Policy Directive

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Newborn Bloodspot Screening

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Functional Sub group Clinical/ Patient Services - Maternity
Clinical/ Patient Services - Baby and child
Clinical/ Patient Services - Nursing and Midwifery

Summary This Policy Directive provides direction to NSW maternity services regarding the requirements of the Newborn Bloodspot Screening Program. This includes the information that parents/guardians must be provided with, consent and documentation that must be gained and the privacy, storage and security of the information collected as well as the conditions screened for by staff.

Replaces Doc. No. Newborn Bloodspot Screening Policy [PD2006_099]

Author Branch Office of Kids and Families

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Applies to Local Health Districts, Board Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Community Health Centres, Public Health Units, Public Hospitals, NSW Health Pathology

Audience All clinical staff in NSW Health Maternity Services

Distributed to Public Health System, Divisions of General Practice, Government Medical Officers, Health Associations Unions, Ministry of Health, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

Review date 18-May-2021

Policy Manual Patient Matters

File No. 14/994

Status Active

Director-General

NSW GOVERNMENT Health
POLICY STATEMENT

NEWBORN BLOODSPOT SCREENING

PURPOSE

This Policy Directive provides direction to maternity services in NSW regarding the requirements of the Newborn Bloodspot Screening Program. This includes the following information: parents / guardians must be provided with information about conditions that are screened for by the Newborn Bloodspot Screening Program; the consent and documentation that must be obtained and recorded; and the requirements in relation to the privacy, storage and security of the information collected.

MANDATORY REQUIREMENTS

All parents / guardians must be provided with the consumer brochure *Newborn Bloodspot Screening* in the last four to six weeks of pregnancy.

All parents / guardians must be told about:

- What information is collected
- Storage of the blood sample
- The potential uses of the information collected
- The potential future uses of the blood sample
- The privacy and protection processes.

All parents / guardians must be provided an opportunity to ask questions about the Newborn Bloodspot Screening program.

All parents / guardians must sign the written consent component of the newborn screening card prior to the blood sample being collected.

All parents / guardians must be offered Newborn Bloodspot Screening for their baby within 48–72 hours of the baby's birth.

A newborn bloodspot screening card must be sent to the Newborn Bloodspot Screening laboratory for every baby born in NSW, even in the event that the parents/guardians have refused the screening test.

IMPLEMENTATION

The Chief Executives of NSW Local Health Districts are ultimately responsible for the implementation of this Policy Directive within their services / facilities.

REVISION HISTORY

Version	Approved by	Amendment notes
May – 2016 (PD2016_015)	Deputy Secretary, Population and Public Health	Revised Policy Directive replacing PD2006_099 All parents / guardians must provide written consent on the newborn bloodspot screening card prior to the collection of the blood sample.
November - 2006	Director-General	Revised Policy replacing PD2005_566

(PD2006_099)		
March - 2005 (PD2005_566)	Director-General	Revised Policy replacing PD2005_273
January - 2005 (PD2005_273)	Director-General	New Policy

ATTACHMENT

1. Newborn Bloodspot Screening Policy: Procedures

Newborn Bloodspot Screening

NSW GOVERNMENT Health
PROCEDURES

Issue date: May-2016

PD2016_015

CONTENTS

1 BACKGROUND

1.1 Introduction

Newborn bloodspot screening (NBS) detects babies at risk of serious disorders including phenylketonuria, primary congenital hypothyroidism, cystic fibrosis, galactosaemia and rare metabolic disorders of amino acids, organic acids and fatty acid oxidation defects. Early diagnosis and treatment by medication or diet can prevent death or serious complications and can lead to significantly improved outcomes. Among the 100,000 babies born each year in NSW and ACT, over 100 babies are diagnosed with one of these conditions.

A checklist (Appendix 1) has been developed for health professionals to ensure that parents have been provided the information at the most appropriate time about the:

- Screening tests and benefits
- Storage and potential uses of bloodspots
- Consent processes
- Legally enforceable privacy safeguards.

