



NSW and ACT Newborn Screening Programme

Sampling Information and Guidelines

**To be used in conjunction with the
2015 NSW Ministry of Health Policy
Directive, compliance of which is
mandatory**

**Notes for midwives, clinical nurse
educators, early childhood/community
health nurses, staff in pathology
laboratories, and other health
professionals**

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INTRODUCTION

The newborn screening test is an essential part of normal newborn care and all babies should have access to this service.

The NSW Newborn Screening Programme screens all babies born in NSW and ACT (over 100,000 babies per year), and about 120 of these are diagnosed with a serious genetic metabolic disorder.

The test is carried out on a blood sample obtained by heel prick, placed on special pre-printed filter paper and processed at the NSW Newborn Screening Programme situated at The Children's Hospital at Westmead.

Certain rare, but treatable, disorders have specific clinical indicators in the newborn baby. Newborn screening programmes allow for early diagnosis and immediate treatment by medication or diet which can prevent serious complications such as mental retardation or death, and can lead to significantly improved outcomes.

Dried blood samples collected from all newborns are tested for:-

- **Phenylketonuria (PKU)**
- **Primary Congenital Hypothyroidism (CH)**
- **Cystic Fibrosis (CF)**
- **Galactosaemia(s)**
- **Medium Chain CoA Dehydrogenase Deficiency (MCAD)**
- **More than 30 other amino acid, fatty acid and organic acid disorders**

Any other disorder recommended by the NSW Newborn Screening Advisory committee may be incorporated into the newborn screening programme as a pilot study.

(See Attachment 1 - Specific problems that can occur with each disorder)

DISORDER	START DATE	INCIDENCE
Phenylketonuria (PKU)	1964	1:10,000
Hypothyroidism (CH)	1977	1: 2,500
Cystic Fibrosis (CF)	1981	1: 3,000
Galactosaemia	1983	1:40,000
MCAD deficiency	1998	1:15,000
> 30 rare metabolic disorders	1998	1: 4,000

*** There are about 120 babies diagnosed each year with one of these serious genetic metabolic disorders.**

Newborn screening tests are based on the analysis of biochemical markers that accumulate if the baby has one of the above disorders. The levels of these vary in the first days after birth. **The optimum time for collection is between 48 and 72 hours, so as to be sure to diagnose the disorders before the onset of any adverse effects.** False positive and negative results may occur when the sample is collected before 24 hours. (Attachment 1).

The period of hospitalisation provides the only certain opportunity for testing. If the baby is discharged before 48 hours, the sample should be collected before the baby leaves hospital, **unless** the hospital of birth has a failsafe community midwifery program.

GUIDELINE (1)

CARE OF BLANK NEWBORN SCREENING SAMPLE CARDS

The Newborn Screening cards are special pre-printed filter paper obtained from the:

NSW Newborn Screening Programme

Telephone No: (02) 9845 3659 / 9845 3255

Fax No: (02) 9845 3800

Email: newborns@chw.edu.au

Address: NSW Newborn Screening Programme
Locked Bag 2012
WENTWORTHVILLE NSW 2145

BEFORE SAMPLE COLLECTION

- Store cards in a clean, dry area.
- Store cards in the dark or normal light (not direct sunlight).
- Remove cards from an area near any type of fumes (eg: paint/varnish/glue/organic solvents – fumes may affix the blood and make testing impossible). **This is very important.**
- When handling cards, **before** or **after** the sample is taken, **DO NOT TOUCH** blood circle area (possibility of contamination).

GUIDELINE (2)

