"GUTHRIE TESTS"

September 2003

A report by the Privacy Commissioner following his inquiry into the collection, retention, use and release of newborn metabolic screening test samples, pursuant to section 13(1)(m) of the Privacy Act 1993.

1. Introduction

1.1 In May 1999 an application was made to the High Court for a direction that Auckland Healthcare Services Ltd produce a blood sample of a child which was the subject of proceedings before the Court. At issue was a Guthrie blood test sample taken from the child and held by the National Testing Centre, a division of Auckland Healthcare Services Ltd. The Court ordered Auckland Healthcare Services Ltd to produce the blood sample card for inspection by the court and/or for the purpose of making any experiment thereon. The blood sample was tested and the father of the child subsequently made an application to the High Court in August 1999 for a declaration of paternity.

1.2 I considered there were information privacy issues as well as other issues of public policy involved in making blood samples available for genetic identification. The judgments of Justices Salmon and Morris did not traverse in detail the public policy issues. I accordingly commenced an inquiry into the collection, retention, use and disclosure of the samples to see if there appeared to be any changes which ought to be made in the law, information supplied to parents, retention of the samples and to consider the implications of the use and disclosure in civil and criminal cases of the samples or the information obtained from them.

1.3 Following is a report of that inquiry. It is my recommendation that legislation be introduced to control the storage and use of Guthrie Blood Test Sample Cards.

1.4 I was assisted in my inquiry and the writing of this report by Kristin Langdon BA LL.B NZRN and Robert Stevens, Barrister.

2. Some history

2.1 Robert Guthrie was an American physician who developed a cheap method for screening blood samples from newborn babies for the genetic condition of phenylketonuria (or "PKU"). Identifying PKU very early on permits dietary treatment, preventing the brain damage which would otherwise occur over the first 3 years of the child's life as a result of their inability to deal with a certain protein component which is in any normal diet (including breast milk and normal infant formulae). PKU is an inherited condition affecting something in the order of 1 baby in 15,000. Routine screening for PKU started in New England in 1961, and quickly spread to other areas and countries.

2.2 The screening programme using the Guthrie test for PKU employed a standard pre-printed card incorporating an absorbent paper area on to which one or more blood spots were placed. Identifying details of the baby were entered on the card in pre-printed fields at the time of taking the sample. The sample for this test was usually taken –normally by a "heel prick"- between 3 and 10 days after birth.

2.3 Many countries which had implemented a routine Guthrie test screening system later used the same collected and marked samples for conducting screening tests for other metabolic disorders. New Zealand presently has fewer than many other countries, applying seven different tests to the card-held blood samples. All of the tests are for genetic metabolic disorders. The tests themselves (apart from the confirmatory test in cystic fibrosis screening) are not tests of the DNA and do not use genetic techniques; rather they test for the presence or absence or quantity in the blood of certain organic substances which then provides a basis for an inference of the presence or absence of the genetic metabolic condition in question.

2.4 The test invented by Dr Guthrie has been replaced in many countries by a different PKU testing process. Colloquially, in many countries including New Zealand, the programme of newborn metabolic disorder screening is still called "the Guthrie test" and the sample cards still called "Guthrie cards". Properly, the programme should be called something like "routine newborn metabolic screening", and the cards referred to similarly. In this paper they will be described just as "the testing programme" and "the sample card".

2.5 In New Zealand several hospitals in large centres commenced newborn screening for Phenylketonuria in 1964-1965. In 1969 the Health Research Council provided a grant to commence newborn screening and the National Testing Centre was established at Otago Medical School. In 1973 the Centre was transferred to Auckland. It is currently located at LabPlus at Auckland Hospital. The National Testing Centre is a division of Auckland District Health Board, formerly Auckland Healthcare Services Ltd. Auckland District Health Board has a contract for service with the Ministry of Health (the Ministry) to carry out the testing for the newborn metabolic screening programme, including follow-up. Whilst I have not examined this contract, I am led to believe that it is limited in its scope to the testing function, and does not extend to the overall running of a newborn metabolic screening programme.