1.2 Key definitions

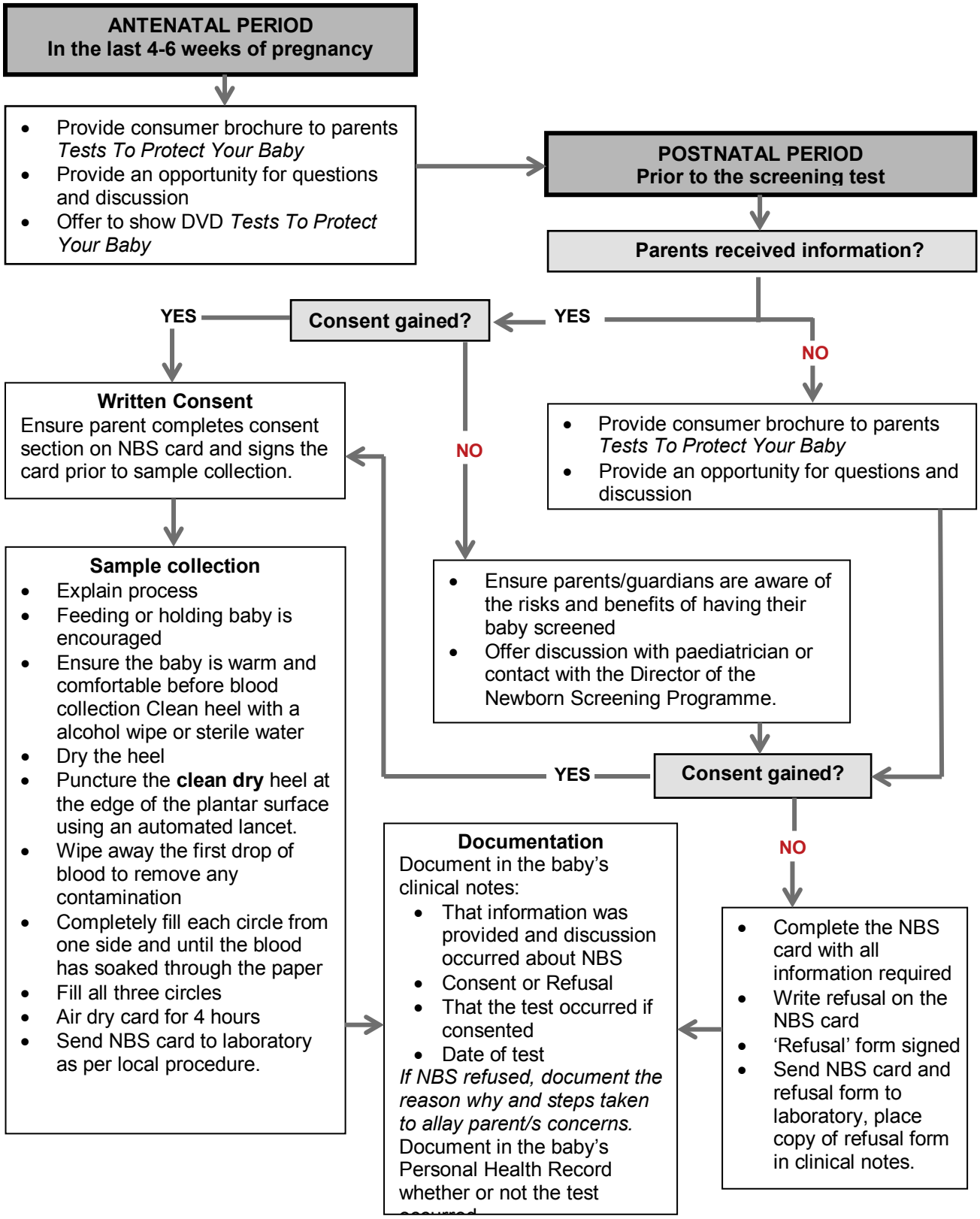
Must - Indicates a mandatory action requiring compliance.

Should - Indicates a recommended action that should be followed unless there are sound reasons for taking a different course of action.

1.3 Abbreviations

CF	Cystic Fibrosis
DNA	Deoxyribonucleic acid
LHD	Local Health District
MCAD	Medium chain acyl coenzyme A dehydrogenase
MOU	Memorandum of Understanding
NBS	Newborn Bloodspot Screening
PHO	Public Health Organisation
PKU	Phenylketonuria
PPM	Privately practising midwife

FLOWCHART: NEWBORN BLOODSPOT SCREENING PROCESS



2 INFORMATION FOR PARENTS / GUARDIANS

All information as outlined below must be provided to parents / guardians prior to the blood sample being collected.

- Parents / guardians:
  - Must be given a copy of the consumer brochure *Newborn Bloodspot Screening* in an appropriate language where possible
  - Should be offered the opportunity to watch the *NSW & ACT Newborn Screening Tests Education Video For Parents*
  - Must be told:
    - What information is collected Section 8.1
    - Storage of the blood sample Section 8.2
    - The potential uses of the health information collected Section 8.3
    - Potential future use of the blood sample Section 8.4
    - The privacy and protection processes Section 8.2
  - Must be provided with the opportunity to ask questions (discussion and questions may occur either in a group situation such as antenatal classes and / or on a one to one basis). An interpreter must be present for this discussion if required.

