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# The storage and use of newborn babies' blood spot cards: a public consultation

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This consultation document has been produced by members of the Social Science Research Unit at the Institute of Education, University of London within the Perspectives, Participation and Research stream in collaboration with Professor Carol Dezateux, Centre for Paediatric Epidemiology and Biostatistics, Institute of Child Health, University College London.

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# The storage and use of newborn babies' blood spot cards: a public consultation

## Summary

This consultation aims to gather the public's views on the storage, use and management of the UK collections of newborn babies' blood spot cards.

First, this document explains the background to the storage of newborn blood spot cards, outlines the potential for research and other uses and explains the current management arrangements for the UK collections of these cards (see Section 1). Second, it provides information about the different uses, and asks for your views about these uses (see Section 2). Third, it outlines the current structures for managing the collections of blood spot cards to serve the interests of the public and keep personal information private (see Section 3).

## 1.0 Introduction

### 1.1 What is the UK collection of newborn screening blood spot cards?

In the UK, newborn babies are screened for a small number of rare but serious conditions, including phenylketonuria (PKU), congenital hypothyroidism (CHT), sickle cell disorders, and cystic fibrosis (CF). When babies are about a week old blood spots are collected from their heel onto blood spot cards (see below) and used for testing. Also included on these cards is basic information about the baby, such as the baby's name, date of birth, contact details and NHS number.

### Newborn blood spot card (this picture is about half the size of the real cards)

The image shows a sample newborn blood spot card form. It includes a barcode at the top left with the number 123 123 1234. The form is divided into several sections:
 

- Parental and Baby Information:** Fields for G.P. Name & Initials, G.P. Address & Tel. No., Mother's Full Name, Baby's Alternative Surname, Baby's D.O.B., Ethnic Group Code, Rank, Gest, Birth Weight (g), and Date of Specimen.
- Medical History:** Fields for 'Has baby had a blood transfusion' and 'Is the baby in hospital' with 'Yes' and 'No' checkboxes.
- Test Results:** A section for Phenylketonuria and Hypothyroidism with checkboxes for 'Normal result' and 'Further test required'.
- Comments and MWHV:** A field for 'COMMENTS (type of feeding, antibiotics, drug therapy, family history, temporary address)' and a field for 'Name of MWHV taking sample (PRINT)'.
- Administrative:** A vertical barcode on the left edge with the number L8703200, a large red number 002287022 on the right, and a 'Surname:' field at the bottom right.

The aim of newborn blood spot screening is to prevent serious disability and even death, through early identification and treatment of these conditions. More information about the screening programme can be found at [www.newbornscreening-bloodspot.org.uk/](http://www.newbornscreening-bloodspot.org.uk/)

Newborn blood spot screening began in the late 1960s and in some areas blood spot cards have been stored since then. In 2004 following a widespread public consultation, the UK Newborn Screening Programme Centre recommended that blood spot cards should be

stored routinely by newborn screening laboratories for at least 5 years to be available for checking the quality of the screening programme for which they were initially collected.

In addition to checking the quality of the screening programme, there are a number of reasons for storing blood spot cards. These reasons may justify keeping the blood spot cards for more than 5 years.

Although these blood spot cards are stored in several laboratories around the country, they are stored for the same purposes and are regulated in the same ways. For this reason we consider these collections together and call them the UK newborn blood spot bank.

Your views will guide the future storage and use of newborn blood spot cards.

### **1.2 What are the potential uses of the blood spot cards?**

Blood spot cards contain four small dried blood spots and some basic information for each baby. Once newborn screening is completed, these cards are stored and can be used in a number of ways, each of which is described in more detail in Section 2.

These potential uses include those linked directly to the screening programme, and other uses that are made possible because these blood spot cards have been stored after screening. This blood spot bank is unique because the spots are collected from almost all babies born in the UK when they are about a week old. This makes them particularly useful for health research relevant to mothers and children.

The blood spot cards can be used after screening to check the result of the original test; to improve the screening programme; to help families identify why a child has died; for other tests recommended by the family's doctor; for research to develop new equipment or tests for public health monitoring; or for research to help improve the health of babies and their families in the UK.