INFORMING AND GAINING CONSENT FROM PARENT/GUARDIAN

1. Informing parents/guardians about the proposed tests

- The pamphlet “Tests to protect your baby” is to be given to all parents. (Order the consumer brochure: SHPN: (NKF) 150398 – www.kidsfamilies.health.nsw.gov.au/publications).
- A shortened version of the pamphlet has been **translated into 9 languages**
- The parent educational video entitled “Newborn Screening Tests” is to be shown at antenatal classes, and /or before the newborn screening sample is taken.
Watch the video at:
<http://www.kidsfamilies.health.nsw.gov.au/3341.aspx>
- **The information** in the pamphlet and the video **MUST BE DISCUSSED** with parents, on a one to one or group basis. Information must include:
 - ▶ Conditions screened, benefits/importance of testing, test process and heel prick
 - ▶ Collection of personal information and what happens to the bloodspot after testing. Personal information is collected and stored, as for any patient record. There is no stored data about DNA except as a direct result of testing for CF and MCAD
 - ▶ Bloodspot sample cards are retained for 18 years after testing by the programme, in accordance with privacy and human tissue legislation and policy that mandates their protection. (attachment 3) After 2 years the parents can request the card to be returned to them or destroyed. All cards are destroyed after 18 years.
 - ▶ Stored identified bloodspots are not used/tested again without parent/guardian consent, except where the use of disclosure is required or authorised under law
 - ▶ Small amount of the bloodspots may be used in non-identifiable form without parent/guardian explicit consent for ethics committee approved research, normal quality control, laboratory audit, developing new tests and for family use (attachment 3)
 - ▶ Parents/guardians have rights in relation to access to cards and records
 - ▶ Test results – are usually available 1 working day after the sample is received in the programme. Individual reports are not issued for results that are within normal limits but a summary report is sent to the hospital, birthing centre or home birth midwife
 - ▶ Verbal consent / written consent

2. Gain consent from parent/guardian

Consent **must** be given by a parent/guardian prior to sample collection
Written signed consent is preferable but verbal or conduct consent is acceptable. All cards printed from 2015 have availability for signed consent.

If parent refuses, see refusal guideline and questionnaire (Attachment 4)

GUIDELINE (3)

SAMPLE COLLECTION PROCEDURE

The newborn screening sample should be taken between **48-72 hours** after birth.

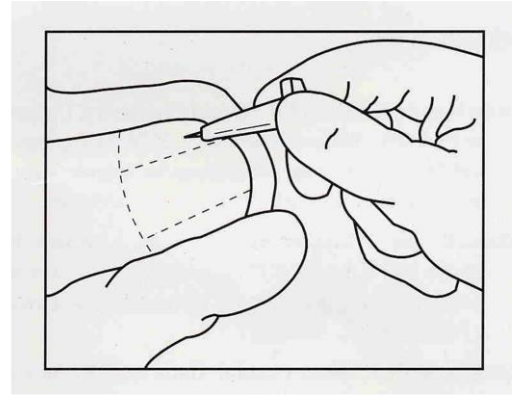
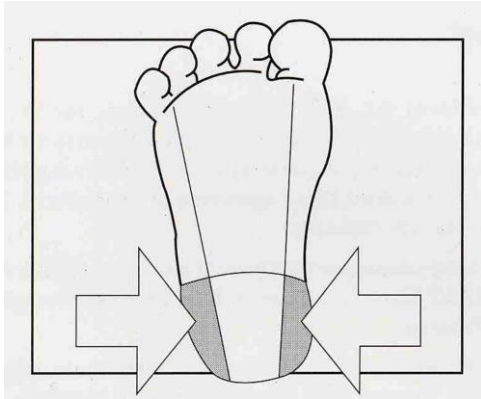
Newborn screening samples are preferably collected by heel prick, but venous or arterial samples are acceptable.

Blood should be dropped directly onto the pre-printed filter paper card. DO NOT USE lithium heparin or EDTA tubes as these anticoagulants **interfere with the test results**

DO NOT USE Vaseline, paraffin etc on the heel as this can **interfere with the test results**

- **Requirements for capillary heel prick sample:**
 - ▶ Newborn screening card
 - ▶ Gloves
 - ▶ Alcohol or sterile water, (no cleaning necessary if immediately after a bath)
 - ▶ Sterile cotton wool swabs
 - ▶ **Retractable sterile lancet** blade length <2.0mm
(lancet must comply with Health and Safety issues and must be fully retractable)
 - ▶ Baby's/mother's file and, if available, special stamp for signatures in file
 - ▶ Baby's Personal Health Record (Blue Book)

- **Warm foot** (take sample after warm bath, use booties, or warm hands). **DO NOT USE** cloths moistened with hot water
- **Place the baby's leg** lower than rest of body
- **Clean area** with alcohol swab or water, no cleaning necessary if after a bath
- **Dry area** with sterile cotton wool
- **Puncture heel firmly once** with retractable sterile lancet (point depth <2.0mm) on inner or outer border of the heel