NOTE: The consumer brochure must not be distributed without discussion.

3 BLOODSPOT SCREENING

Newborn bloodspot screening is highly recommended for all babies. Among the 100,000 babies born each year in NSW and ACT, over 100 babies are diagnosed with one of the conditions tested for. Early diagnosis and immediate treatment by medication or diet can prevent death or serious complications including intellectual disability, and lead to significantly improved outcomes.

Therefore:

- Newborn bloodspot screening must be offered to all babies.
- Parents / guardians should be informed about newborn bloodspot screening during the last four to six weeks of their pregnancy to allow sufficient time for consideration, clarification and informed decision-making
- Prior to the blood sample being collected, the person taking the sample must:
  - Check that parents / guardians have received a copy of the consumer brochure *Newborn Bloodspot Screening*
  - That they have had opportunity for discussion and clarification
  - That they consent to the screening test
  - Cross check patient identification.

4 CONDITIONS SCREENED

The Newborn Bloodspot Screening program screens for approximately 25 medical conditions. Only a small number of babies will be diagnosed with one of the medical conditions of which the following are the more common conditions detected.

Table 2: Conditions screened for

Condition	Incidence	Caused by	If left untreated	Treatment
Primary congenital hypothyroidism:	1 in 2,600 live births (about 40 babies per year).	Absence or abnormal formation or function of the thyroid gland.	Causes growth and intellectual disability if not treated.	Medication with thyroid hormone started early results in normal growth and development.
Cystic Fibrosis (CF):	1 in 3,700 live births (about 30 babies per year).	A dysfunctional gene results in thick mucus in different organs throughout the body in particular the lungs and gastrointestinal tract.	Without treatment severe chest infections occur and often very serious failure to thrive leading to early death.	Early commencement of treatment greatly improves the health of individuals with CF.
	NOTE: Newborn bloodspot screening detects about 95% of babies with CF. Screening will also detect some babies who may only be healthy carriers. For these babies a sweat test at about six weeks of age determines whether the baby has CF or is a healthy carrier.			
Phenylketonuria (PKU):	1 in 10,000 live births (about 10 babies per year).	Inability of the body to break down the essential amino acid phenylalanine.	High blood levels of phenylalanine cause severe intellectual disability if left untreated.	A carefully managed diet low in phenylalanine, started in the first two to three weeks prevents this damage.
Medium chain acyl coenzyme A dehydrogenase (MCAD) deficiency:	1 in 15,000 births (about 6-8 babies a year).	Inability of the body to completely break down fat.	May be life-threatening or cause severe disability during times of common childhood illnesses.	Extra precautions are taken to ensure adequate energy intake during illnesses.
Galactosaemia:	1 in 40,000 births (about 1-3 babies per year).	Inability of the body to process galactose, a component of lactose found in milk and other foods.	Life-threatening liver failure and infections can occur.	A galactose-free diet commenced before 2 weeks of age is lifesaving.
Other rare metabolic disorders:	Rarer disorders that in total affect approximately 20 babies a year.	Some disorders of the metabolism of amino acids, urea cycle, organic acids and fatty acid oxidation can be detected.	Without appropriate management they can have severe disability or death.	Early detection is important as diet and medications can treat most of these disorders.
NOTE: For further information on disorders screened for please see: http://www.schn.health.nsw.gov.au/health-professionals/statewide-laboratory-services/nsw-newborn-screening-programme				

5 OBTAINING AND RECORDING OF CONSENT OR REFUSAL

5.1 Consent

Offering the screening test and obtaining consent should comply with PD2005_406 Consent to Medical Treatment – Patient Information. As the baby is a patient under the age of 14 the consent of a parent or guardian is necessary.

The following are the levels of consent required by NSW Health for the Newborn Bloodspot Screen.

Table 3: Consent	
Procedure	**Level of consent and documentation**
Obtaining newborn blood sample for screening	Verbal consent required and to be documented in the baby's clinical notes. Written consent by parent / guardian is documented on the NBS card at the time of taking the sample.
Storage of the sample for longer than 2 years	Written consent by parent / guardian is documented on the NBS card at the time of taking the sample.
Use of the sample for de-identified research	Parent / guardian indicates yes / no on NBS card at the time of taking the sample. NOTE: *Cards without consent for de-identified research will not be used for de-identified research.*
Use of the sample for identified research	Written consent from either the parent or the child (dependent on the age of the child at the time of the research) will be required prior to the research being commenced.

5.2 Processes for obtaining consent to newborn bloodspot screening

In newborn bloodspot screening, valid consent requires provision of full information about the test including information about what happens to the bloodspot sample after testing as outlined in Section 7.

