40

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

NH DIVISION OF Public Health Services
Improving health, preventing disease, reducing costs for all

Nicholas A. Toumpas
Commissioner

José Thier Montero
Director

January 7, 2013

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 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 termination of the research study. The vendor will pay for the use of Dried Blood Spot Specimen cards up to $3,500.00 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.

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 $1,750.00 from the Trustees of Dartmouth College, effective date of Governor and Council approval through June 30, 2013 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 100% Other

SFY 2013

Class/Object	Class Title	Current Modified Budget	Increase (Decrease) Amount	Revised Modified Amount
003-403177	Revolving Funds-Filter Paper Fees	926,062.00	1,750.00	927,812.00
Total Revenue		$926,062.00	$1,750.00	$927,812.00
010-500100	Personal Services	56,097.00	0.00	56,097.00
020-500200	Current Expense	12,958.00	1,750.00	14,708.00
026-500251	Organizational Dues	300.00	0.00	300.00
030-500310	Equipment	1,000.00	0.00	1,000.00
060-500602	Benefits	26,203.00	0.00	26,203.00
066-500544	Employee Training	100.00	0.00	100.00

070-500704	In State Travel	656.00	0.00	656.00
080-500710	Out of State Travel	3,154.00	0.00	3,154.00
102-500731	Contracts for Program Services	825,594.00	0.00	825,594.00
Total Expenses		$926,062.00	$1,750.00	$927,812.00

EXPLANATION

Other Funds received after State Fiscal Year 2013 will be included in the Operating Budgets for State Fiscal Years 2014 and 2015.

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 Trustees of Dartmouth College will be provided the 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. The Guthrie Cards that will be provided Trustees of Dartmouth College will not contain any confidential information that could be associated with any one infant.

Since the establishment of RSA 132:10a, Protection For Maternity and Infancy, Newborn Screening Tests Required; Newborn Screening Advisory Committee, in 1965 the State has been responsible for the 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-three (33) 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 2010, the New Hampshire Newborn Screening Program identified eighteen (18) infants with disorders requiring treatment and ongoing specialty evaluation. In 2009 the program identified twenty-seven (27) 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 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.

Trustees of Dartmouth College will reimburse the Department at a rate of ten dollars ($10.00) per Dried Blood Spot card for an estimated 350 cards, up to three thousand five hundred dollars ($3,500.00) for the term of this agreement. Upon completion of the research study , this agreement shall terminate. It is anticipated that this agreement will terminate in State Fiscal Year 2014 or 2015.

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 will be used to offset expenditures in Class 020 (Current Expense) for Newborn Screening expenses related to this project.

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,

for

José Thier Montero, MD
Director

Approved by:

Nicholas A. Toumpas
Commissioner

BA/sc

CONTRACT AND DATA USE AGREEMENT

This Data Use Agreement ("Agreement") is made and entered into as of this 17th day of December, 2012 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.

Data Recipient Initials: cb
Date: 12/17/12

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.

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 Concord Hospital Internal Review Board (see attached approval letter dated 2.28.12) and Dartmouth Committee for the Protection of Human Subjects.**

Data Recipient Initials: cb
Date: 12/17/12

4. The Data Receipient 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 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 an estimated 350 cards for the duration of this phase of the project, up to $3,500 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: cliane@dhhs.state.nh.us

Data Recipient Initials: cb
Date: 12/17/12

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.

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.

Data Recipient Initials: cb
Date: 12/17/12

E. TERM AND TERMINATION

1. The provisions of this Agreement shall be effective on the date of Governor and Council approval and shall terminate 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.

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

Any notices from the Data Recipient to the Department should be sent to the attention of:
Patricia Tilley, MS Ed
Administrator
New Hampshire Department of Health and Human Services

Data Recipient Initials: cb
Date: 12/17/12

Division of Public Health Services
29 Hazen Drive
Concord, New Hampshire 03301-6504
Phone: 603-271-4526
Email: ptilley@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.

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.