### **1.3 What are the current arrangements to protect the interests of the public and keep personal information private?**

#### **➤ Parents give informed consent for their babies to be screened**

All parents are offered newborn blood spot screening for their babies. A national leaflet is given to all parents. It can be accessed from [www.newbornscreening-bloodspot.org.uk/](http://www.newbornscreening-bloodspot.org.uk/)

This leaflet contains the following wording:

#### **What happens to your baby's blood spots after screening?**

After screening, newborn blood spots are stored for at least 5 years and may be used in a number of ways:

- To check the result or for other tests recommended by your doctor
- To improve the screening programme
- For research to help improve the health of babies and their families in the UK. This research will not identify your baby, and you will not be contacted.

The use of these blood spots is governed by a Code of Practice, available from your midwife or via [www.newbornscreening-bloodspot.org.uk](http://www.newbornscreening-bloodspot.org.uk)

In the future there is a small chance researchers may want to invite you or your child to take part in research linked to the blood spot programme. If you do not wish to receive invitations to take part in research please let your midwife know.

➤ ***Storage of blood spot cards is regulated***

Newborn screening laboratories are responsible for testing newborn blood spots for the screening programme. The laboratory directors become 'custodians' of the blood spot cards, storing them, and ensuring guidelines about their storage and use are followed. There is strict guidance about who is allowed to access these blood spot cards and how the cards can be used.

➤ ***Use of blood spot cards is regulated***

Laws cover the use of the blood spot cards, in particular the Human Tissue Act 2004, the Data Protection Act 1998, and the Health and Social Care Act 2001. The specific guidance relating to the management of the blood spot bank has been developed with careful reference to these laws. These Acts are not described in detail here, but further information can be accessed via the Office of Public Sector Information at [www.opsi.gov.uk/legislation/](http://www.opsi.gov.uk/legislation/)

In 2004 the UK Newborn Screening Programme Centre consulted parents and health professionals about the screening programme and stored blood spot cards. Taking into account their views, the Centre developed guidance for laboratory directors on the storage, use and release of blood spot cards. This guidance can be found in 'The Code of Practice for the Retention and Storage of Residual Spots' available from [www.newbornscreening-bloodspot.org.uk/](http://www.newbornscreening-bloodspot.org.uk/)

One of the requirements of both the Code of Practice and the Human Tissue Act described above is: blood spot cards can only be used in research projects if they have approval from a committee that considers the ethics of the research (a Research Ethics Committee). More information about research ethics committees is available from the Central Office for Research Ethics Committees at [www.corec.org.uk/](http://www.corec.org.uk/)

The Code of Practice also requires that only research that makes good use of blood spot cards by addressing important questions with high quality methods can be allowed to use blood spots. All potential research projects must therefore be reviewed by other scientists before they can be approved. This process is known as 'scientific peer review'.

Practical procedures (often called Standard Operating Procedures) are currently being developed by newborn screening laboratories, in consultation with the UK Newborn Screening Programme Centre. These procedures will ensure that both the blood and the information stored on the blood spots cards are stored securely and can only be accessed by authorised members of staff.

The UK Newborn Screening Programme Centre also provides advice to newborn screening laboratories about the use of blood spot cards, and will record the use of the blood spot cards as part of an annual report.

Steps are taken to keep private any personal information contained in, or linked in any way to, the UK newborn blood spot bank. This is done in different ways, depending on what the spots are used for, and is guided by the Code of Practice and Research Ethics Committees described above. Individuals' identities are protected by removing identifying information from the blood spots before they can be used.

#### **1.4 What does this consultation ask and what will happen to the findings?**

This consultation asks about:

1. Public attitudes to the various uses of stored blood spot cards.
2. Public attitudes about how the UK newborn blood spot bank is managed to serve the interests of the public and keep personal information private

The consultation is guided by an advisory group of experts with backgrounds in public health, ethics, law, genetics, laboratory science and patient involvement in research and health policy. This group advises on how the consultation should be conducted.

The consultation is conducted by a research team with experience of public health, laboratory science, social science and public involvement in research and health policy (listed at the front of this document).

We are gathering public attitudes from:

- a web-based consultation in Autumn 2005 (this document)
- interviews and focus groups with members of the public in Autumn 2005
- a working group made up of members of the public which will meet in Spring 2006. This group will discuss in depth how blood spots can be used and public attitudes to this. The group will help draft a report of the public's views on the uses and management of the UK newborn blood spot card bank.