Any NSW Public Health Organisation (PHO) caring for babies must ensure the following:

- Both sections on the newborn bloodspot screening card *Consent for the collection and testing of sample* and *Storage >2 years* must be completed by the parent/guardian
- The newborn bloodspot screening card must be signed by the parent /guardian
- Documentation in the baby's clinical record includes the following:
    - That discussion about the newborn bloodspot screening test has occurred
    - That the parent / guardian has consented
    - That the newborn screening test has occurred. Use of a pre-inked stamp similar to the example below is recommended.
- Documentation in the baby's Personal Health Record (PHR) "Blue Book" whether or not the newborn bloodspot screen occurred.

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:

5.3 Refusals

Parents / guardians may refuse the newborn bloodspot screening test on behalf of the baby. In this circumstance, it is suggested that parents/guardians:

- Are provided an opportunity to discuss their concerns with a paediatrician or specified health professional who is aware of all the implications of not screening
- Are offered the option of telephoning the Director of the Newborn Screening Programme to answer any further questions they may have Telephone (02) 9845 3659
- Are advised to notify their health care worker, in the event of the child requiring medical attention, that the child has not been screened.

Clinicians should undertake the following:

- Document the reason for refusal in the baby's medical record
- Complete a newborn bloodspot screening sample card, with all information completed on both sides, and write "refusal" on the card
- Send the card and the completed refusal form to the laboratory
- Retain a copy of the refusal form in the baby's clinical notes.

NOTE: PD2005_406 Consent to Medical Treatment – Patient Information provides guidance concerning refusals and care and protection of minors based on the Children and Young Persons (Care and Protection) Act 1998[1].

NOTE: A refusal form is available for use by hospitals in the NSW Newborn Screening Programme Sampling Information and Guidelines (see Section 9).

6 COLLECTING THE BLOODSPOT SAMPLE

- The process for collecting the bloodspot must be explained to parents
- A blood sample is obtained by heel prick ideally when the baby is 48 to 72 hours old
- The blood sample is placed on a special pre-printed filter paper card
    - Do not use the card if damaged

[1] NSW Children and Young Persons (Care and Protection) Act, 1998

- Do not touch the sample area.

- The heel is the preferred site to obtain the sample. In the event that a sample cannot be obtained at the heel and a venepuncture is being undertaken for other tests, this blood can be used for Newborn Bloodspot Screening. In this case clinicians should ensure that the blood obtained is not mixed with other solutions or taken from a tube containing preservative prior to placing the sample on the card. Any blood sample obtained should be placed directly onto the card before being used for other testing purposes
- Mothers / parents / guardians are encouraged to be present and hold the baby during the procedure
- To relieve discomfort for the baby, breast-feeding is encouraged or alternatively comfort measures should be provided
- Should an adverse reaction or injury occur when obtaining the blood sample, a notification should be made through the NSW Health Incident Information Management System (IIMS).

Table 4: Sample collection	
Step	**Action**
1	Ensure the baby is warm and comfortable before blood collection
2	Puncture the clean **dry** heel at the edge of the plantar surface using an automated disposable lancet (Point < 2mm)
3	Wipe away first drop of blood
4	Completely fill each circle from one side and until the blood has soaked through the paper Do NOT layer blood
5	Allow spots to dry before mailing (4 hours)
6	Return completed card **without delay** To: NSW Newborn Screening Programme Locked Bag 2012, WENTWORTHVILLE NSW 2145

6.1 Discharge prior to 48 hours of age

Arrangements must be made for the blood sample to be collected between 48 and 72 hours for all babies discharged prior to 48 hours of age.

The bloodspot sample should only be collected prior to 48 hours of age if:

- The baby is being discharged prior to 48 hours of age, and
- Availability for sample collection post discharge is compromised.

7 RESULTS

The receipt of each baby's bloodspot card is confirmed with the hospital of birth. Results are usually available within two working days after receipt of the sample. In most cases

the results are normal and no further notification is made. Hospitals are only advised of individual results when retesting is necessary.