Data Recipient Initials: cb
Date: 12/17/12

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

Lisa L for
José Thier Montero
Director

12/21/12
Date

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
DATA RECIPIENT

Christine Bothe
Name: Christine Bothe
Title: Associate Director
Office of Sponsored Projects
12/17/12
Date

Approved as to form, execution and substance:

OFFICE OF THE ATTORNEY GENERAL

Jeanne P. Herrick
By: Jeanne P. Herrick
Assistant Attorney General

Date: 31 DEC. 2012

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:_____

STATE OF NEW HAMPSHIRE
COUNTY OF Grafton

On this the 17th day of December 2012, before me, Renee Brown, *(name of notary)* the undersigned officer, Christine Bothe *(contract signatory)* personally appeared who acknowledged him/herself to be the Associate Director, OSP *(signatory's title)* of the Trustees of Dartmouth College *(legal name of agency)* a corporation, and that he/she, as such Associate Director, OSP *(signatory's title)*, being authorized so to do, executed the foregoing instrument for the purposes therein contained, by signing the name of the corporation by him/herself as Associate Director *(signatory's title)* of the Trustees of Dartmouth College *(legal name of agency)*

In witness whereof I hereunto set my hand and official seal.

Renee Y Brown
Notary Public/Justice of the Peace

My Commission expires: RENEE Y. BROWN, Commissioner of Deeds My Commission Expires May 21, 2013

Approved as to form, execution and substance:

OFFICE OF THE ATTORNEY GENERAL

By:_____
Assistant Attorney General

Date:_____

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:_____

Dartmouth College HANOVER • NEW HAMPSHIRE • 03755

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 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 vote remains in full force and effect as of the date hereof and are 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
Kathryn Page	Associate Director, Office of Sponsored Projects	July 1, 2001
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 17th day of December, 2012.

Marcia J. Kelly

Marcia J. Kelly, Assistant Clerk
Trustees of Dartmouth College

Trustees of Dartmouth College • Dartmouth-Hitchcock Medical Center

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

Vijay Thadani, MD, PhD, Chair CPHS A, B and D
Howard Hughes, PhD, Chair CPHS C

63 South Main Street • HB 6254 • Hanover, NH 03755-1404
Telephone (603) 646-6482 • Fax (603) 646-9141

Date:	07/06/10	**Submission:**	Renewal/Revision
To:	Margaret Karagas, PhD	**Action:**	Approved
Department:	Community & Family Medicine	**Action Date:**	07/01/10
From:	The Committee for the Protection of Human Subjects	**Expiration Date:**	06/30/11
CPHS #:	20844	**Review Type:**	Full Committee
Study:	New Hampshire Birth Cohort Study - Pilot Project		

Comments: Revision:
- Sponsor Protocol v. 6/11/10
- CPHS Study Plan v. 6/11/10
- Addition of Co-Investigator: Tracy Punshon
- Updated study documents
- Consent form v. 6/9/10, stamped with CPHS approval date 7/1/2010

Thank you for sending renewal information for the above referenced research study. The Committee for the Protection of Human Subjects (CPHS) has **approved the renewal/revision** of this continuing research project. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized.

Please be reminded that 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.

Date Stamped CPHS Consent Form:
The CPHS "date stamps" final approved consent form(s). The stamped approved consent form accompanies this approval letter. Please photocopy and use only the CPHS date stamped consent form for this project.

Any revision to previously approved materials must be approved by the CPHS prior to initiation. Please use the Revisions or Addition Review form for this procedure.

Unanticipated problems involving risks to subjects or others as well as certain adverse drug events and medical device effects should be promptly reported to the CPHS. Please refer to the information and forms to make these reports on the CPHS web site at www.Dartmouth.edu/~cphs. In addition, please promptly report to the CPHS office any known instances of noncompliance and complaints made by subjects in connection with this study.

Based on the risks, this project requires Continuing Review by the CPHS on an annual basis.