- **Allow time** for puncture to ooze and **wipe away** first drop of blood with sterile wool swab
- **Gently massage** above puncture site to encourage blood flow and drop free flowing blood onto one side of the filter paper only
- **Completely fill** each circle. **Blood must soak through card to other side**
- **Apply gentle pressure to the puncture site until bleeding stops.** It is preferable not to use sticky plasters
- **Hold newly collected samples horizontal** for a few seconds, so the blood remains even
- **Cards should be kept horizontal and dried completely**, preferably in a drying rack designed for the purpose or laid flat with blood spots overhanging a surface so air can circulate. Drying the card takes 4 hours and should be at room temperature away from artificial heat or sunlight. The drying racks are obtainable from the NSW Newborn Screening Programme.

- **Do not layer successive drops of blood**
- **Do not squeeze heel – Squeezing causes interstitial fluid to ooze out with the blood, contaminating the sample**
- **Avoid the heel rubbing on the card**
- **Do not let card near milk formulae, antiseptic solutions, lotions, water, urine, etc**

**CONTAMINATION ADVERSELY AFFECTS THE SAMPLE
AND MAY LEAD TO A MISSED DIAGNOSIS**

GUIDELINE (4)

DOCUMENTATION OF INFORMATION

- **Use black ball point pen only – DO NOT USE pencil, ink or felt pens**
- **All information to be handwritten and legible** with family name written in capitals
- **All information to be completed.** The baby's feed (cow's-milk-based/soy-based etc) and relevant clinical information is of the utmost importance eg meconium ileus (MI), mother on thyroxine, sibling has PKU, CF, galactosaemia, congenital hypothyroidism or any other metabolic disorder. Include any family history of the above disorders and relation to the baby.

NB: It is useful to have a hospital label with the mother's/baby's information on the **BACK** of the card. However, this label must sit below the spots and not cover any signatory information. The name on the sticker must match the name hand written on the front. Alternatively, the baby's medical record number can be written on the back of the card.

- **The name of the paediatrician or doctor who is prepared to initiate follow-up of a baby** with an abnormal result **must** be written on the card, and is the doctor that the NSW Newborn Screening Programme will contact. The name of the obstetrician is **not** useful in most hospitals.
- **Document** in the mother's/baby's file that:
 - ▶ Pamphlet has been given, \pm video shown
 - ▶ Contents of pamphlet and video discussed
 - ▶ Verbal consent /written consent given
 - ▶ Newborn screening test has been completed
- **Pre-inked stamp or equivalent**, similar to example below, may be used. All parts need to be completed.

Baby's name: _____	
Signature (Health Professional)	
Provision of the NBS pamphlet: _____	Date: _____
Discussion of NBS information: _____	Date: _____
Verbal/written consent: _____	Date: _____
Completion of sample collection: _____	Date: _____

GUIDELINE (5)

SENDING SAMPLES

- **Stack the cards** for posting, alternating the direction of the cards so that the blood spots do not touch each other
- **Wrap samples together** in a sheet of plain paper or put in a paper bag – Australia Post will only transport wrapped samples in an envelope. **Approx. 6 cards will fit into a standard envelope**
- **Do NOT** place samples in any form of **plastic bags**
- **Post daily** or send by courier regularly

NEVER PUT WET SAMPLES IN A PLASTIC BAG/WRAP
because this enables bacterial growth and **INVALIDATES** test results

SEND SAMPLES DAILY

Postal Address: NSW Newborn Screening Programme
Locked Bag 2012
WENTWORTHVILLE NSW 2145

Courier Address: NSW Newborn Screening Programme
Level 1, Building 5 (Redbank Road entrance)
The Children's Hospital at Westmead
WESTMEAD NSW 2145

Telephone Contacts:

Programme Secretary	(02) 9845 3659
Programme Clinical Nurse Consultant	(02) 9845 3255
Fax:	(02) 9845 3800

SAMPLES MUST NOT BE *BATCHED* BUT:
POSTED DAILY OR
SENT BY COURIER REGULARLY

GUIDELINE (6)

REFUSALS

Parents may refuse the newborn screening test on behalf of their baby. However, the program diagnoses about 120 babies each year for which treatment is urgently needed and refusal of the test might unnecessarily risk the baby's health.