7.1 Repeat blood test

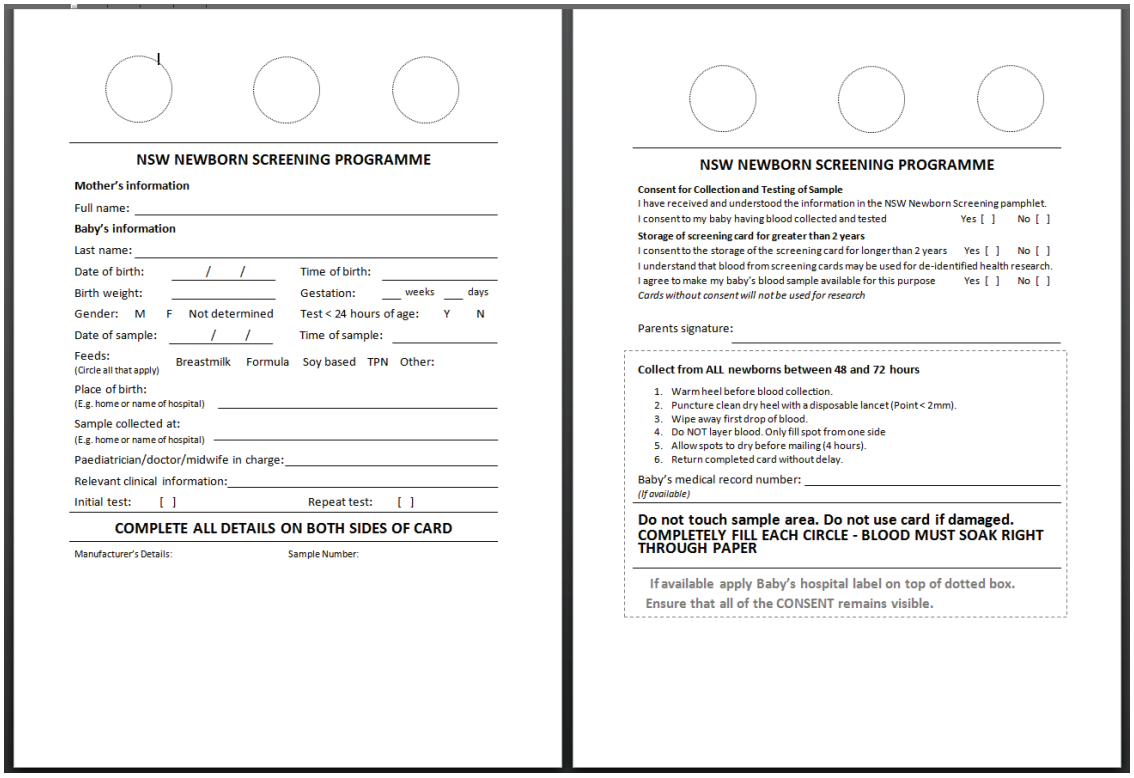
A few babies will need to have a second blood test usually because the first test did not give a clear result or the sample was unsuitable for testing. The reason for retesting should be explained to parents / guardians and most second tests will give normal results.

Routine repeat tests are required for babies with special circumstances such as those with very low birth weight and those who have received blood products as specified in the NSW and ACT Newborn Screening Programme: Sampling Information and Guideline (section 10).

7.2 Abnormal results

The paediatrician / doctor / privately practising midwife (PPM) identified on the newborn bloodspot screening card is notified of test results which are abnormal, the disorder being considered and any appropriate further samples required. It is the responsibility of this person to ensure that the baby is promptly referred for further investigation and treatment. The name of the person responsible must be filled in on the test card. Where there is uncertainty regarding whose name is to be written, it is recommended that the name be that of the paediatrician of the day.

8 NEWBORN BLOODSPOT SCREENING CARD



NSW NEWBORN SCREENING PROGRAMME

Mother's information

Full name: _____

Baby's information

Last name: _____

Date of birth: ___/___/___ Time of birth: _____

Birth weight: _____ Gestation: ___ weeks ___ days

Gender: M F Not determined Test < 24 hours of age: Y N

Date of sample: ___/___/___ Time of sample: _____

Feeds: (Circle all that apply) Breastmilk Formula Soy based TPN Other:

Place of birth: (E.g. home or name of hospital) _____

Sample collected at: (E.g. home or name of hospital) _____

Paediatrician/doctor/midwife in charge: _____

Relevant clinical information: _____

Initial test: [ ] Repeat test: [ ]

COMPLETE ALL DETAILS ON BOTH SIDES OF CARD

Manufacturer's Details: Sample Number:

NSW NEWBORN SCREENING PROGRAMME

Consent for Collection and Testing of Sample

I have received and understood the information in the NSW Newborn Screening pamphlet.

I consent to my baby having blood collected and tested Yes [ ] No [ ]

Storage of screening card for greater than 2 years

I consent to the storage of the screening card for longer than 2 years Yes [ ] No [ ]

I understand that blood from screening cards may be used for de-identified health research.

I agree to make my baby's blood sample available for this purpose Yes [ ] No [ ]

Cards without consent will not be used for research

Parents signature: _____

Collect from ALL newborns between 48 and 72 hours

1. Warm heel before blood collection.
2. Puncture clean dry heel with a disposable lancet (Point < 2mm).
3. Wipe away first drop of blood.
4. Do NOT layer blood. Only fill spot from one side
5. Allow spots to dry before mailing (4 hours).
6. Return completed card without delay.