This report will be considered by the consultation's advisory group. Taking into account the views of the public, as well as information about the costs and practical requirements of storage, this advisory group will make recommendations to researchers, policy-makers and practitioners about what the UK newborn blood spot bank should be used for and how it should be managed.

## 2.0 Uses of the UK newborn blood spot bank

Here we ask you to tell us your views about what the blood spot cards are used for. We shall ask you later to share your views on how the UK newborn blood spot bank is managed to serve the interests of the public and keep personal information private (see Section 3).

### **2.1 Blood spot cards are used to monitor and improve the screening programme**

The UK Newborn Screening Programme Centre standards for newborn blood spot screening require all blood spot cards to be stored for at least 5 years to maintain the high quality of the screening programme.

Newborn screening laboratories and the UK Newborn Screening Programme Centre use information from existing blood spot cards to monitor and improve the screening programme. They use the blood spots to double check the accuracy of the screening tests they are using. For example they may retest a number of blood spots from time to time to confirm result.

The laboratory may also use stored blood spots to develop and check new methods of testing for conditions for which screening is currently offered. Stored blood spots might also be used to develop tests for different conditions for which screening might be offered in future.

Using blood spots to monitor and improve screening is essential for the screening programme. If blood spots could not be used for these purposes the newborn blood spot screening programme would provide a poorer service to parents. It would not be so successful in saving lives and preventing severe disability from a few rare but serious conditions. Nor could it make improvements as new tests and new technologies are developed.

Using blood spots to develop tests for different conditions, which might be included in routine screening in the future, may raise concerns about whether families will be contacted with results they were not expecting. This problem is prevented by testing blood spots only after they have been separated from information identifying individuals, so the testing is done anonymously.

Q1a. Please consider the following statement and tick one of the 5 options below:

*It is appropriate that blood spot cards can be used by laboratories as described above to monitor and improve the screening programme.*

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

Q1b. Do you have other comments about the use of blood spot cards to monitor and improve the screening programme?

## **2.2 Blood spot cards are used to directly benefit individuals and families**

Stored blood spot cards may be used for the direct benefit of the family or child. For example if a baby has died but the cause is unclear, at a doctor's request, the baby's blood spot card can be tested after an interval of many years to try to identify the cause. This may provide valuable information for parents about the cause of death, and can provide families with information about their risk of having another baby with that condition.

Blood spots might also be tested to try to identify the body of someone who has been killed in a disaster when there is no other way to identify them. For example, newborn blood spot cards have been used to identify bodies of people killed in a factory fire and those killed in the tsunami on Boxing Day 2004.

These uses of the blood spot cards are uncommon but are of direct benefit to individuals or their families. When they are used to help in situations such as those described above, this can be of enormous value to the family involved. A few families may benefit from these uses in the first 5 years, when the spots are stored for the screening programme. However, if blood spot cards are stored for longer, these benefits will continue to be possible over a longer period.

Q2a: Please consider the following statement and tick one of the 5 options below:

*It is appropriate that stored blood spot cards be used for the benefit of individuals and their families.*

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

Q2b: Please consider the following statement and tick one of the 5 options below:

*Blood spot cards should be stored for more than 5 years for uses that directly benefit families.*

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree

5. Strongly disagree

Please give your reasons for your answer:

Q2c. Do you have other comments about the use of blood spot cards for individuals and their families?

### **2.3 Blood spot cards are used to monitor health in the general population**

Blood spot cards can be used as part of public health monitoring, to answer questions about the health of the general population, to inform health service planning and to monitor how well public health policies prevent or manage disease. The blood spots are particularly valuable because it is possible to find out information about mothers health from their babies blood spots.

Care is always taken to keep personal information private when blood spot cards are used in this way. Identifying information is removed from the blood spots so they are anonymised.

For example, 15 years ago we were unsure how widespread HIV infection was in the UK and whether it was becoming more common. By testing the stored blood spots of newborn babies anonymously so it was impossible to identify individuals and their results, it was shown that the number of HIV-infected pregnant women was steadily increasing. This information led directly to the introduction of a national policy to recommend voluntary HIV testing to all pregnant women in 1999. Advances in methods to prevent a mother transmitting HIV infection to her child has reduced the risk of a baby being infected from 1 in 5 to less than 1 in 50, and now almost 90% of pregnant women accept voluntary testing for HIV. At the same time anonymous HIV testing of stored blood spots is continuing so that the effectiveness of the voluntary screening programme can be monitored.