Hospitals **must develop** a protocol for parental refusal of a newborn screening test for their baby.

- **Parents must be given the pamphlet** "Tests to Protect your baby" and offered a viewing of the video "Newborn Screening Tests"
- **Parents must be properly informed** by the midwife about the test and its importance
- **IF THE TEST IS REFUSED**
 - **A Paediatrician is to re-enforce importance** of newborn screening
 - **Parents to be given the telephone number of newborn screening** and the option of speaking to a senior officer of the programme for any further information
- **IF THE TEST IS STILL REFUSED - Parents sign the hospital's disclaimer form** (suggested disclaimer form attached to this guideline – attachment 3). This form is put in baby's or mother's hospital file, copy sent to the Newborn Screening Programme
- **Complete all information** on the newborn screening card as usual, write "REFUSAL" on it and send the card to newborn screening. (This is important for legal protection of both the hospital and the programme)
- **Questionnaire** – Midwife asks the parents if they will complete a "refusal" questionnaire (attachment 4), which is to be sent with the newborn screening card to the newborn screening programme. The results of these questionnaires will be discussed in the programme, and maybe further information can be given to encourage parents to allow their babies to be screened.

GUIDELINE (7)

HOSPITAL NOMINATED NEWBORN SCREENING LIAISON PERSON:

In accordance with the 2015 Health Department Policy Directive hospitals should ensure that a **nominated person** (eg community liaison midwife, nurse unit manager of maternity etc) is responsible for newborn screening. The nominated person should have a **relief** newborn screening person for holiday/sick and other types of leave. The name and position of the nominated and relief person should be notified in writing to the NSW & ACT Newborn Screening Programme.

Responsibilities of the nominated newborn screening liaison person are:

- **Act as the contact** for NSW & ACT Newborn Screening Programme
- **Check that all babies have been offered the test**
- **Check that all babies have had samples taken**
- **Check the quality of blood samples and data on cards** before arranging for cards to be **sent daily** by post or courier
- **Contact the parents within a reasonable timeframe** when a **repeat** sample is necessary and give them the fact sheets, which are provided by the programme with the request for a repeat
- **Inform the baby's doctor** of the need and indication for the repeat
- **Ensure resample** is collected from all babies whose initial sample was <24 hours.
For these babies IT IS EXPECTED THE HOSPITAL WILL AUTOMATICALLY SEND ANOTHER SAMPLE
- **Check the confirmation report against the hospital births as soon as possible**

The following actions are to be taken as necessary:

- Contact the programme concerning any baby whose name is missing from the list and check if the sample has been received
- If a baby has missed having a sample collected, arrange collection. The reason the baby was missed should be documented in the file
- Fax or send any corrections required, such as name, date of birth, date of sample etc to the programme for update of the sample card and database

The hospital of birth is responsible for ensuring all babies are offered the newborn screening test and arrange for any repeat samples, including babies who are transferred to another hospital

GUIDELINE (8)

COMMUNITY MIDWIVES PROGRAMMES:

Apply Guidelines 1, 2, 3, 4, 5 & 6 with particular attention to the following:

After a newborn screening sample has been taken:

either

- lay card flat with the actual blood spots overhanging: ie not touching the surface of shelf etc **or**
- place horizontal in drying rack in small polystyrene insulated box. Punch holes in lid to allow for air circulation

**DO NOT PUT A FREEZER BRICK IN INSULATED BOX
DO NOT PUT SAMPLE IN PLASTIC**

The sample must **not** be left in a hot car. (The heat in the car may 'bake' the sample making the results unreliable).

The following decisions could be made:

- Take any completed cards in the insulated box into each visit
- If the parents seem reliable ask them to keep the card, wrap it, and post the next day when dry

Post or courier the sample as soon as possible

IMPORTANT NEWBORN SCREENING ISSUES

1. The hospital of birth is responsible for collection of all newborn screening samples

2. Timing of sample collection

- Recommended time is when the baby is 48 – 72 hours old. If the baby **is** discharged before 48 hours old, the test must be carried out before the baby leaves the hospital **unless** the hospital of birth has a **fail-safe community midwifery program**. The repeat sample may be collected in the community after 48 hours of age.
- When blood is collected **before 24 hours**, it is expected the hospital will **automatically** send another sample collected as soon as possible after 48 hours of age.
- If the baby is moribund, collect the sample **before** the anticipated neonatal death. This allows testing which may significantly benefit the family.