Baby's medical record number: _____ *(if available)*

Do not touch sample area. Do not use card if damaged. COMPLETELY FILL EACH CIRCLE - BLOOD MUST SOAK RIGHT THROUGH PAPER

If available apply Baby's hospital label on top of dotted box.
Ensure that all of the CONSENT remains visible.

Newborn bloodspot screening cards are provided by the NSW Newborn Screening Programme, and used in accordance with the NSW Newborn Screening Programme Sampling Information and Guidelines. Contact details are provided in Section 9.

8.1 Information collection and process

The newborn bloodspot screening card collects written information and three bloodspots. ALL INFORMATION must be completed on the card as each field has been included for a specific purpose.
Once the heel prick process has occurred the newborn bloodspot screening card is sent to the laboratory at the NSW Newborn Screening Programme at The Children's Hospital at Westmead. The laboratory:

- Transfers the written information to an electronic record
- Tests the blood
- Retains the card containing the unused portion of the three bloodspots for a minimum of two years.

NOTE: All results are recorded in the electronic record, not on the card.

8.2 Privacy, storage, security and retention periods

8.2.1 Privacy, storage and security

The NSW Newborn Screening Programme as a NSW Health facility, is the custodian of the bloodspot cards and records. Both the electronic record and the bloodspot card are subject to the privacy protection requirements of NSW privacy legislation[2,3,4]. The bloodspot cards are stored in a secured locked area with appropriate safeguards to prevent unauthorised use, disclosure, loss or other misuse.

8.2.2 Retention of cards and data

Cards

- In accordance with National Pathology Accreditation Advisory Council requirements the laboratory must retain the cards for a minimum of 2 years for quality assurance and audit purposes
- In general the cards are retained for 18 years (age a child can legally consent for themselves)
- After this time the cards are destroyed.

Data

- In accordance with National Pathology Accreditation Advisory Council requirements the data is stored for 100 years.

[2] NSW Health Privacy Manual for Health Information as at March 2015: http://www.health.nsw.gov.au/policies/manuals/Documents/privacy-manual-for-health-information.pdf
[3] Privacy and Personal Information Protection Act, 1998
[4] Health Records and Information Privacy Act, 2002

8.2.3 Deoxyribonucleic acid (DNA) testing and data

Newborn bloodspot screening involves biochemical testing. Approximately 1% of the samples show an increased risk for cystic fibrosis and MCAD deficiency (a fatty acid oxidation disorder) from the biochemical testing. As part of routine testing these samples are then retested for the most common mutations in the DNA associated with each disorder. No DNA tests are done on any other samples and no other DNA records are held.

8.3 Potential uses of bloodspots

Stored bloodspots have a number of potential uses (Table 5). Any further use must be in compliance with privacy law, NSW Human Tissue Act[5] and the NSW Human Tissue Legislation Amendment Act 2012[6]. Potential benefits from stored bloodspots include obtaining clinical information for the child and/or the family. Whilst requests for use for this purpose are rare, the information potentially available to families is extremely valuable. Bloodspots may also be used for research to improve newborn screening techniques or develop new tests. Individual consent will be sought before research on any identified sample. However, de-identified samples may be used for ethics committee approved research with the approval of the NSW Newborn Screening Advisory Committee.

8.3.1 Table 5: Potential uses of bloodspot samples

Table 5: Potential uses of bloodspot samples	
Consent given on the card covers the following:	**SEPARATE consent other than on the card is required for the following:**
Directly related clinical purposes • Retesting to confirm result • Provide information to a person or organisation providing ongoing care to the baby.	***Clinical use for the individual and family*** • Further testing at the request of the parents or guardians that may provide medical information for the benefit of the child or family e.g. was an infection present at birth such as cytomegalovirus • Diagnostic information for future reproductive decisions.
Research using non-identifiable bloodspot samples • Samples may be released only with approval by the appropriate health research ethics committee and the NSW Newborn Screening Advisory Committee	***Research using identified bloodspot samples*** • Research requires approval from the parent/guardian, the appropriate health research ethics committee and the NSW Newborn Screening Advisory Committee.
Laboratory quality control	***Third party access*** • Access to stored samples or information by employers, insurers, police, legal representatives, other relatives or medical practitioners requires written consent of the parent/guardian (or child if of age of consent) or by court order.
Patient access	***Coronial purposes***

[5] NSW Human Tissue Act, 1983
[6] NSW Human Tissue Amendment Act, 2012

Table 5: Potential uses of bloodspot samples	
Consent given on the card covers the following:	**SEPARATE consent other than on the card is required for the following:**
• Parents/guardians on behalf of the child or the patient at adulthood have the right to access personal information held about them	• A memorandum of understanding (MOU) between NSW Health and NSW police 2002[14] sets out parameters and processes for requests for access to newborn bloodspot screening cards.
	Access for law enforcement purposes and access and disclosure authorised by law • It is possible that access to samples and disclosure of information may be required by court order.