3 The present system in New Zealand

3.1 The testing programme is operated nationally, is voluntary but is close to universally administered, and is given without charge. It tests for 7 metabolic disorders, namely:

- Phenylketonuria (incidence approximately 1:15,000, lack of enzyme to break down phenylalanine)
- Biotinidase deficiency (incidence approximately 1:50,000, lack of enzyme required to recycle biotin)
- Congenital adrenal hyperplasia (incidence approximately 1:20,000, lack of enzyme required to produce various hormones in the adrenal cortex)
- Cystic fibrosis (incidence approximately 1:3,000, lack of a gene vital for making a protein which is needed for the body's transportation of salt)
- Galactosaemia (incidence approximately 1;50,000, lack of enzyme required to break down sugar in milk)
- Maple syrup urine disease (incidence approximately 1:250,000, lack of enzyme required to break down certain amino acids)
- Hypothyroidism (incidence approximately 1:4,500, abnormal development of the thyroid gland potentially leading to multiple developmental problems).

3.2 Under the New Zealand system for birth care, a "lead maternity carer" ("LMC") is established for every birth and this individual (who may be a midwife or a doctor) is responsible for offering the metabolic screening service, obtaining informed consent from the mother, having the sample taken, completing the sample card and sending it off to a central testing unit.

3.3 It is thought that almost 100% of babies born in New Zealand are tested in this programme. There are not infrequent accounts received by the National Testing Centre of mothers refusing the test, although there is no requirement or established practice of notifying the Centre of such refusals. However, at least for the past two years, the number of newborns tested has slightly exceeded the number of births as registered by Statistics New Zealand or by New Zealand Health Information Services.

3.4 As soon as a sample card is received at the National Testing Centre, which is located in Auckland, it is examined to ensure that the sample appears to be adequate and, if not, the lead maternity carer is advised by letter sent on the same day that the sample is received at the unit. The actual testing takes place very soon afterwards. Any positive (i.e. abnormal) results are communicated by letter (and normally a telephone message too, where the condition in question is one which justifies urgent action) sent to the LMC who sent in the sample. This communication will be usually 48 hours of the sample being received by the National Testing Centre.

3.5 The card, when received at the National Testing Centre, should have been (and almost always is) completed by the LMC with the following information:

NHI number
Surname
First name
Sex
Date of birth
Place of birth
Birth weight
Gestation age
Sample collection date and time
Over 48 hours old (yes/no)
First sample taken (yes/no)
Feeding (breast, formula or other)

Mother's surname
Mother's first name

Lead maternity carer's name
registration number
address
phone, mobile or pager number for contact

3.6 There are four printed rings on the absorbent (filter paper) panel at the top of the sample card. A blood spot should have been placed on each of the four rings. Some cards have only three blood spot samples.

3.7 There is a perforated line separating the top (sample-carrying) part of the card from the remainder of the card. Above the line is the sample-carrying absorbent panel and also preprinted lines for the baby's name and NHI number; that information is also asked for on the body (remainder) of the card.

3.8 Cards are sent to the National Testing Centre by mail. There are some delays, either in the mail service or by the LMC sending them off. The average time lag between taking the sample and its receipt at the National Testing Centre is estimated to be five and a half days, which might occasionally give cause for concern. Instructions to the LMC printed on the reverse of the sample card require the cards to be mailed "daily".

3.9 When a card is received, each part is immediately labelled with a permanently attached matching barcode sticker which denotes the date received, the batch number, and the number of the card within that batch. The barcode stickers are machine-readable. Then it is separated into its two parts at the perforation, but the batches of each part are kept physically together. The sample portion of the card will also have been marked by the LMC with the baby's surname and NHI number. The barcode sticker is an additional link to the separated remainder of the card, which contains the additional identifying information. A computer index record is also made, and results of the tests are recorded in that computer record.

3.10 Of the 55,000 or so babies tested each year, around 30 to 35 are found to be positive (after retests to make sure) for one or other of the conditions tested for. Cystic fibrosis is the most common such condition.

