

[REDACTED]

Attention; Dr. Hillary Valance, MD
BC Children's Hospital
Newborn Screening Laboratory, Department of Pathology
4480 Oak Street, Room 2F27
Vancouver, BC, V6H 3V4

February 09, 2010

Dear Dr. Valance,

I am submitting a Request for Access to Records under the Freedom of Information and Protection of Privacy Act. I seek your records pertaining to;

- 1) Where blood samples obtained as part of the BC Newborn Screening Program are stored, how long blood samples are stored for and how blood samples are destroyed.
- 2) How many blood samples are currently stored and over what time period these samples were collected.
- 3) Who has access to blood samples.
- 4) Which organizations, entities or individuals outside of Canada have had access, or are able to access blood samples.
- 5) A list of all organizations, entities or individuals (excluding any individual who obtained the original blood sample) who have accessed blood samples collected (including any individual, entity or organization that has accessed blood samples for research purposes).
- 6) How many written consents (provided by the newborns parent or surrogate) are stored authorizing the collection of blood samples from newborns.

I look forward to receiving your response within the prescribed 30 days.

Regards

[REDACTED]

Cc.
Provincial Health Services Authority
President and Chief Executive Officer: Lynda Cranston, 700-1380 Burrard St.
Vancouver, B.C. V6Z 2H3

Feb 17, 2010

[REDACTED]

Dear [REDACTED]

Thank you for your letter dated February 9th 2010 requesting information on storage and use of newborn screening blood spot cards. I've responded to each of your questions below:

- 1) Where blood samples obtained as part of the BC Newborn Screening Program are stored, how long blood samples are stored for and how blood samples are destroyed

After newborn screening tests are complete, the blood spot cards are stored within the newborn screening laboratory for 2 – 3 years. Due to on-site space constraints, older cards are stored offsite at an Information Management company endorsed by the Provincial Health Service Authority (Iron Mountain storage). Standard laboratory practice is followed for the disposal of blood spot cards. As for blood samples, they are put in biohazard containers and incinerated.

- 2) How many blood samples are currently stored and over what time period these samples were collected?

Newborn screening cards dating back to 1999 are currently in storage. There are approximately 40,000 births per year. Therefore, there are approximately 800,000 blood spot cards in storage at the current time. There currently is no written policy on duration of storage. Duration of storage is an agenda item at the next Newborn screening advisory committee meeting.

- 3) Who has access to blood samples?

Only the lab director can authorize release of stored blood spot cards. In compliance with BC Children's hospital, Dept of Pathology and laboratory Medicine, Standing operating procedure (SOP) on "retention and ownership of specimens", blood samples that are collected for diagnostic purposes may be used for method development to establish normal values and ranges. This SOP also stipulates that specimens used for establishing norms and other testing must have all patient identifiers removed to ensure patient confidentiality

- 4) Which organizations, entities or individuals outside of Canada have had access, or are able to access blood samples.

4500 Oak Street, Vancouver, BC V6H 3N1
BC Children's Telephone: 604-875-2345 • Website: www.bcchildrens.ca
BC Women's Telephone: 604-875-2424 • Website: www.bcwomens.ca
Toll-Free in BC: 1-888-300-3088 (both facilities)

BC Children's Hospital and BC Women's Hospital & Health Centre, working in partnership, are academic health centres affiliated with the University of British Columbia, Simon Fraser University, the Child & Family Research Institute, and the Women's Health Research Institute.

Newborn Screening Program of British Columbia

No organizations, entities or individuals outside of Canada have access to newborn screening blood spot cards

If requested, the newborn screening laboratory will release a baby's blood spot card to the Parent(s) / Guardian.

The BC Newborn Screening Program is committed to protecting the privacy of personal information. It collects, uses and discloses personal information only as authorized under section 26 (c) of the BC Freedom of Information and Protection of Privacy Act and other legislation. We take all reasonable steps to make sure that personal information is treated confidentially, is only used for the intended purpose and is securely stored

5) A list of all organizations, entities or individuals (excluding any individual who obtained the original blood sample) who have accessed blood samples collected (including any individual, entity or organization that has accessed blood samples for research purposes).

Newborn screening blood spot cards have never and will never be released for research purposes without ethics approval (UBC Clinical Research Ethics Boards).
The Newborn screening advisory committee currently has a policy of allowing only research studies on **anonymized** blood spot cards.