8.4 Transfer of cards to parents / guardians

The laboratory must retain the bloodspot cards for a minimum of 2 years for quality assurance and audit purposes in accordance with National Pathology Accreditation Advisory Council requirements. Any requests from parents/guardians for the destruction or transfer of the screening cards must be made in writing and must be supported with identification.
NOTE: Destruction or transfer of a screening card can only occur after the 2 year retention period is complete.
NOTE: For further information on sample storage and laboratory practice, please see: http://www.schn.health.nsw.gov.au/health-professionals/statewide-laboratory-services/nsw-newborn-screening-programme

9 SAMPLING INFORMATION AND GUIDELINES

The NSW and ACT Newborn Screening Programme provide a guideline: *Sampling Information and Guidelines* which details procedures for:

- Storage of blank NBS cards
- Refusal of screening tests
- Collection of the blood sample for NBS
- Drying and storage of NBS cards prior to sending to laboratory
    - Hospital
    - Community
- Sending of NBS cards to laboratory
- When to take the sample if the baby needs a blood transfusion
- Low birth weight babies
- Stillbirths and neonatal deaths.

These are updated as required to incorporate new information and procedures and are supplied to hospitals / maternity units and privately practising midwives.

The Guideline is available either online at http://www.schn.health.nsw.gov.au/files/attachments/newborn_screening_guidlines_2015.pdf or from:

The NSW Newborn Screening Programme

Locked Bag 2012

WENTWORTHVILLE NSW 2145

Telephone: (02) 9845 3255 / 3659

Facsimile: (02) 9845 3800

Email: newborns@chw.edu.au

10 QUALITY ASSURANCE AND MONITORING

10.1 Role of the hospital/Local Health District (LHD)

The hospital of birth is responsible for ensuring all babies are offered the newborn screening test and arranging for any repeat samples, including those babies who have been transferred to another hospital and require a repeat sample.

Hospitals with maternity units and those who care for babies must nominate a liaison person (e.g. community liaison midwife or midwifery unit manager) to be responsible for newborn bloodspot screening. The name and position of the nominated (and relief person) should be notified in writing to *The NSW Newborn Screening Programme* (see Section 9). Responsibilities of the nominated newborn screening liaison person are detailed in The NSW and ACT Newborn Screening Programme Sampling Information and Guidelines and include the following:

- Ensuring that all parents / guardians are provided information on newborn bloodspot
- Ensuring that all babies have newborn bloodspot screening cards sent to the laboratory irrespective of whether the sample has been collected (Section 5.3)
- Ensuring that when a repeat or extra sample is requested by the laboratory that it happens in a timely manner
- Ensuring that staff are kept up to date with changes to the NSW Newborn Screening Programme Sampling Information and Guidelines.

Reports from the NSW Newborn Screening Programme are regularly provided to hospitals regarding screening samples and quality issues related to screening activities. LHDs are encouraged to ensure these reports are monitored locally to identify trends in relation to quality and compliance with this policy. Timely action must be taken when issues are identified that may adversely affect the efficacy of the screening test.

The Implementation Checklist for LHDs in relation to Newborn Bloodspot Screening is at Section 15

11 CONSUMER INFORMATION

Newborn Bloodspot Screening Consumer Brochure

For information on ordering hard copies of the consumer brochure (English only) please visit http://www.kidsfamilies.health.nsw.gov.au/publications/

The consumer brochure can also be downloaded from the Office of Kids and Families website http://www.kidsfamilies.health.nsw.gov.au/publications/tests-to-protect-your-baby-newborn-bloodspot-screening/

The consumer brochure is also available for download in Arabic, Traditional Chinese, Indonesian, Japanese, Khmer, Korean, Serbian, Turkish and Vietnamese, Thai, Bengali, Nepali, Tamil and Hindi at http://www.kidsfamilies.health.nsw.gov.au/publications/tests-to-protect-your-baby-newborn-bloodspot-screening/

NSW & ACT Newborn Screening Tests Education Video for Parents
Available to view online at http://www.schn.health.nsw.gov.au/health-professionals/statewide-laboratory-services/nsw-newborn-screening-programme