3. Babies who are at increased risk of a delayed or missed screening test include:

- Neonates transferred from one hospital to another
- Neonates who are transferred to a community midwifery program

Special care must be taken by hospitals and community programs to ensure that a sample is collected. The hospital protocol for transferring and/or receiving babies should be followed. If possible, a sample should be collected before transfer to another hospital. The receiving hospital should check if another sample needs to be collected.

As previously stated it is the hospital of birth that is responsible for all babies being offered the newborn screening test and ensuring that it is taken, including any required repeat samples.

4. Arterial Lines

A blood sample may be taken from an arterial line after a minimum of 1ml of blood has been taken prior to that used for the sample

5. Blood transfusions

- A newborn screening sample must be taken **BEFORE** any blood transfusion. If this does **not** occur, a sample should not be taken until 48 hours after the blood transfusion for most disorders. However, a repeat sample should be collected **2 weeks post** transfusion to ensure accurate results for congenital hypothyroidism. While enzyme tests to confirm galactosaemia will be invalidated after any blood

transfusion for 3 months and **DNA tests** to confirm cystic fibrosis or other metabolic disorders will be invalidated **for 6 months** after a blood transfusion.

- **Document** on the newborn screening card in “relevant clinical information”:
date and **time** of blood transfusion

6. Feeds

- Milk feeding is **not** required before a newborn screening sample is collected regardless of weight and maturity of baby, but accumulation of metabolites and interpretation of results is easier after at least one feed
- The feeding status of the baby at time of sample must be clearly stated on the card by circling the appropriate type of feed/s. It is important for the laboratory to know which type of artificial formula is being given (i.e. soy based v. animal milk based)
- TPN can alter the newborn screening results so it is essential this is marked on the card so that interpretation of the results is correct

7. Low Birth Weight Babies (≤ 1500 grams)

It is possible to miss a metabolic disorder, especially congenital hypothyroidism, in a baby whose birth weight is ≤ 1500 grams. It is expected that a repeat sample will be sent when the baby is one month old. A reminder letter will be sent **only if** a sample is not received and once it is deemed **overdue**.

8. Stillbirths / Neonatal Deaths

For completeness of records, data collection and legal purposes please return cards from:

- **Stillbirths** – complete details and mark card *stillbirth*

STILLBIRTH DEFINITION IS: The complete expulsion or extraction from its mother of a product of conception of at least **20 weeks gestation or 400 grams birth weight** who did not, at any time after delivery, **breathe or show any evidence of life such as a heart beat**.

- **Neonatal Deaths** - If the baby dies unexpectedly, complete details and mark card *neonatal death* and return to newborn screening

NEONATAL DEATH DEFINITION IS: The death of a live born infant within 28 days of birth. Collection of a newborn screening sample prior to death is required **IF** a neonatal death is anticipated.

If a sample has been collected from a baby prior to death, please state the date and time of death on the card.

9. Sample Collection Problems

- **Contamination** - any alcohol or other fluid detected on the card may adversely affect a test result. Make sure the foot is dry before puncturing the heel.

- **Layering** - Layering successive drops of blood on the same circle spot could give inaccurate test results
- **Insufficient** - allow time for a large drop of blood to form so that it soaks evenly through the card to the other side. Small drops do not soak through though they may look adequate from one side
- **Incorrect puncturing** - Puncturing the heel at sites other than the **OUTER OR INNER BORDER OF HEEL** may predispose to bony injury and infection (see diagram page 11)
- **Squeezing causes haemolysis** - Squeezing the baby's heel too hard may cause interstitial fluid to ooze out with the blood and contaminate the sample. *If blood flow diminishes and circles are not filled, repeat the puncturing technique*

10. Test Results

Results are usually available the next working day after receipt of sample.