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

Sincerely,

Susan Adams
CPHS Director (Designee for Chair, CPHS D)

CONCORD HOSPITAL

2/28/2012 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: 2/28/2012 **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 #: 1563
Expiration Date: 11/21/2012
On Agenda For: Procedure
Reason 1: Modification
Description: A change has been made for additional sample collection and use. The Status Report and summary of changes are copied below. The revised Informed Consent has been posted on the Bridge.
NUMBER OF SUBJECTS SCREENED:Local: 1346 National: 2729

NUMBER OF SUBJECTS ENROLLED: Local: 415 National: 701

NUMBER OF WITHDRAWALS FROM THE RESEARCH
Local: 3 National: 6

Reasons for withdrawals:
Local: Fetal demise 1, No reason given 2
National: Too anxious with pregnancy 1,
Family/friends did not support participation 1,
Lab services took too long 1,
Infant passed away 1,
No reason given - 2

NUMBER AND EXPLANATION OF ANY COMPLAINTS: N/A

SUMMARY DESCRIPTION OF SUBJECT EXPERIENCES: N/A

TOTAL NUMBER OF ANY UNANTICIPATED OR SERIOUS ADVERSE EVENT(S) IN THIS STUDY TO DATE
None

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

We are requesting permission to obtain "blood spot" (Guthrie) cards from the New Hampshire Department of Health and Human Services (NH DHHS) at the time of expiration (6 months) for infants enrolled in our study from our participants. Per the policy of the NH DHHS, the blood spot cards will be returned to the NH DHHS and

destroyed once we have conducted our analysis

Added Information:
"Contact information for the person giving permission to obtain the cards:
Lisa Bujno, APRN
Chief, Bureau of Population Health & Community Services
Division of Public Health, NH DHHS
29 Hazen Drive
Concord, NH 03301
Phone: 603-271-4516
Email: lbujno@dhhs.state.nh.us

The NH DHHS Screening Program currently screens for the following:
Biotinidase; Congenital Adrenal Hyperplasia; Congenital Hypothyroidism; Cystic Fibrosis; Galactosemia; Hemoglobinopathies; Homocystinuria; Maple Syrup Urine Disease; Medium Chain Acyl CoA Dehydrogenase Deficiency; Phenylketonuria; Toxoplasmosis
Argininosuccinic Aciduria; Argininemia; Carnitine Uptake Defect; Carnitine Palmitoyltransferase II Deficiency; Citrullinemia I (ASA Synthetase Def); Cobalamin A,B; Glutaric Aciduria Type I; 3-Hydroxy-3 Methylglutaryl-CoA Lysase Deficiency; Hyperornithinemia Hyperammoninemia, Homocitrullinemia Syndrome; Isovaleric Acidemia; Long Chain 3-hydroxyacyl-CoA Dehydrogenase Deficiency; 3- Methylcrotonyl-CoA Carboxylase Deficiency; Methylmalonic Acidemia; Mitochondrial Acetoacetyl-CoA Thiolase Deficiency; Multiple Acyl-CoA Dehydrogenase Deficiency; Multiple Carboxylase Deficiency; Propionic Acidemia; Trifunctional Protein Deficiency; Tyrosinemia;Very Long Chain Acyl-CoA Dehydrogenase deficiency

Parents are given the option to decline but must sign a form indicating such. Release of these cards or their data is to be done only with written authorization."

We are not planning to reconsent patients, only consenting patients going forward since the cards are destroyed after 6 months anyway and would not be available (since they are destroyed) for the majority of the patients already consented.

We are also requesting permission to extend our pediatric medical record review to age 3 for children enrolled in our study.

New Documents:
Study Document--Results Notification Letter Urine v.12.6.11
Study Document -- Enrollment Information Form_Concord_10 19 11 finaStudy Protocol --
CommOutreachCard_1 Survey (v 12 01 11)

Revised Documents:
CH_NHBCS Informed Consent_01.31.12
Submission Summary_Supplement_Concord IRB_Revised_01.31.12
Research Plan Supplemental Information_Concord_01.31.12
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 and 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)" policy which can be found on the Concord Hospital Bridge under Medical Staff Info, Human Investigation Committee. 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