12 APPENDIX 1: CHECKLIST FOR HEALTH PROFESSIONALS

Table 3 Checklist for health professionals	
During pregnancy	Provide the consumer brochure *Newborn Bloodspot Screening* to parents preferably in the last four to six weeks of pregnancy. Provide an opportunity for discussion and questions and offer to show the DVD *NSW & ACT Newborn Screening Tests Education Video for Parents*.
After birth	Make sure that parents / guardians have been provided the consumer brochure *Tests to protect your baby.* Make sure that parents/guardians have been provided with an opportunity for discussion and questions.
Inform parents/ guardians about:	1. Conditions tested – phenylketonuria, galactosaemia, hypothyroidism, cystic fibrosis and rare metabolic disorders. 2. Benefits of testing - diagnosis and treatment can prevent death or serious disability. 3. Collection of blood sample – encourage mothers to be present and breastfeed or offer alternative comfort measures. 4. Information collected – name, date of birth, hospital, etc. 5. Bloodspot storage - minimum of 2 years and in general are stored for up to 18 years – written consent on the back of the card. 6. Bloodspots and record security – governed by privacy and human tissue legislation and Health Department policy. 7. Potential uses of, access to, and storage of bloodspot cards: • Identified cards may be used for family benefit or research and only with separate consent obtained before testing • Non-identifiable cards, i.e. with identifiers permanently removed may be used for research approved by a health research ethics committee and with the approval of the NSW Newborn Screening Advisory Committee – consent on the back of the card • Parents have a right to access their child's information. Other access requires parental consent except where there is a court order. 8. Inform the parents about how results are conveyed • Normal results • Retesting • Abnormal results.
After all the above information has been provided and discussed:	1. Record in the mother's / baby's medical record that information has been provided and discussed. 2. Obtain and document parent / guardian consent in the baby's clinical record. 3. Hospital staff are required to complete the relevant section of the baby's Personal Health Record (Blue Book). 4. If parents refuse testing, see Section 5.3 of this Policy for further guidance 5. Conduct the test following sampling guidelines provided by the NSW Newborn Screening Programme.

13 APPENDIX 2: RELEVANT DOCUMENTS

Type	Published by	Publication
Policy Directive	NSW Health	PD2005_406 Consent to Medical Treatment – Patient Information
Policy Directive	NSW Health	NSW Health Privacy Manual for Health Information as at March 2015: http://www.health.nsw.gov.au/policies/manuals/Documents/privacy-manual-for-health-information.pdf
Information Bulletin	NSW Health	General Retention and Disposal Authority – Public Health Services: Patient/ Client Records (GDA 17), NSW Department of Health Information Bulletin No 2004/20, http://www.health.nsw.gov.au/archive/cib/information-bulletins/2004/ib2004-20.pdf
Policy Directive	NSW Health	Health Care Records - Documentation and Management http://www0.health.nsw.gov.au/policies/pd/2012/pdf/PD2012_069.pdf
Legislation	NSW Act	Human Tissue ACT 1983
Legislation	NSW Act	Health Records and Information Privacy Act, 2002
Legislation	NSW Act	NSW State Records Act, 1998
Legislation	NSW Act	Privacy and Personal Information Protection Act, 1998
Legislation	NSW Act	NSW Children and Young Persons (Care and Protection) Act, 1998
Resource	Office of Kids and Families	Consumer brochure: Newborn Bloodspot Screening
Resource	Sydney Children's Hospital Network	Consumer video: NSW & ACT Newborn Screening Tests Education Video for Parents
Other Guidelines	National Health and Medical Research Council	National Statement on Ethical Conduct in Research Involving Humans, 2007 http://www.nhmrc.gov.au/guidelines/publications/e72
Other Guidelines	Australian Government, Department of Health	National Pathology Accreditation Advisory Council, Retention of laboratory records and diagnostic material.

14 IMPLEMENTATION CHECKLIST

LHD/Facility:			
Assessed by:		**Date of Assessment:**	
IMPLEMENTATION REQUIREMENTS	**Not commenced**	**Partial compliance**	**Full compliance**
1. Ensure all clinical staff working in maternity services are updated on the changes to the policy	❑	❑	❑
	Notes:		
2. Ensure all women are provided with the Consumer Brochure *Newborn Bloodspot Screening*	❑	❑	❑
	Notes:		
3. Ensure that written consent is provided by a parent/guardian prior to collection of the blood sample	❑	❑	❑
	Notes:		
4. Ensure that the name and position of the hospital-nominated newborn screening liaison person is notified in writing to the NSW Newborn Screening Programme	❑	❑	❑
	Notes:		
5. Ensure that Executive oversight for newborn screening activites occurs at facility level to ensure regular monitoring of the NSW Newborn Screening Programme reports	❑	❑	❑
	Notes:		