Research studies conducted on stored newborn screening blood spot cards:

Investigator: Dr. Vallance, Director, Newborn screening program
CREB 06-70421: Determination of the incidence and natural history of Carnitine Palmitoyltransferase (CPT I) variant in BC
Community consultation: First Nations Health Council – written approval April 2009
Project period: 2006 - present

Investigator: Dr. T. Oberlander
Dept of Pediatrics, BC Children's Hospital
Pilot study of developmental neurogenomic factors in archived dried blood spots.
▼ Project period: Start date: November 1 2007 End Date: December 31 2008

6) How many written consents (provided by the newborns parent or surrogate) are stored authorizing the collection of blood samples from newborns

Written consent is not required for newborn screening. However, newborn screening is not mandated. An opt out process, "informed refusal", is available for those parents who wish to decline screening for their baby.

Newborn Screening Program of British Columbia

The newborn screening program informs parents and families on the benefits of newborn screening through an information pamphlet which can be accessed on the newborns screening website (www.newbornscreeningbc.ca).

Health care providers are encouraged to share information about newborn screening during the 3rd trimester (prior to delivery). In addition, birthing hospitals are encouraged to provide information during admission for delivery.

Sincerely,



Hilary Vallance MD, FRCPC, FCCMG
Clinical Professor, University of British Columbia
Director, Newborn Screening Program of BC and Yukon
Children's & Women's Health Center of B.C.
4480 Oak Street, Rm 2F22
Vancouver, BC V6H 3V4
Email: hvallance@cw.bc.ca

[REDACTED]

Attention; Dr. Hillary Vallance, MD
BC Children's Hospital
Newborn Screening Laboratory, Department of Pathology
4480 Oak Street, Room 2F27
Vancouver, BC, V6H 3V4

February 23, 2010

Dear Dr. Vallance,

Thank you for your letter dated February 17, 2010.

Further to the responses given in the aforementioned letter, please clarify the following;

- 1) Under which circumstances could law enforcement agencies or other governmental agencies sequester blood spot cards or related genetic information?
- 2) How are individual blood spot cards tracked and accounted for?
- 3) Are any identifiable details stored with the blood spot cards e.g. name / care card number / date of birth / address / physician?
- 3) Which individuals or entities have the authority to requisition stored blood spot cards from Iron Mountain information management?
- 4) Why are the blood spot cards stored in an off-site location as opposed to being incinerated?
- 5) Have any government agencies, departments or law enforcement agencies made enquiries, tentative or otherwise, with regards to obtaining access to blood spot cards or information derived from them?

[REDACTED]

We hereby notify that the Newborn Screening Program Unit of BC and all affiliated health centre's (the "Program") does not have our consent to store the blood spot cards or blood samples ("blood spot cards") for our children, nor do we provide our consent to

allow research studies on our children's blood spot cards. To clarify and confirm, our consent was never provided, nor were we at any point advised that our children's blood spot cards would be stored after testing was completed, or made available for research studies.

We are submitting a Request for Access to Records under the Freedom of Information and Protection of Privacy Act. **We require the release and return of the blood spot cards, along with any other samples in your possession, pertaining to our children. We also require that you provide us with copies of all information and data to include but not limited to digital files, manual transcripts and any other file stored locally or remotely relating to [REDACTED] ' bloodspot screening test results and information derived from the blood samples provided.**

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

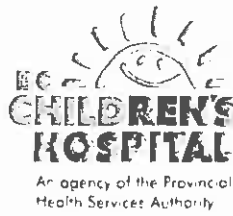
Please also confirm whether any research studies were conducted on [REDACTED] ;' blood spot cards.

Should you require any further information in order to comply with our Request for Access to Records, please contact us as soon as possible.