- **Urgent Follow-Up**
The paediatrician / doctor / independent midwife shown on the newborn screening card is notified by telephone of test results which are clearly abnormal and could indicate any one of the disorders. It is the responsibility of this person to ensure that the baby is promptly referred for further investigation and treatment.
- **Retesting**
A repeat dried blood spot sample is requested in the following circumstance:
 - ▶ Slightly abnormal results, which are likely to be transient but require confirmation – a written request for resample is sent by the programme
 - ▶ Insufficient / contaminated test samples – a written request for repeat sample is sent

When blood is collected before 24 hours, it is expected the hospital will automatically send another sample collected as soon as possible after 48 hours.

11. Babies From Overseas

- **Babies arriving in Australia** up to 1 year of age, who have not had a newborn screening test in their country of birth, may be offered the newborn screening test, and results will be interpreted according to the age of the baby

SPECIFIC PROBLEMS IN SCREENING FOR EACH DISORDER

- **PHENYLKETONURIA (PKU)** can be missed if the sample is taken **before the baby is 24 hours old**. Babies with phenylketonuria have a normal phenylalanine level at birth (accumulation of phenylalanine does not occur in utero because of the mother's normal metabolism). It may be possible to miss hyperphenylalaninaemia (the mild form of PKU) if the sample is collected before 48 hours.
- **PRIMARY CONGENITAL HYPOTHYROIDISM:** There is a **thyroid stimulating hormone (TSH)** surge on day 1 and the result can be elevated if the sample is taken before day 2. Of babies tested on day 1, 2% have falsely elevated results and require a second test.
- **CYSTIC FIBROSIS (CF):** The screening protocol for cystic fibrosis involves a test for immunoreactive trypsin (IRT), with elevated results having a specific DNA test. This protocol will result in the identification of about 97% of CF cases. One to two cases of CF may be missed each year. The initial screening test is not valid if the sample is collected after 8 weeks of age, as the IRT level falls rapidly with age.
- **GALACTOSAEMIA:** Babies with classical galactosaemia **have no symptoms** in the first 48 hours. Milk feeding is **not** required before a newborn screening sample is collected regardless of weight and maturity of the baby but information on the feeds given at the time of sampling is important. It must be made clear on the card whether the baby is on a cow's-milk based (ie galactose containing) or soy-based (ie no galactose) formula. However, if a baby has suggestive symptoms and is not on milk feeds (breast/cow-based formula) and has not had a blood transfusion, the laboratory can perform an enzyme test if notified of clinical symptoms (provided the baby has not had a blood transfusion).
- **OTHER RARE METABOLIC DISORDERS:** over 30 rare metabolic disorders such as amino acid, organic acid and fatty acid oxidation defects are screened by using tandem mass spectrometry. The incidence of these three groups of disorders, excluding phenylketonuria, is 1:4,000. These are autosomal recessive disorders resulting in an enzyme deficiency (enzymes are essential for the body's metabolism). These rare metabolic disorders which can be detected by newborn screening are treatable by medically controlled diet and/or medication. Fact sheets about some of the disorders are available for health professionals.



NEWBORN SCREENING IN NEW SOUTH WALES: STORAGE OF SAMPLES

All babies in NSW and the ACT are offered testing for treatable disorders by collecting blood onto filter paper. The dried blood samples are **stored for 18 years** after the testing is completed and destroyed after the child turns 18 years. The storage is explained in the newborn screening pamphlet handed to parents, "Tests to protect your baby". It is possible for the parents to request the card be returned to them after the child is 2 years old. In the case of the parents being concerned about the storage of the card, supply them with the contact details of the NSW Newborn Screening Programme so that they may make arrangements for the return or destruction of the card once the child has turned 2 years.

The reasons for storage are:

- **For laboratory audit.** If a baby is later found to have a disorder that was missed by the newborn screening test, the laboratory needs to know what went wrong, so as to be able to rectify the problem
- **To develop new tests.** The screening programme must be able to develop new tests for treatable conditions. If there is a disorder recognised during childhood, when damage has already occurred, research can be done on the newborn screening sample to see if the disorder could have been diagnosed by a newborn test. This is the major reason why blood samples are stored in identifiable form.
- **For family use.** Some families are able to make use of stored samples. Sometimes a likely diagnosis emerges sometime after a child has died. The stored sample may be able to be used to confirm this diagnosis. This helps families come to terms with what has happened, and also may be useful for prenatal diagnosis in future pregnancies

Samples are stored securely in a locked area. Only authorised staff from the screening programme can access them. The data stored is also secured by a multiple password system. The stored data consists of very basic demographic data (as written on the front of the newborn screening card), plus the results of tests.

