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## Guthrie Cards in Scotland: Ethical, Legal and Social Issues

Knowledge Transfer



**STORAGE, USE AND ACCESS TO THE SCOTTISH  
GUTHRIE CARD COLLECTION:  
ETHICAL, LEGAL AND SOCIAL ISSUES**

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Scottish Government Social Research  
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# **GUTHRIE CARDS IN SCOTLAND: ETHICAL, LEGAL AND SOCIAL ISSUES**

## **EXECUTIVE SUMMARY**

This report considers the ethical, legal and social issues surrounding the existence, continued storage and future uses of the newborn screening collection held in Scotland (also known as the Guthrie card collection). The report was written over a four year period, 2009-2013, during which time earlier drafts of the report ensured that Guthrie Cards were included in the developing governance regime for biomedical collections within Scotland. This final version is an account of developments as of April 2013 and involves an evaluation of the current arrangements as far as this is possible in a fast-moving field. The report also serves as a platform for future dialogue and development in light of wider social and international changes that are occurring, most notably in terms of the growing role for empowered citizens to contribute to, and benefit from, the future direction of health-related research.

The Scottish Guthrie card collection began in 1965 and now contains more than 2.5 million cards which include blood/DNA samples and personal information relating to children born in Scotland since the inception of the collection until the present day. Numerous purposes are possible with respect to this collection but there is no dedicated legal framework that applies to it. Accordingly, this report approaches the resolution of the ethical and social issues from first principles, acknowledging the potential value of the resource while considering areas of law that might apply to it. Matters are complicated by the long-term nature of the collection – historically and into the future – whereby social attitudes and governance frameworks have changed over time and might change again in years to come. The prospect of the Guthrie collection being seen as a “de facto DNA database” means that these issues require on-going attention. Challenges in other countries such as Australia, Ireland, New Zealand and the United States with respect to similar newborn screening collections have demonstrated that a failure to address the issues appropriately and in a timely fashion can have very serious consequences, including destruction of whole collections in some cases. Such an outcome is not, however, inevitable. Scotland can learn much from the experience in other countries and this report highlights some of the pertinent lessons.

The report argues that a robust, flexible and adaptive system is required to govern the Scottish Guthrie card collection. This must remain fit-for-purpose over time and must strike a delicate balance between maximising the value of the collection as a public resource to be managed for the public good while minimising the risks to individuals whose samples and data are held as part of the collection. While much attention has been paid to governance arrangements in the last four years, current practices could be improved further towards an optimal governance system for the collection and which would strike the appropriate balance of interests.

The report details options for consideration as to how practices could be improved. In some cases it makes specific recommendations for action; in others, it identifies

opportunities for future dialogue about this and other biomedical collections. It is argued that public engagement should be undertaken in the development, implementation and on-going operation of policies with respect to the collection and potential and future uses.

The report covers the following areas:

**Legal basis:** The legal basis for the collection in Scotland is not captured in any single piece of legislation governing its existence. The position is complicated by the fact that the collection contains both personal information and DNA samples – the complicating factor is that separate legal regimes apply to data and tissue. While in England the equivalent collection appears to be treated as ‘tissue’, and is therefore regulated under the Human Tissue Act 2004 (HTA 2004), this Act does not, in the main, apply in Scotland and there is no equivalent legal regime. The one notable area of overlap between the two countries is, however, section 45 of the HTA 2004 which does apply in Scotland. This section creates a criminal offence for non-consensual DNA analysis. Unlike England, evidence in Scotland suggests that the entire collection is treated as part of the medical record and therefore is ‘data’ and subject to the provisions of the Data Protection Act 1998. It is recommended that for the avoidance of doubt and to ensure effective and robust protection of individual interests, the Guthrie collection in Scotland should be treated as both information and tissue for the purposes of legal governance. In addition, all practices with respect to the collection must be tested for human rights compliance. Any governance regime should reflect examples of ‘best practice’ from data and tissue regulation regimes while at the same time adopting a mechanism of *proportionate governance*, that is – a system of oversight and control that is proportionate to the risks involved and the benefits that can be achieved and which does not create undue regulatory burden on legitimate uses of the collection.