3.11 After testing, the cards are stored indefinitely by the National Testing Centre.

3.12 The National Testing Centre is, as explained, owned by the Auckland District Health Board and carries out for that body the functions contracted for by the Ministry of Health. The National Testing Centre has an Advisory Committee, to whom its Director looks for direction on matters legal and ethical. The Committee was apparently started under the aegis of the Department of Health when the National Testing Centre was under that body's wing. The membership of that Committee is currently Dr Pat Tuohy (chair), Dr Joanne Dixon, Dr Nigel Dickson, Dr Wayne Cutfield, The Commissioner for Children, Mr Barry Borman, Dr Bridget Wilcken, Dr Callum Wilson and Dr Dianne Webster (*ex officio*). This Committee meets on an irregular basis and has to seek funding for each meeting from the Ministry of Health through the Committee's chair, who is a senior Ministry official. The Committee has

been particularly concerned in questions of third party access to the sample cards, and questions about the extent of authority and identification of persons requesting return of the sample material.

4. Further access to and use of the samples.

4.1 There appears to be no authoritative and comprehensive statement of the uses to which the retained samples may be put, or of any finite time for which they are to be stored. The National Testing Centre considers that it adheres to an "Administration Manual" of Auckland District Health Board, dated 25 November 2002. This states as follows:

> *"Newborn screening samples are retained indefinitely for the purpose of screening program audit.*
>
> *Samples retained by the screening program remain the property of the people from whom they were collected.*
>
> *Release by the screening program of all or part of the retained newborn screening sample requires either the fully informed consent of the person from whom the sample was collected or an appropriate parent or caregiver, or a police search warrant and the approval of the Clinical/ Technical Head of the Screening Program, the Advisory Committee and the [Legal Adviser], Auckland Healthcare. Without these approvals, the Clinical/Technical Head of the screening program should consult widely before determining a course of action.*
>
> *Note that a search warrant requires that the police be permitted to search it is not a requirement that the requested material be produced. This however must be done under a subpoena.*
>
> *Cards will be returned to parents who request this, following completion of all testing. Return requires a request identifying the relationship of the requester to the person from whom the sample was taken, and the signature of the requester/s. The returned card is accompanied by a letter requesting that it be stored in a safe place.*
>
> *Use of residual newborn screening samples for research purposes requires the approval of the Advisory Committee."*

4.2 In fact, the sample cards are retained long after they could be needed for the purposes of auditing the screening programme. There is no formal audit process which involves going back to a representative sample of cards and retesting the samples. However, when a child is diagnosed with one of the conditions tested for, and this had not been spotted in the screening programme tests, there will then be a re-test of the original sample. For most of the conditions in question, such a diagnosis would be made within a year or two. For some of the conditions, particularly a mild case of hypothyroidism, it is possible that they would not show up and be diagnosed for ten or fifteen years. Western Australia has considered that the needs of quality assurance in its testing programme would be sufficiently served by keeping the samples for only two years, and it now destroys them at that stage.

4.3 The National Testing Centre considers that its handling procedures, rather than any questions of "reading" or evaluating samples or test results, are what matters in terms of quality assurance. The Centre undergoes regular accreditation audits. These do not involve subsequent re-testing of samples or their retention for that purpose.

4.4 A draft Policy Statement on the Retention, Storage and Use of Sample Cards from Newborn Screening Programs, prepared jointly in 2000 by the Human Genetics Society of Australasia and the Division of Paediatrics of the Royal Australasian College of Physicians, includes a set of recommendations which may well be a better account of subsequent uses of the retained sample cards in New Zealand at present. It states:

> *"Investigation of cases missed by the screening program*. This is the primary purpose of retention of screening samples ……
> *Screening program development, method development, and establishing normal ranges for new or existing tests* ……
> *Requests from Health Professionals.* Any request from a health professional to release a card from a deceased person to determine the cause of death or to gain genetic information for family reasons must be accompanied by a request from a custodial parent or next-of-kin.
> *Research studies.* Requests to use the sample cards in research studies are permissible if the researcher has appropriate approval from a local ethics committee and the screening program advisory committee …. The research should be performed under conditions established by the screening program advisory committee and the ethics committee and conform to NH&MRC guidelines.
> *Coronial and forensic.* Material should be released from dead or missing persons for coronial or forensic investigations with parental or next-of-kin permission. In exceptional circumstances, if legal authorities have a reason for not seeking parental permission an appropriate legal permission (search warrant, court order) should be obtained."