The value of stored blood spot cards for monitoring health in the general population is increased enormously if blood spot cards can be stored beyond the initial 5 years required by the screening programme.

Q3a. Please consider the following statement and tick one of the 5 options below:

*It is appropriate that blood spot cards can be used to monitor health in the general population.*

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

Q3b. Do you have comments about the storage of blood spot cards, beyond the 5 years required by the screening programme, for monitoring health in the general population?

## **2.4 Blood spot cards are used to answer questions about health problems**

Researchers can use blood spot cards to answer questions about specific health problems.

For example, researchers exploring the reasons why a child develops leukaemia have used the blood spots of individuals who have developed the condition in later childhood, to see if the condition was present when these children were a week old.

Researchers have also used anonymised blood spots to identify how common certain infections are among pregnant women, including rubella and other viruses such as Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). The advantage of using the blood spot bank to do this, is that cards are available for almost all babies, and these questions can therefore be answered quickly and cheaply.

Researchers have also used blood spots to test for viral infections in children and to try and answer questions about how these infections affect children's long-term health. For example, researchers have used blood spots to explore links between infections and conditions such as leukaemia. Some research has been carried out to test stored blood spots for environmental and chemical exposures, such as pesticides.

Stored blood spot cards have also been used to investigate genetic conditions. For example, researchers have used anonymised blood spots to look for links between Sudden Infant Death Syndrome (SIDS or 'cot death') and specific genetic variations. Other studies have used blood spots from a large section of the population to try and identify any genetic causes of conditions such as cerebral palsy, childhood leukaemia, and other cancers.

Research using blood spot cards, particularly genetic research, may result in the type of information about individuals that insurance companies would be interested in. However, access to this information by insurance companies is not currently permitted in the UK.

The value of stored blood spot cards for research about health increases considerably if blood spot cards are stored beyond the initial 5 years required by the screening programme.

Q4a. Please consider the following statement and tick one of the 5 options below:

*It is appropriate that blood spot cards can be used to answer questions about health problems.*

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

Q4b: Do you have other comments about the storage of blood spot cards, beyond the 5 years required by the screening programme, for research to answer questions about health problems?

## **2.5 Blood spot cards are used to develop equipment and tests**

Blood spot cards can be used to develop new equipment and tests, which may make it possible to identify more conditions early, when babies are just a few weeks old, leading to early treatment and preventing serious disability in later life.

For example, newborn blood spot cards have been used to develop equipment called a tandem mass spectrometer. This allows tests to be carried out on very small amounts of blood.

The development of new health care equipment and tests relies heavily on the biomedical industry. Commercial organisations working with newborn screening laboratories may wish to use blood spot cards directly to ensure new equipment meets required standards. In addition researchers may wish to do research funded by commercial organisations using the blood spot cards. University researchers and commercial organisations increasingly work alongside one another. This means it can be difficult to distinguish between research by university researchers and research by industry.

In the future commercial organisations may be interested in accessing whole collections of blood spots. This has not occurred in relation to newborn blood spot cards, although it has happened with other adult blood samples, for example the DeCode project in Iceland [see [www.decode.com/](http://www.decode.com/) for more information].

Like other uses of the UK newborn blood spot bank, commercial uses of the blood spot cards are strictly regulated (see Section 3 for more information).

Use of the blood spot cards by commercial organisations raises the issue of who owns the knowledge gained. This issue is particularly important where there are financial implications from the findings, either for the researchers, or for the company which funds the research.

Q5a. Please consider the following statement and tick one of the 5 options below:

*It is appropriate that blood spot cards are stored, beyond the 5 years required by the screening programme, to develop equipment and tests.*

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

Q5b. Do you have any comments about commercial companies using blood spot cards to develop equipment or tests?

## **2.6 Blood spot cards are used with additional 'linked' information**

Public health monitoring (2.3 above) and research (2.4 and 2.5 above) about health conditions using newborn blood spot cards are often most beneficial if the blood spot cards can be linked to additional information. As explained below, steps are taken to ensure that personal information is protected and that the identity of individuals is not revealed.

More information about the use of personal information in medical research is available from [www.mrc.ac.uk/pdf-pimr.pdf/](http://www.mrc.ac.uk/pdf-pimr.pdf/)

Additional information about individuals is available via the Office of National Statistics, for example, information may be obtained from birth registration records. Additional information about individuals is also available through the NHS Hospital Episode System. This system includes data about when people attend hospital, for example, information that a child has been admitted to hospital for a sickle cell disorder or diabetes.