**Consent and anonymisation:** Both consent and anonymisation are legal and ethical mechanisms used to protect and respect individuals and are accordingly of considerable importance. However, neither approach is a complete solution to challenges faced by large-scale, long-term biomedical collections. Each measure has limitations when considering how to strike the balance between individual rights and the pursuit of the public good. Close scrutiny is required of procedures both as to recruitment and withdrawal from the collection as well as to the role of anonymisation in legitimating research use. Although the law does not require it, consideration should be given to whether explicit consent should be obtained from people whose information and samples are held in the collection. Consideration should also be given to the details of an effective opt-out system, and whether mature minors should be allowed to opt-out. Other issues that requires attention are whether ‘consent for consent’ should be sought to facilitate research access, and whether consent should be sought from individuals if access is contemplated for non-healthcare purposes. As a minimum, there should be clear, transparent and accessible information about the collection, its uses and operation arrangements and mechanisms for citizens to enquire about its operation. It is important that a regular Privacy Impact Assessment be carried out on the operation and use of the resource.

**Access and storage:** The growing awareness of the value of the Guthrie collection as an important potential resource for genetic and other forms of health-related

research means that access policies and procedures require priority and on-going attention. Moreover, the prospect of non-health related access, such as by the police, necessitates robust measures to protect individual interests. In light of the provisions of the Data Protection Act and human rights considerations, those responsible for the collection must also clearly define the purposes of the collection and link these to justifiable periods of retention. The appropriateness of the physical environment in which the collection is held and the way in which it is archived must be kept under regular review. It is recommended that a clear, robust and transparent and publicly available access policy should be operated; this should include guidance for decision makers on relevant factors to be taken into account when contemplating access/research requests. A written protocol for the release of samples and information to the police should be developed and should be publicly available. Personnel within the NHS should act as gatekeepers with respect to access requests and most notably and ideally Caldicott Guardians – as those persons responsible for patient confidentiality within the NHS - should be involved in the decision-making processes. Access policies must not only be transparent and easily intelligible, but these must also be kept under regular review and augmented with periodic updates on the kinds of uses of the collection that have been granted. Policies and procedures regarding feedback of information to individual citizens should be developed.

**Governance:** Good governance of biomedical collections is essential and procedures must apply to all aspects of the resource from initial taking of consent and samples, to storage, quality assurance, access, networking, feedback and contingency planning. The relationship between:

- The Southern General Hospital (SGH) in Glasgow (as custodian of the national resource for the first two years; archival storage thereafter)
- NHS Greater Glasgow and Clyde Health Board (as responsible authority for SGH and the historic collection),
- Healthcare Improvement Scotland (as the national inspectorate body for quality care and services), and
- NHS Research Scotland (as the national strategic organisation),

needs to be clarified, especially with respect to lines of accountability. The role of advisory and monitoring bodies also requires exploration, as does the input of the Caldicott Guardians. Reflecting the recommendations in the previous section, robust and transparent policies and governance mechanisms should be maintained and regularly reviewed. Relevant governance bodies should deploy reflexive governance whereby they engage in mutual learning about developments involving the resource and remain responsive to future challenges.

**Public attitudes and engagement:** There is a lack of research in the UK generally and Scotland in particular on public and professional attitudes to the storage and further use of newborn blood collections. Research conducted elsewhere suggests that although there is majority support for storage and appropriate, well-governed use, there are concerns about access, consent and the provision of information. Effective governance should be based on a sound empirical knowledge of public views and a programme of public engagement to ensure that governance arrangements are socially acceptable and ethically robust now and into the future.



**Future Considerations:** The transformative potential of biomedical collections for individual, local and global health is exponential. Scientific and technological advances mean that the possible future uses of the Guthrie collection are constantly changing and these no longer depend only on developments in the health sector – cloud computing and mobile applications mean that these valuable resources can be enriched and shared in ways never before contemplated. This also raises the possibility of a far more engaged role for the citizen interested in contributing to and influencing the future direction of research. While some of the more speculative possibilities are beyond the scope of this report, the fact that these can be foreseen makes it all the more important that Scotland develop a long-term, robust, responsive and imaginative approach to the management of its biomedical collections.

## CHAPTER 1 - INTRODUCTION

1.1 This report explores the ethical, legal and social issues surrounding the existence, continued storage and future uses of the Guthrie cards collection held in Scotland. The report has been prepared by Professor Graeme Laurie<sup>1</sup> and Dr Kathryn Hunter<sup>2</sup> under the auspices of the School of Law, University of Edinburgh, and includes a chapter on public attitudes and engagement from Professor Sarah Cunningham-Burley<sup>3</sup>, Centre for Population Health Sciences, University of Edinburgh.

