Per accident)	\$
							PROPERTY DAMAGE (Per accident)	\$
								\$
	<input type="checkbox"/> <b>UMBRELLA LIAB</b> <input type="checkbox"/> EXCESS LIAB <input type="checkbox"/> DED <input type="checkbox"/> RETENTION \$						EACH OCCURRENCE	\$
							AGGREGATE	\$
								\$
	<b>WORKERS COMPENSATION AND EMPLOYERS' LIABILITY</b> ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						PER STATUTE	
							OTH-ER	
							E L EACH ACCIDENT	\$
							E L DISEASE - EA EMPLOYEE	\$
							E L DISEASE - POLICY LIMIT	\$

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

## CERTIFICATE HOLDER

The State of New Hampshire  
Department of Health and Human Services  
129 Pleasant Street  
Concord, NH 03301

## CANCELLATION

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

AUTHORIZED REPRESENTATIVE  
of Marsh USA Inc.

Manashi Mukherjee

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# CERTIFICATE OF LIABILITY INSURANCE

7/1/2016

DATE (MM/DD/YYYY)

7/7/2015

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.

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<b>PRODUCER</b> Lockton Companies 8110 E. Union Avenue Suite 700 Denver CO 80237 (303) 414-6000	<b>CONTACT NAME:</b> <b>PHONE (A/C, No, Ext):</b>	<b>FAX (A/C, No):</b>
	<b>E-MAIL ADDRESS:</b>	
<b>INSURER(S) AFFORDING COVERAGE</b>		<b>NAIC #</b>
<b>INSURER A:</b> American Casualty Company of Reading, PA		20427
<b>INSURER B:</b> Midwest Employers Casualty Company		23612
<b>INSURER C:</b> Transportation Insurance Company		20494
<b>INSURER D:</b>		
<b>INSURER E:</b>		
<b>INSURER F:</b>		

**COVERAGES** DARCO02      **CERTIFICATE NUMBER:** 13565662      **REVISION NUMBER:** XXXXXXXX

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
	<b>COMMERCIAL GENERAL LIABILITY</b> <input type="checkbox"/> CLAIMS-MADE <input type="checkbox"/> OCCUR  GEN'L AGGREGATE LIMIT APPLIES PER: <input type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC OTHER:			NOT APPLICABLE			EACH OCCURRENCE \$ XXXXXXXX DAMAGE TO RENTED PREMISES (Ea occurrence) \$ XXXXXXXX MED EXP (Any one person) \$ XXXXXXXX PERSONAL & ADV INJURY \$ XXXXXXXX GENERAL AGGREGATE \$ XXXXXXXX PRODUCTS - COMP/OP AGG \$ XXXXXXXX \$
	<b>AUTOMOBILE LIABILITY</b> <input type="checkbox"/> ANY AUTO <input type="checkbox"/> ALL OWNED AUTOS <input type="checkbox"/> SCHEDULED AUTOS <input type="checkbox"/> HIRED AUTOS <input type="checkbox"/> NON-OWNED AUTOS			NOT APPLICABLE			COMBINED SINGLE LIMIT (Ea accident) \$ XXXXXXXX BODILY INJURY (Per person) \$ XXXXXXXX BODILY INJURY (Per accident) \$ XXXXXXXX PROPERTY DAMAGE (Per accident) \$ XXXXXXXX \$ XXXXXXXX
	<b>UMBRELLA LIAB</b> <input type="checkbox"/> OCCUR <b>EXCESS LIAB</b> <input type="checkbox"/> CLAIMS-MADE DED    RETENTION \$			NOT APPLICABLE			EACH OCCURRENCE \$ XXXXXXXX AGGREGATE \$ XXXXXXXX \$ XXXXXXXX
A C	<b>WORKERS COMPENSATION AND EMPLOYERS' LIABILITY</b> ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y/N	N/A	2099375438 (AOS) 2099375472 (CA)	7/1/2015 7/1/2015	7/1/2016 7/1/2016	<input checked="" type="checkbox"/> PER STATUTE <input type="checkbox"/> OTH-ER E.L. EACH ACCIDENT \$ 1,000,000 E.L. DISEASE - EA EMPLOYEE \$ 1,000,000 E.L. DISEASE - POLICY LIMIT \$ 1,000,000
B	Excess Work Comp	N	N	EWC008364	7/1/2015	7/1/2016	WC - Statutory; EL Limit \$1,000,000

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

**CERTIFICATE HOLDER**

13565662  
 NH DHHS  
 129 Pleasant St.  
 Concord, NH 03301

**CANCELLATION**

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AUTHORIZED REPRESENTATIVE

*Charles M. McDaniel*

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