4.5 The above excerpts omit certain conditions which it is recommended should be attached to some of the above uses or releases. The full draft policy statement may be seen at *www.hgsa.com.au/policy/d_psrsuscnsp.html*

4.6 The following numbers are reported by the National Testing Centre for access over recent years:

	Family Health	Forensic	Parents	Civil Court Order
1995	0	1	0	0
1996	1	1	1	0
1997	3	1	7	0
1998	9	4	4	0
1999	11	2	94	2
2000	12	3	142	0
2001	16	3	353	1
2002	46	1	775	1

4.7 There is presently another civil court order outstanding, requiring the National Testing Centre to produce the sample card for a child who is still living and whose

mother will not co-operate in a paternity testing procedure demanded by a man who claims to be the child's father.

4.8 To put the above numbers in a scale context, there are around 55,000 new births and sample cards per year, and the total collection of samples is now in the order of 1.9 million.

4.9 "Family health" in the table above refers to requests from a family or a doctor working with the family for access to a sample of a family member with the intention of testing the sample for the presence of some inherited condition other than those covered by the newborn screening programme. Sometimes this will be done where a child has died, perhaps of what was called "cot death", and the family is concerned that future children of the family may have an inherited condition which was a possible cause of the deceased child's death. Otherwise it might be done where for some clinical reason it would be preferable to use the sample taken two or three days after birth rather than getting a new sample when the child will be more developed and less stressed.

4.10 "Parents" in the table above refers to requests by parents for return of the entire remaining samples. It is immediately obvious that this is a rapidly growing trend. Provided that the National Testing Centre is satisfied that the person requesting return of the sample is indeed the parent of the child concerned, the samples are returned (by mail, with a covering letter advising the requester about the value of the sample and exhorting them to keep it safely).

4.11 Most of the requests for return are received with the original sample card from the LMC, and take the form of a copy of an informed consent form annotated with the request, or a brief note or letter from the mother.

4.12 It is noteworthy that the access by third parties does not show any use of the samples by researchers.

5. <u>A developing area</u>

5.1 The range of conditions or propensities which can be detected from blood samples such as those collected and kept by this programme is increasing rapidly all the time. In California this year, a voluntary trial of tandem mass spectrometry testing for 40 newborn conditions is apparently operating successfully, with the intention of introducing the extended range of tests on a compulsory basis at some point in the future. The technology is available to automate such testing, bringing down the cost at the same time as the technological capability extends what can be done.

5.2 DNA "fingerprinting" -identification of individuals by variation in the "junk" non-coding part of their DNA- is well known and accounts for the "forensic" uses shown above; the blood samples on the sample cards are a satisfactory source of DNA and much more than identification analysis is possible. Gene mapping is certainly not out of the question technically.

5.3 In New Zealand, developments in this area appear to be held back not just by the quotidian lack of funding, but by what appears to be a lack of organisational control and leadership in this area of national (as opposed to regional) health functions. In communications, the Auckland District Health Board stands between the National

Testing Centre and the Ministry of Health. There does not seem to be any individual or agency responsible for the whole scope, development and overall conduct of the programme.

5.4 Other jurisdictions are also making various attempts to grapple with these issues. The Australian Law Commission has this year issued a report (ALRC Report 96 "Essentially Yours: The Protection of Human Genetics Information in Australia") which deals in part with this matter. Recommendation 19-1 of the Report reads:

> *"The Australian Health Ministers' Advisory Council (AHMAC)), in consultation with the Human Genetics Commission of Australia (NHMRC) and key professional bodies, should develop nationally consistent rules in relation to the collection, storage, use and disclosure of, and access to, newborn screening cards. In particular, and in consultation with state and territory Attorney-General's Departments and police services, AHMAC should develop nationally consistent rules governing disclosure of newborn screening cards for law enforcement purposes. These rules should provide for disclosure only: (a) with the consent of the person sampled or a person authorised to consent on his or her behalf; or (b) pursuant to a court order."*

6. The legal framework

6.1 The taking of the blood samples and carrying out of the screening tests is voluntary in New Zealand. In a few countries overseas, notably most states of the USA, the newborn metabolic screening test is required by law.