1.2 The evidence-base for this report has been developed from a literature review of pertinent legal and sociological materials; from an analysis of existing guidance and relevant documentation; from a comparative exploration of practices in other countries, and through discussions with key stakeholders, including the custodians of the collection. In the course of research the following persons and bodies were consulted: Mr David Aitken, Director and Ms Joan MacKenzie, Screening Co-ordinator, The Scottish Newborn Screening Laboratory; Mr David Edward, the Human Tissue Authority; Ms Patricia Ruddy, Information Services Division, NHS National Services Scotland; Ms Christine Cavanagh, Programme Manager, UK Newborn Screening Programme Centre; Dr Deirdre Madden, Senior Lecturer in Law, University College Cork, Professor James Chalmers, Glasgow Law School; Mr Gerard Porter, Edinburgh Law School; and Dr Mark Taylor & Ms Jessica Wright, Sheffield Law School, respectively Principal Investigator and Research Coordinator of the European Commission *Privileged* project.<sup>4</sup> We are grateful to all parties for their time and contributions, including participants in a roundtable discussion on 21 January 2010 on an earlier draft of this report. Before and since then we have benefited from input from colleagues in Scottish Government – Gill Clark, Craig Gilbert and Vivian Leacock – who have worked with us over the years as governance arrangements within Scotland have developed. The inspiration for this work came from Dr Rosalind Skinner, Principal Medical Officer, Scottish Government (2009).

1.3 The Scottish Guthrie card collection began in 1965 and now contains more than 2.5 million cards which include blood/DNA samples and personal information relating to children born in Scotland since the inception of the collection until the present day. Numerous purposes are possible with respect to this collection but there is no dedicated legal framework that applies to it and therefore the resolution of social and ethical arising from its continued retention and future use require careful attention. Matters are complicated by the long-term nature of the collection – historically and into the future – whereby social attitudes and regulatory frameworks

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<sup>1</sup> Professor of Medical Jurisprudence and Founding Director of the JK Mason Institute for Medicine, Life Science and the Law, School of Law, University of Edinburgh. Research for the report began while Laurie was Director of AHRC/SCRIPT, a law and technology research centre based in Edinburgh Law School and sponsored by the Arts and Humanities Research Council (2002-2012).

<sup>2</sup> Dr Hunter was Research Manager for AHRC/SCRIPT at the time research for this report began and subsequently held the post of Senior Lecturer in Law at Northumbria University.

<sup>3</sup> Professor of Medical and Family Sociology, Head of School of Molecular, Genetic and Population Health Sciences, University of Edinburgh.

<sup>4</sup> The EC Privileged Project examines privacy in law, ethics and genetic data. See: <http://www.privileged.group.shef.ac.uk/>

have changed over time and might change again in years to come. The prospect of the Guthrie collection being considered as a “de facto DNA database”<sup>5</sup> means that these issues require on-going attention. Equally, as the transformative potential of biomedical collections grows at an exponential rate – bringing potential changes for health and well-being at the individual, local and global level through networked sharing of resources and data – the need to institute robust and flexible governance mechanisms has never been greater. These must perform the dual role of protecting the personal interests of people whose samples and data form the basis of the collection while also responsibly promoting legitimate uses of the collection as a valuable research resource that can realise the potential that they hold.

1.4 This report argues that a robust, flexible and adaptive system is required to govern the collection and deliver on these dual aims. This must remain fit-for-purpose over time and must strike a delicate balance between maximising the value of the collection as a public resource to be managed for the public good while minimising the risks to individuals whose samples and data are held as part of the collection. Evidence suggests that current practices could be improved towards an optimal governance system for the collection and which would strike the appropriate balance of interests. An important feature of this system would be its ability to engage with citizens on issues about how the resource is managed and run, including future dynamic ways that people can contribute to the resource and benefit from it.

1.5 The legal landscape is complicated because the collection contains both personal information and DNA samples and the law treats information and tissues differently. Nonetheless, there is evidence that the collection is treated as part of the health record in Scotland, making it subject primarily to data protection legislation; this is in keeping with recent human rights pronouncements about how DNA samples should be treated and suggests an obvious regulatory framework. A first question to address is the legal position with respect to the collection. Thereafter, even if it is the case that data protection is the primary legal concern, careful and sensitive exercises of judgment will have to be made about granting access to, and allowing use of the resource. Governance arrangements must be robust and inspire confidence. Our work on public engagement has informed the recommendations on what good governance might look like in order to deliver these objectives.