If blood spot cards can be linked to these different types of additional information it allows researchers to relate the results of tests done on the stored blood spots to subsequent health status. It is also possible to select blood spots from children with and without specific diseases and to test them for different infections or genetic markers. For example, researchers can explore whether certain genetic variations might predict diabetes.

Researchers recognise the importance of keeping personal information private and take steps to do this. Studies that link blood spots to additional information do not identify individuals.

Linking additional information to the blood spots in these ways is strictly controlled. More explanation and an opportunity to comment on these arrangements are provided in Section 3.

Q6a. Please consider the following statement and tick one of the 5 options below:

*It is appropriate that blood spots can be linked to additional information for research or public health monitoring*

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

Q6b. Do you have any other comments about the linking of additional information to the blood spots? If yes, please specify exactly what you are concerned about and why.

## **2.7 Blood spot cards are used for forensic police work**

Police may access the blood spot cards of specific deceased or missing persons for forensic purposes only if they first obtain a court order. This is extremely unusual.

Police may want to use a blood spot card to identify the body of someone who has been killed in a disaster when there is no other way to identify them. For example blood spot cards were used to identify some of the victims of the Boxing Day 2004 tsunami.

Current guidance set out in the Code of Practice (see section 3.1) is that samples from individuals who are alive and not missing would not be released without a court order for this purpose since alternatives are available.

The use of blood spot cards to help solve crimes raises the issue of whether police should be able to test a large number of spots in the hope of identifying a criminal. The courts do not currently permit this. Although police keep their own database of blood spots acquired from suspected criminals for such purposes, this is not related in anyway to the stored newborn blood spots cards. Testing large numbers of blood spot cards to identify a criminal is not allowed.

Storing blood spot cards beyond the initial 5 years required by the screening programme, extends the potential for the blood spot cards to help with forensic police work.

Q7a. Please consider the following statement and tick one of the 5 options below:

*It is appropriate for stored blood spot cards to be used to help with forensic police work with a court order.*

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Q7b: Do you have other comments about the storage of blood spot cards beyond the initial 5 years required by the screening programme, to help with forensic police work?

## **2.8 Balancing the uses of blood spots**

To summarise, newborn blood spots have valuable uses for individuals, families and the population as a whole. Currently only four blood spots are collected for screening. Blood spots from very few individuals are used for reasons other than screening or anonymous HIV testing. The likelihood of needing to use blood spots after screening for individuals or their families is also very, very low. On the very rare occasions that they are used to directly benefit individuals or their families, the information from test results is very valuable.

This raises the issue about whether blood spots from an individual should only be used for research or public health monitoring if there is enough blood left afterwards for the family. In other words, should some blood always be kept in case it might be needed for the direct benefit of that individual or their family in the future?

Q8a: Please consider the following statement and tick one of the 5 options below:

*If blood spots are requested for research or public health monitoring, the request should be refused if it would use up all the remaining blood (ie leave insufficient blood for tests which may directly benefit the individual or their family in the future.)*

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

Q8b. Do you have other comments about keeping some blood especially for uses that directly benefit the family?

### **3.0 Overseeing the storage and use of the UK newborn blood spot bank**

This section explains in more detail, how blood spots are collected for newborn blood spot screening, and the current arrangements for how storage and use of blood spot cards is regulated.

We would like to know your views on these current arrangements.

#### **3.1 Current arrangements managing the UK newborn blood spot bank**

As outlined in Section 2, there are a number of ways in which the storage and use of the newborn blood spot bank are managed:

➤ **Parents give informed consent for their babies to be screened**

When parents are offered newborn blood spot screening for their baby, they are provided with a pre-screening leaflet enabling them to make an informed choice about screening.

As outlined in Section 1, this leaflet contains the following wording:

#### **What happens to your baby's blood spots after screening?**

After screening, newborn blood spots are stored for at least 5 years and may be used in a number of ways:

- To check the result or for other tests recommended by your doctor
- To improve the screening programme
- For research to help improve the health of babies and their families in the UK. This research will not identify your baby, and you will not be contacted.