6.2 No specific law covers the operation of the programme, or the retention of the samples.

6.3 The Guardianship Act 1968 provides that a guardian may give effective consent to a medical procedure on behalf of a child. The screening programme operates on the basis that consent –and that means "informed consent"- is required and will be obtained by the LMC.

6.4 Information about the child and its mother is collected at the time of taking the sample, and is retained indefinitely even when the sample has been released. This is covered by the Privacy Act 1993, the Health Information Privacy Code issued under that Act, and regulations issued under the Health Act as to the minimum retention periods for health records. However, neither the Privacy Act and its Code or the Health Act regulations apply to the holding and use of medical testing samples. An expanded regulation-making power in the Health (Screening Programmes) Amendment Bill currently before Parliament would allow regulations to be made covering retention of bodily samples.

6.5 The Code of Health and Disability Services Consumers' Rights 1996, issued under the Health and Disability Commissioner Act 1994, brings legal force to the ethical requirement for informed choice and informed consent where a health care procedure is not required by law – see Right 7(1). Right 7(9) gives every consumer the right to decide as between return or disposal of any bodily substance obtained, and Right 7(10) requires that informed consent be obtained for the storage or use of any bodily

substance obtained in a health care procedure. Right 7 is set out in full as Appendix 2 in this report.

6.6 The Human Tissues Act 1964 has little bearing on any aspect of this programme. The National Testing Centre, having taken legal advice, acts as if each sample belongs to the individual from whom it came and is held by the Centre as a caretaker, but this stance appears to owe more to ethics than to law.

7. Privacy concerns

7.1 What gives rise to unease in terms of privacy concerns is a combination of the following features of the programme:

- The developing range of information which can be obtained by analysis of old blood samples
- The decreasing cost of carrying out such analysis
- The presence of a large, named, collection of blood samples covering more than half of the population and growing all the time
- No clear legal protection for the samples against access by third parties or against future uses.

7.2 To these background causes for some concern, there is added a further dimension of concern which will be explored shortly, and this is the feeling that retention of the samples:

- Is not well known or understood by the sample subjects or their parents
- Although notionally voluntary, has often not been the subject of any separate and explicit consent.

7.3 These concerns are not new.

7.4 Recently in the New Zealand political arena there was a flurry of press statements in which the Green Party spokeswoman called for legislative controls on what was effectively a DNA databank and the leader of the United Party spoke of the Guthrie sample collection as being potentially “a powerful weapon in the fight against crime”.

7.5 A memorandum of understanding between the National Testing Centre and New Zealand Police about the circumstances in which Police might seek access to a sample card is said to have been “being considered” for some years.

7.6 An article by Katie Elkin and Professor Gareth Jones in the periodical New Zealand Bioethics Journal of October 2000 called for “more specific legislation, particularly with respect to current and potential secondary uses of Guthrie Cards”. The article also called for improvement in the processes of gaining informed consent for collection, testing and storage of the blood spot samples.

7.7 An investigation by the Health and Disability Services Commissioner into a 1999 complaint (referenced HDC09011) concluded with the opinion that the blood sample had been obtained, tested and held without informed consent and therefore in breach of the rights of the (now deceased) baby.

8. The information given to the mother

8.1 Central both to privacy concerns and to the matter of informed consent is the question of what information is given to the mother prior to the collection of the heel prick blood sample. To the extent that the mother makes a conscious and informed decision agreeing to the taking of the sample, its testing in certain ways, and its retention for some understood related or unrelated purposes, the actions which follow and which comply with what was communicated and agreed to will comply with legal and ethical obligations both in the handling of the sample and the handling of the health information which is collected, used and held along with that sample.

8.2 The obligation to provide the mother with that information and obtain her informed consent is affixed contractually to the LMC. The LMC may not have received any specific training in this task. She or he will normally have available a leaflet produced by the National Testing Centre entitled "Your Newborn Baby's Blood Test". The Centre distributes these to LMCs in approximately the same numbers as there are births. However, the LMC in the Health and Disability Commissioner investigation mentioned above apparently stated that she had not seen that leaflet. In any event, issue of the leaflet is insufficient either to inform the mother about use of health information in compliance with Rule 3 of the Health Information Privacy Code or for obtaining informed consent. Its shortcomings have been pointed out both by the Health and Disability Services Commissioner in his August 2000 opinion on the complaint, and by the authors of the October 2000 periodical article. Yet I note that the leaflet was reprinted in April 2002 without any change except for an updating of the National Testing Centre's telephone number and email address.