1.6 The report details options for consideration as to how practices could be improved. In some cases it makes specific recommendations for action; in others, it identifies opportunities for future dialogue about this and other biomedical collections. It is argued that public engagement should be undertaken in the development, implementation and on-going operation of policies with respect to the collection and potential and future uses.

1.7 The remainder of this report is organised as follows:

**Chapter 2** outlines current practice and the challenges associated with the collection, especially in light of recent experiences in other countries involving the management of similar collections.

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<sup>5</sup> Genewatch, ‘Keeping blood spots from newborn babies’, January 2006, available at: <http://www.genewatch.org/pub-507666>

**Chapter 3** details that core considerations for this report, that is, the factors that must be taken into account in delivering an appropriate governance mechanism and when balancing the range of interests at stake.

**Chapter 4** explores the legal basis for the collection

**Chapter 5** examines issues related to consent and anonymisation

**Chapter 6** is concerned with matters of storage and access

**Chapter 7** addresses governance

**Chapter 8** considers public attitudes and the role of public engagement in addressing the range of issues identified

**Chapter 9** concludes with a summary of questions for consideration and offers recommendations on how various challenges could be met as well as opportunities for dialogue about the future direction of biomedical collections.

## CHAPTER 2 - CURRENT PRACTICE & CURRENT ISSUES

2.1 This chapter outlines current practice with respect to the Guthrie collection and asks key questions about the legal, ethical and social issues arising from that practice. Subsequent chapters will address each of these questions in turn. The discussion is set against the international scene from which Scotland has much to learn.

### Key questions are:

- **Is it lawful to continue to hold the collection when consent has not been obtained from the majority of people whose cards are kept? Which laws apply to the collection, who is responsible, and what are their obligations?**
- **Should specific consent be sought from all persons whose blood spots and data are held as part of the collection? What are the arguments for and against this approach? What does the law and good practice require? What are the alternatives?**
- **Can the collection be kept and used if the cards are anonymised? Is it possible or practical to do so? What are the pros and cons of anonymisation?**
- **What kinds of uses should the collection be put to and which are lawful? Should access be allowed for health research? What about non-health research? What is the position about future requests about police access and access by commercial companies?**
- **Who is legally liable if things go wrong? Can existing oversight bodies in Scotland assist with the governance challenges of the Guthrie collection?**
- **What do the public think about the Guthrie collection? How far, and how, should public opinion shape the use of the collection over time? Is a public education campaign needed? How could this be achieved?**
- **Can lessons be learned from other countries or other biomedical collections?**

### Current practice

2.2 The Scottish collection of Guthrie Cards was started in 1965. Between 1965 and 2005 (when the current computerised database was introduced) 2.5 million cards were collected. New cards are initially stored in chronological order at the Southern General Hospital (SGH), Glasgow. Cards over two years old are then kept in secured document storage at optimum temperature and humidity. All of this is done under the auspices of Greater Glasgow and Clyde Health Board. Thus, unlike the position in the rest of the United Kingdom, **one entity is primarily responsible**

**for the management and governance of the collection. This brings considerable advantages in terms of consistency of policies and streamlining of procedures as well as clear lines of legal responsibility.** However, this custodian of the collection must interact with a number of other local and national bodies in ways that can leave lines of accountability unclear. For example, SGH operates within NHS Greater Glasgow and Clyde Health Board, and both in turn are subject to oversight by Healthcare Improvement Scotland (HIS) as the national inspectorate body for quality care and services.<sup>6</sup> Furthermore, NHS Research Scotland was established in 2009 in order to ensure that NHS Scotland provides the best possible environment to support health research.<sup>7</sup> NHS Research Scotland has issued National Guiding Principles for Governance of NHS Scotland Tissue for Research and these principles are monitored by the Accreditation Scheme for the Collection and Storage of NHS Tissue in Scotland, operated by Healthcare Improvement Scotland.<sup>8</sup> All Scottish biomedical collections – known as biorepositories – must adhere to these Principles. More details are required, however, on what happens if something goes wrong. Boards are accredited by Healthcare Improvement Scotland and therefore accountable for their practices, but the position on sanctions could be more transparent. Similarly, the possible sanction that a Board might impose on a biorepository operating under its auspices is also unclear.