The use of these blood spots is governed by a Code of Practice, available from your midwife or via [www.newbornscreening-bloodspot.org.uk](http://www.newbornscreening-bloodspot.org.uk)

In the future there is a small chance researchers may want to invite you or your child to take part in research linked to the blood spot programme. If you do not wish to receive invitations to take part in research please let your midwife know.

➤ **Storage of blood spot cards is regulated**

Laboratories test the blood spots for the conditions within the blood spot screening programme. More information about this programme can be accessed at [www.newbornscreening-bloodspot.org.uk/](http://www.newbornscreening-bloodspot.org.uk/)

The blood spot cards are stored for 5 years for the direct purpose of the screening programme. Blood spot cards are stored beyond this initial 5 years for a number of potential uses, discussed in detail in Section 2.

As outlined in Section 1, the laboratory directors are 'custodians' of the blood spot cards, storing them, and ensuring guidelines about their use are followed. There is strict guidance about who is allowed to access these blood spot cards and how the cards can be used.

### ➤ **Use of blood spot cards is regulated**

As described in Section 1, the management of the storage and use of the blood spot cards is guided by laws, a code of practice and standard practical procedures.

Laws cover the use of the blood spot cards, in particular the Human Tissue Act 2004, the Data Protection Act 1998, and the Health and Social Care Act 2001. The specific guidance relating to the management of the blood spot bank has been developed with careful reference to these laws. These Acts are not described in detail here, but further information can be accessed via the Office of Public Sector Information at [www.opsi.gov.uk/legislation/](http://www.opsi.gov.uk/legislation/)

In 2004 the UK Newborn Screening Programme Centre consulted parents and health professionals about the screening programme and stored blood spot cards. Taking into account their views, the Centre developed guidance for laboratory directors on the storage, use and release of blood spot cards. The guidance can be found in 'The Code of Practice for the Retention and Storage of Residual Spots' available from [www.newbornscreening-bloodspot.org.uk/](http://www.newbornscreening-bloodspot.org.uk/)

One of the requirements of both the Code of Practice and the Human Tissue Act described above is: blood spot cards can only be used in research projects if they have approval from a committee that considers the ethics of the research (a Research Ethics Committee). More information about research ethics committees is available from the Central Office for Research Ethics Committees at [www.corec.org.uk/](http://www.corec.org.uk/)

The Code of Practice also requires that research must make good use of blood spot cards by addressing important questions with high quality methods. All potential research projects must therefore be reviewed by other scientists before they can be approved. This process is known as 'scientific peer review'.

Practical procedures (often called Standard Operating Procedures) are currently being developed by newborn screening laboratories, in consultation with the UK Newborn Screening Programme Centre. These procedures will ensure that both the blood and the information stored on the blood spots cards are stored securely and can only be accessed by authorised members of staff.

The UK Newborn Screening Programme Centre also provides advice to newborn screening laboratories about the use of blood spot cards, and will record the use of the blood spot cards as part of an annual report.

Steps are taken to keep private any personal information contained in, or linked in any way to, the UK newborn blood spot bank. This is done in different ways, depending on what the spots are used for, and is guided by the Code of Practice and Research Ethics Committees described above. Individuals' identities are protected by removing identifying information from the blood spots before they can be used.

### **3.2 Public involvement in managing the UK newborn blood spot bank**

The public are currently represented in the management arrangements for the UK newborn blood spot bank in a number of ways. These have included:

- public input into a 2004 consultation about the UK Newborn Screening Programme Centre's Code of Practice;
- public input into the laws that relate to this UK newborn blood spot bank;
- ongoing public involvement through members of the public who routinely sit on research ethics committees.

We suggest two more ways for involving the public in the management of the UK newborn blood spot bank.

➤ **A public scrutiny panel**

This panel would consist of around ten members of the public with access to additional scientific advisors and administrative support.

At the end of each year, this panel would receive a report from the UK Newborn Screening Programme Centre of the individual, public health monitoring and research uses of the stored blood spot cards. It would then issue guidance to the UK Newborn Screening Programme Centre and to the laboratory directors about these uses, raise any areas of concern, and identify opportunities for improvement. This panel would also be available to advise on the potential use of the blood spot cards should any controversial issues arise that are not resolved by the procedures outlined in the Human Tissue Act and the Code of Practice.

A public panel such as this would need support and funding. Existing public panels may be able to take on this role, for example those set up within the NHS to advise on health care planning or research.