8.3 As has been pointed out before (Elkin and Jones) the leaflet "does not present screening as a choice but as something that will happen." I observe also that it does not adequately explain the reasons for retaining the sample, nor the uses to which the retained sample may be put. It does mention that the sample card can be returned after testing, but does so in a way which is both misleading (it implies that the request for return must be submitted at the time that the sample is initially sent to in for testing, and is silent as to whether a later request for return will be acted upon) and imposing an impracticable requirement (it asks for a letter requesting return of the card to be sent to the Centre "with the test card" but the card has to be sent in by the LMC daily and the mother would not often have time or facilities to write that letter within the short time frame purportedly available). A transcript of the back page of this leaflet, which deals with matters of retention or return, is attached as Appendix 1 to this report.

8.4 The National Testing Centre's Director has observed that there is a good deal of misinformation in the community about the programme, including a myth that "the fourth spot on the sample cards goes to the Police" (and a number of the cards are indeed received with only three sample spots filled). The spread of such erroneous beliefs may be one reason why the number of parent requests for return of the sample cards is increasing rapidly. But there appears to be no resources available to improve the degree and the accuracy of information given to New Zealand parents about this programme.

8.5 The matter of the leaflet wording and reprinting seems to me to illustrate the lack of overall national control of the programme and resources. The National Testing Centre

is owned by Auckland District Health Board (previously Auckland Healthcare Ltd). The Health and Disability Commissioner found in the 1999/2000 complaint investigation that Auckland Healthcare had breached the baby's rights in not obtaining informed consent. Auckland Healthcare has since modified its own procedures and documentation so as to record the obtaining of informed consent. Nobody has taken steps on a national basis to amend procedures and documentation anywhere else in the country, nor even to amend the leaflet which the Centre distributes. The Centre is fully aware that the obtaining of informed consent for the newborn metabolic screening programme elsewhere in the country is "patchy" at best, but appears to consider that it is neither obliged nor given resources to do anything about this: it remains the responsibility of the individual LMCs.

8.6 Despite its shortcomings, the leaflet is a lot better than nothing. It is good in its description of the initial tests which are carried out in the programme. Its presentation to the mother, if made by the LMC, at least provides a natural opportunity for the LMC to explain those matters in which the leaflet is inadequate in its explanation, but even the leaflet distribution appears to be unreliable. An informal survey carried out by my office late in 1999 contacting 11 maternity hospitals in New Zealand demonstrated that the assumption mothers received the pamphlets was erroneous. Of the 11 hospitals contacted 7 distribute the pamphlets to mothers, 1 hospital relied on midwives to distribute the pamphlets, 1 hospital had no policy and when staff were questioned found a pamphlet in the tea-room, 1 hospital had no pamphlets while the 11th hospital had some pamphlets lying around but no policy on their distribution. There have probably been changes in practice since the survey was done.

8.7 A quite detailed survey, writing out to some 1,000 LMCs with questionnaires, was initiated by the National Testing Centre early in 2003. The survey is looking into matters of the information given to mothers and the obtaining of informed consent in relation to the newborn screening programme. Responses were received from some 760 LMCs, and these are still being evaluated with a view to reporting findings soon. Pressure of other work, and lack of sufficient resources, has caused the delay in analysing the responses received, although the National Testing Centre acknowledges that this is a matter of importance.

9. Conclusions and recommendations

9.1 The fast-rising number of requests for return of the sample cards would seem to indicate either a lack of knowledge about existing practices or a lack of faith in the programme's ability to withstand future demands for access by third parties to the stored samples. I find such concern understandable in the absence of clear, formal and enforceable barriers to protect the samples. In the analogous field of personal information holdings, I have found that the use of such resources by third parties tends to grow incrementally. That pattern seems to be evident here in the latest court order mentioned above –apparently the first such case where the child is alive and in New Zealand and the mother has not consented to the access.