2.3 As stated, for the first two years the Guthrie collection is held and maintained by the Scottish Newborn Screening Laboratory within SGH. This is a National Specialist Service commissioned and funded by the National Services Division (NSD) and in turn this is a division of NHS National Services Scotland (NSS).<sup>9</sup> Additionally, **the collection is subject to guidelines and policies issued by both the UK National Screening Committee<sup>10</sup> and the UK National Screening Programme Centre,<sup>11</sup> albeit that each part of the UK determines when, and how, to put the policies into practice.**<sup>12</sup> This further complicates the chains of accountability.

2.4 Since 2005, when a new card was introduced in Scotland, the blood spots and the personal information have been separated as soon as they reach the Glasgow laboratory, and the personal information has been entered in a database. **Both parts of the card (bloodspot and personal information) are bar coded, which means that the cards are not irreversibly anonymised. This has implications for personal privacy.**

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<sup>6</sup> <http://www.healthcareimprovementscotland.org/> (established 1 April 2011).

<sup>7</sup> <http://nrs.mtcserver8.com/> (last visited 8 April 2013). For the strategy see: “Investing in Research|Improving Health: The Research Strategy for Health and Healthcare” (2009), available at - <http://www.nhsresearchscotland.org.uk/cms/documents/CSO%20Investing%20in%20Research%20-%20Improving%20Health.pdf>

<sup>8</sup> For details of the Accreditation Scheme (2011), see [http://www.sehd.scot.nhs.uk/cmo/CMO\(2011\)07.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2011)07.pdf). Note, Para 4 of the Scheme makes it explicit that it extends to the Guthrie card collection.

<sup>9</sup> NSS is a non-departmental public body. As such, it is subject to Freedom of Information requests and applications for judicial review of its policies and decisions.

<sup>10</sup> <http://www.screening.nhs.uk/about>

<sup>11</sup> <http://newbornbloodspot.screening.nhs.uk/programmecentre>

<sup>12</sup> <http://www.screening.nhs.uk/policyreview>

2.5 With the exception of cards from 2000-2005, cards already stored have not been catalogued. As the old cards did not permit separation of the blood spots from the data, personal information and the blood samples are kept together. In 2007, the laboratory introduced a policy whereby new cards are kept at -20C degrees for two years and then moved and stored in a temperature controlled environment thereafter. These observations have implications for security, quality assurance procedures, data management procedures and, ultimately, effective and protective use of the resource.

2.6 From 1965 to 2003, consent to inclusion in the Guthrie collection was 'presumed', and parents were not told that the cards were to be kept. Since 2003, however, written consent has been sought from parents.<sup>13</sup> Currently, parents of newborn babies in Scotland are offered the opportunity to have their baby screened for five conditions: Phenylketonuria (PKU), Congenital Hypothyroidism, Cystic Fibrosis, Medium Chain Acyl - CoA Dehydrogenase Deficiency (MCADD) and Sickle Cell Disorders (SCD). The consent form in Scotland allows parents to choose to have their babies screened for individual tests, all tests, or none of the tests. **Thus, while current practice is based on a model that aspires to "informed consent", the majority of the collection is held without any such consent.**

2.7 If parents choose to have their baby screened for one or more of the tests, the newborn blood spot card is retained, in the first instance, for a 12-month testing period, so that tests may be repeated if necessary.<sup>14</sup> Scottish practice on initial retention is different from the practice in England where newborn blood spot cards are retained for a minimum of 5 years, in keeping with the UK Newborn Screening Programme Centre's Code of Practice for the Retention and Use of Residual Blood Spots.<sup>15</sup>

2.8 In Scotland, at the time initial consent for the tests is requested (5-7 days after birth), parents are also asked to provide permission to allow the blood spot card to be stored beyond the 12-month testing period and the information leaflet states: "Left over blood spots can also be used anonymously for other monitoring and laboratory purposes such as comparing different screening methods and developing new tests. Occasionally it is necessary to use identifiable specimens, in which case the parents' permission would always be sought. If you do not want the stored blood spot card to be used for research, please ask the midwife to write 'no research' in the comments box on the blood spot card."<sup>16</sup> It is confirmed that parents are not asked when research is done anonymously, but will be approached if they or their baby can be identified. **The wording of the leaflet raises two important issues: (1) are parents being invited actively to consent to retention or to opt-out of retention? This is**

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<sup>13</sup> This was initiated because Scotland started screening for Cystic Fibrosis at that time. The CF test is done in two stages; the second stage involves DNA analysis, which was a departure from the kinds of tests that were done previously. Due to sensitivity around DNA testing, explicit consent was introduced for newborn blood spot screening.