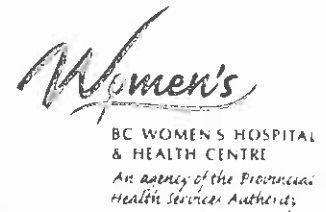
Yours faithfully,

[REDACTED] [REDACTED]

Cc.
Provincial Health Services Authority
President and Chief Executive Officer: Lynda Cranston, 700-1380 Burrard St,
Vancouver, B.C. V6Z 2H3



NEWBORN SCREENING PROGRAM OF BC
Department of Pathology and Laboratory Medicine
4480 Oak Street, Rm 2F27, Vancouver, BC V6H 3V4
Phone: 604-875-2148 or 604-875-2345 x 7444 Fax: 604-875-3836



March 18 2010

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dear [REDACTED]

Thank you for your letter dated February 23, 2010

I've responded to each of your questions below:

1) Under which circumstances could law enforcement agencies or other governmental agencies sequester blood spot cards or related genetic information?

In order to release any patient results, the individual requesting must provide their legal authority to do so. In most cases, either consent from the patient/family is required or a court order. However, certain bodies do have legislation which establishes their legal authority to access without consent or an order. For example, the coroner's act under 15(2) allows the coroner access to records for the purpose of investigation. However, if the crown is requesting, they either require consent or an order of the court.

In practice, the newborn screening program has not received such a request since I have been director (1996 - present).

2) How are individual blood spot cards tracked and accounted for?

The laboratory has a secure password-protected laboratory information system which tracks newborn screening cards by an accessioning number. Only authorized laboratory staff has access to the lab information system. Once testing is complete, the cards are stored by sequential accession number in a secure storage area.

3) Are any identifiable details stored with the blood spot cards e.g. name / care card number / date of birth / address / physician?

As you can see from the enclosed newborn screening cards on your 2 children, name,

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BC Children's Hospital and BC Women's Hospital & Health Centre, working in partnership, are academic health centres affiliated with the University of British Columbia, Simon Fraser University, the Child & Family Research Institute, and the Women's Health Research Institute.

Newborn Screening Program of British Columbia

PHN, date of birth, date of collection, hospital of birth, gender and physician / midwife name are indicated on the newborn screening cards. This information is necessary to positively identify newborns and ensure that results are reported to the correct health care provider. Birth weight, the time interval between birth and blood collection, whether the child has had a transfusion or is on total parenteral nutrition (TPN) are all pieces of information required to properly interpret newborn screening results.

3) Which individuals or entities have the authority to requisition stored blood spot cards from Iron Mountain information management?

The Medical Director and the Laboratory Scientist for the newborn screening laboratory have the authority to request newborn screening cards to be returned to the newborn screening laboratory.

4) Why are the blood spot cards stored in an off-site location as opposed to being incinerated?

There is limited space within the newborn screening laboratory. Therefore, off-site storage is used to safely store older newborn screening cards.

The primary reason for storing the blood spot cards rather than incinerating them is for quality assurance. The stored cards are used for checking normal ranges and establishing and adjusting screening cut offs. We strive to detect all infants with the treatable metabolic disorders included on our test panel. Although test sensitivity is high, it is not 100%. For quality assurance purposes, we would want to know if we missed a case. Our quality assurance program monitors all aspects of testing to ensure that our lab processes and procedures are the best they can be.

In accordance with standard newborn screening laboratory practice, if a child who had a normal newborn screen was diagnosed during childhood with one of the conditions on our test panel, the stored card provides an opportunity to re-test. For example, one of the newborn screening tests is for a disorder called hypothyroidism (low or absent thyroid hormone). Hypothyroidism may be congenital meaning that it is present at birth or less commonly, acquired meaning that it can develop later during childhood. If an older child is diagnosed with hypothyroidism, we can go back to the newborn screening card and re-test. If the repeat test is the same as the first, we assume the child has acquired hypothyroidism. However, the repeat test could also reveal that there was a problem with the first test.

5) Have any government agencies, departments or law enforcement agencies made enquiries, tentative or otherwise, with regards to obtaining access to blood spot cards or information derived from them?

Newborn Screening Program of British Columbia

No government agencies, departments or law enforcement agencies have ever made enquiries, tentative or otherwise, with regards to obtaining access to blood spot cards or information derived from them.

6) We have enclosed the 2 newborn screening cards on your 2 children listed below. Other than the newborn screening reports, there is no other stored information on your 2 children in our laboratory.

[REDACTED]

No research studies were conducted on [REDACTED]'s blood spot cards.

Sincerely,



Hilary Vallance MD, FRCPC, FCCMG
Clinical Professor, University of British Columbia
Director, Newborn Screening Program of BC and Yukon
BC Children's and BC Women's Hospitals
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