9.2 I also consider that the reported spread of misinformation about future uses of the samples, especially by Police, is an understandable result of the lack of clear statements and enforceable safeguards around such potential uses.

9.3 When I look around for some agency or person having overall responsibility and authority for the operation of the programme – an agency or person who might be

expected to remedy these apparent deficiencies- it is hard to discern anyone in that position. I believe that this aspect of the matter should be remedied with urgency, before there is a loss of faith in the programme's integrity. In the absence of ongoing responsibility and authority, the sort of *ad hoc* development of rules for the programme which has been advocated by the Australian Law Reform Committee (in the recommendation quoted above) would be less effective and would be vulnerable to changing future conditions.

9.4 Given that the vital purpose –the *raison d'être*- of a newborn metabolic screening programme is to make timely identification of health conditions which can be managed so as to avoid unnecessary death or disability or suffering, any retention and other uses of the sample material must be limited so that they do not compromise that primary function. New Zealand appears to have a voluntary screening scheme which has worked well, but its uptake is vulnerable to a decline in trust.

9.5 I have not learned of any wrong actions on the part of the National Testing Centre, but I am concerned that it has been left to stand up alone and without formal protective barriers against potential demands for access to the growing bank of sample material which it holds.

9.6 There are difficult questions to be answered as to any finite retention periods for the newborn metabolic screening samples. Around the world, I understand that practices vary from destruction immediately after testing (France), through destruction after two years (Western Australia), to periods of twenty or fifty years and many countries (like New Zealand) having indefinite storage. The formulation of rules and permission-granting structures for potential third party access is complex too. Privacy is but one of the components in considering these matters, although it is of course an important component. I believe that these matters require a group approach, including consultation with the Privacy Commissioner.

9.7 I therefore make three recommendations:

1. That the Ministry of Health allocate clear responsibility and authority for the operation of the newborn metabolic screening programme.
2. That the body thus appointed move urgently to develop clear rules for retention of the samples and any further use or third party access to those samples, consulting widely with stakeholders and with the Privacy Commissioner.
3. That these rules, and any permission-granting structures they involve, be incorporated in legislation in such a way that they are clear, robust and enforceable.

B H Slane
Privacy Commissioner
25September 2003

APPENDIX 1

Page 6 of 'Your Newborn Baby's Blood Test'

"Notes

The information collected about you baby on the newborn screening card is used to:

- correctly interpret the results
- ensure any abnormal results are given to your lead maternity caregiver.

It may also be used in comparison with hospital birth data to check that all babies receive a screening test.

When the testing of your baby's blood is completed, the sample card is stored so that if a baby has one of the conditions tested for, but does not have a positive test result we can find out why the mistake occurred and try to ensure the same mistake does not happen again. Some of the blood might be used to set up new screening tests; if a leftover scrap of your baby's blood is used for this all the information about your baby will be disconnected from the blood so any results cannot be traced back to you and your baby. If you would like your baby's card returned to you after testing write and ask for this and send the letter with the test card.

If you would like to discuss this, or would like more information about newborn baby blood tests, you can contact us on phone 09-307 4949 ext 6759; fax 09-307 4936; email ntc@adhb.govt.nz or mail P O Box 872, Auckland.

[logo] New Zealand Genetic Services

National Testing Centre, Auckland, New Zealand. April 2002.Code 300.

APPENDIX 2

Code of Health and Disability Services Consumers' Rights

Right 7
Right to make an informed choice and give informed consent

(1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

(2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.

(3) Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.

(4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where—

- (a) It is in the best interests of the consumer; and
- (b) Reasonable steps have been taken to ascertain the views of the consumer; and
- (c) Either,—
  - (i) If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
  - (ii) If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

(5) Every consumer may use an advance directive in accordance with the common law.

(6) Where informed consent to a health care procedure is required, it must be in writing if—

- (a) The consumer is to participate in any research; or
- (b) The procedure is experimental; or
- (c) The consumer will be under general anaesthetic; or
- (d) There is a significant risk of adverse effects on the consumer.

(7) Every consumer has the right to refuse services and to withdraw consent to services.

(8) Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.

(9) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.

(10) Any body parts or bodily substances removed or obtained in the course of a health care procedure may be stored, preserved, or utilised only with the informed consent of the consumer.