There is no stored data about DNA. About 1% of the samples have a test for a common change in the DNA (a mutation) associated with two of the disorders, as part of the routine testing. No DNA tests are done on the vast majority of samples, and absolutely no other DNA records are held.

No tests other than routine newborn screening tests are carried out on any identified sample without the written permission of the parents or guardian, or the child, if old enough.

There is a memorandum of understanding between NSW Police and NSW Health that samples would only be sought by police to identify remains. The police have only very occasionally requested access to samples, for identification of a deceased person, and in each case, with written permission from parents/guardians. In general it is only thought useful to access samples for forensic purposes if the subject is dead, or believed dead, and when the newborn screening card is the **only** available sample to help in identification.

The newborn screening programme complies with the Health Records and Information Privacy Act (HRIP) of 2002. These issues have been discussed with the Privacy Commissioner. It is considered that the present policy of storing samples is of benefit to the children of New South Wales and the Australian Capital Territory rather than a risk.

A/Prof Veronica Wiley, PhD, FHGSA, FFSc(RCPA)
Director, NSW and ACT Newborn Screening Programme



NSW NEWBORN SCREENING PROGRAMME
SUGGESTED DISCLAIMER FOR NEWBORN SCREENING TEST

NSW & ACT Health offers free newborn screening tests to all babies born in New South Wales and the Australian Capital Territory to detect rare metabolic disorders. A blood sample is ideally taken at 48-72 hours of age, by heel-prick, and sent to the NSW & ACT newborn screening programme. About 120 babies each year are found with one of these rare disorders, which are treatable either by diet or medications or both.

The pamphlet ‘Tests to protect your baby’ should be given to you, and a video shown to you prenatally and/or before the newborn screening sample is taken, the contents discussed and your verbal consent given. If for any reason you are reluctant to let your baby have the tests, it is important to discuss the implications with a paediatrician or telephone a senior officer of the NSW Newborn Screening Programme (Tel: (02) 9845 3255 or (02) 9845 3659) before you make your final decision.

Sign the following disclaimer if your final decision is to refuse consent for your baby to be screened.

- - - - -

We have been given the brochure "Tests to Protect Your Baby", and shown the educational video "Newborn Screening Tests", and had the information discussed.

We understand the possible risks to our baby if the newborn screening tests are not performed.

We understand that neither the hospital, and its staff, nor the NSW Newborn Screening Programme can be held responsible for any consequences suffered by our baby as a result of not being tested.

Signed:

Mother: _____ Print Name: _____

Father: _____ Print Name: _____

Witness: _____ Print Name: _____

Date: ____/____/____

Attachment 4

Questionnaire: Sample collection refusal

In order to improve our service, please take the time to complete this questionnaire.

Date ___ / ___ / ___

Your Name (Optional) _____ Baby's Hospital of birth _____

About the testing process:

Is this an initial or a repeat blood sample? Initial Repeat

Is this your... 1st child? 2nd child? 3rd child? Other _____

Did your previous children have this test? Yes how many? _____ No N/A

This Pregnancy/birth:

YES NO

Were you given the pamphlet "Tests to protect you baby"

Did the midwife explain to you: - The collection procedure

- The disorders tested

- The reasons for testing

- The reasons for storing samples

About yourself:

YES NO

Your country of birth _____ Is English your 1st language

Your age at time of baby's birth _____ years.

What is the highest level of education you have completed (Mark 1 box only)

Did not go to school Primary School Year 10 Year 12

University Other Tertiary qualification

Reason for refusal: (More than one response may be relevant)

Fear/Concern regarding the baby's heel prick

Cultural/Religious beliefs

Please specify _____

Concerns regarding storage of samples/information

Please specify _____

Previous traumatic experience

Please specify _____

Concern about identification of genetic issues eg. paternity

Insufficient information provided to make an informed decision

Do not want baby to have a second heel prick

Other ... Please specify _____

Any other comments: _____

Thank you for your participation.

Clinical Nurse Consultant Tel: (02) 9845 3255