➤ **A 5-yearly public consultation exercise**

This 5-yearly public consultation could invite members of the public to comment on the uses and management of the UK newborn blood spot bank (in a similar way to this consultation).

A 5-yearly public review such as this would need funding and a clear route for reporting its findings to ensure the public's views were taken into account by those managing the UK newborn blood spot bank.

Q9a: Do you agree that there is a need for ongoing public involvement in the management of the UK newborn blood spot bank?

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

Q9b: Which of the proposed models do you think should be used?

1. Neither the public panel nor the 5 yearly public consultations
2. The public panel only
3. The 5 yearly consultations only
4. Both the public panel and the 5 yearly consultations

Please give your reasons for your answer:

Q9c: Do you have any other suggestions or comments about ongoing public involvement in the management of the stored blood spot cards?

***Thank you for answering our questions***

Q10: The questions above ask for your views on:

- the benefits and challenges of research using stored newborn blood spot cards, and
- the management of the UK newborn blood spot bank

Are there any other questions that you feel are important for us to consider?

If you have any other views about the storage, use or management of newborn blood spot cards please add them below.

## Responding to the consultation

Please submit response online at: <http://eppi.ioe.ac.uk/questionnaire/>

If we receive your response electronically, there is no need for you also to send a paper copy. If you should prefer to respond by post or by fax, you may send completed responses to:

Blood Spot Public Consultation  
Social Science Research Unit  
Institute of Education, University of London  
18 Woburn Square  
London  
WC1H 0NR

Fax: 0207 612 6400

Additional copies of this document can be downloaded from our website:  
<http://www.ioe.ac.uk/ssru/reports/publicconsultationbloodspots.pdf>

For printed copies, please contact us at the above address.

Thank you.

**CLOSING DATE FOR RESPONSES: 6<sup>th</sup> January 2006**

## Details of respondents

We would like to know more about you, to allow us to take into account the range of people responding to this consultation. All personal information will be stored securely and will only be accessed by the research team. We will only report your responses if you give us your permission to do so, and if you prefer us to only do this anonymously, we will adhere to your wishes. Please indicate your preferences below.

**Please complete and return with your responses by 6<sup>th</sup> January 2006**

Name:

Organisation:

Address: (optional)<sup>1</sup>

Telephone:

Email:

**Are you responding individually on your own behalf, or on behalf of your organisation?**

- Individual
- Organisation

**Please tick which description(s) best describe you:**

A newborn screening provider:

- A health professional involved in screening, or their representative
- A national or international screening organisation

A child, parent or other family member:

- A child or young person under the age of 18 unaffected by the screened conditions
- A child or young person under the age of 18 affected by the screened conditions
- A parent of a child unaffected by the screened conditions
- A parent of a child affected by one of the screened conditions
- A family member (other than a parent) of a child unaffected by the screened conditions

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<sup>1</sup> Please note that if we do not have your address we will not be able to send you a copy of the report when it is published.

- A family member (other than a parent) of a child affected by one of the screened conditions
- A member of a support group related to one of the screened conditions
- A member of a support group not related to the screened conditions
- A member of a genetic interest group

A potential user of the UK newborn blood spot bank;

- A researcher
- A research funder
- A research organisation

A member of ethical or moral structures within UK society

- A member of an organisation protecting consumer rights
- A member of an ethical or religious group

Other member of the public:

- A member of the public with no particular involvement or links to newborn screening or the UK newborn blood spot bank
- Other (Please specify .....)

**Please indicate your view regarding the following statements:**

***This response may be published as part of an appendix to the final report***

- Yes
- No
- Anonymously only

***This response may be quoted in the report***

- Yes
- No
- Anonymously only

***This response may be made available to other researchers interested in the topic***

- Yes
- No
- Anonymously only

**If you have answered 'yes' to any of the above questions, please indicate your name and/or the title of your organisation, as it should appear in print:**

Name:

Organisation:

**Please let us know where you heard about the consultation:**

- Website
- Sent an invitation to respond
- Other (please state)

**We would like to be able to contact you again about this topic. May we keep your contact details for this purpose? We will only use these details as specified above and will not pass them to third parties without your specific permission.**

**Yes, you may keep my contact details**

- Only until the Report is published, so that you can send me a copy
- Until I notify you otherwise
- Please **do not keep my contact details**

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