<sup>14</sup> "Your Guide to Newborn Screening Tests" (2012):  
<http://www.healthscotland.com/documents/4258.aspx>

<sup>15</sup> Newborn blood spot screening in the UK – Policies and Standards, April 2005. ISBN 0955013801, available at: <http://newbornbloodspot.screening.nhs.uk/cms.php?folder=2547>. This document remains current and embodies as Code of Practice on how the retained Guthrie cards will be used, see:

<http://newbornbloodspot.screening.nhs.uk/public#13>

<sup>16</sup> Your Guide to Newborn Screening Tests, p20, n14 above.

important for parental expectations and also practically in terms of what will be done in the event that the comments box is left blank. Moreover, does a non-response indicate meaningful consent or is it mere silence? (2) The informed nature of any apparent assent is very limited. The expression “[m]onitoring and laboratory purposes” suggests a narrow range of use and yet the potential research uses of biomedical collections such of these is extensive. This raises issues for consent and governance and we explore these later in the respective chapters.

2.9 If parents do not agree to allow the retention of the blood spot card beyond the 12-month testing period, the card is destroyed;<sup>17</sup> otherwise, parents can agree to continued retention of their child’s card either in the health interests of the child only, or for research purposes. **Retention after the initial 12-month period becomes de facto indefinite retention, although operational practice is to respect subsequent wishes for destruction.**<sup>18</sup> The NHS Research Scotland Guiding Principles make it clear that any biorepository that receives a written request for destruction of samples and data must comply so far as this is practicably, i.e. – sometime data might no longer be within the control of the biorepository managers.<sup>19</sup>

2.10 In governance terms, the Scottish collection is subject to the guidance of the UK Newborn Screening Programme Centre on issues such as quality assurance and performance management and the UK National Screening Committee which advises on screening policy. The Greater Glasgow & Clyde Health Board has an independent Biorepository Governance Board that considers operational matters for the Guthrie card collection and this includes requests for access. Primary responsibility for receiving recommendations in this report must, accordingly, rest there. As a first step, however, the Board must address issues of transparency.<sup>20</sup> This must be an immediate priority given the extensive issues to be addressed – and lessons from other countries which have arisen in large part because of lack of transparency (see further below).

## Current issues

### *Is the collection lawful?*

2.11 The legal status of the Guthrie card collection in Scotland has never been tested in court nor addressed directly by Parliament. Current arrangements operate on a complex 'soft law' hybrid approach whereby the UK Newborn Screening Programme Centre has issued a Code of Practice (2005) and Standards Guidelines (2008;<sup>21</sup> 2013 Consultation report<sup>22</sup>) but leaves regions to decide on best practice

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<sup>17</sup> Procedures exist to record parental wishes about use/non-use and parents who express a wish that retention does not continue after 12-months are re-contacted to confirm this.

<sup>18</sup> Pers. comm.

<sup>19</sup> Available on request from Chief Scientist Office.

<sup>20</sup> <http://www.nhsggc.org.uk/content/default.asp?page=s1685>.

<sup>21</sup> UK Newborn Screening Programme Centre, Standards and Guidelines for Newborn Blood Spot Screening, August 2008.

<sup>22</sup> UK Newborn Screening Programme Centre, Consultation on the newborn blood spot screening standards mapped to the generic standards framework: 20th December 2012 – 4th February 2013 - Consultation report, March 2013: <http://newbornbloodspot.screening.nhs.uk/standards-consultation-2012-13>.



independently. This has given rise to disparate approaches to the Guthrie collections around the UK. For example, information leaflets to parents are not standardised and the range of parental options differ between the countries (i.e. Scotland gives a one-year retention option while this is not available in England). Furthermore, while England has carried out a public consultation,<sup>23</sup> no specific public engagement has thus far taken place in Scotland.

2.12 Furthermore, the legal landscape in Scotland can at times differ from the rest of the United Kingdom. This is particularly true with respect to human tissues because the Human Tissue Act 2004 does not, with a notable exception, extend to Scotland. Similarly, freedom of information requests are dealt with under specific Scottish legislation.<sup>24</sup> In contrast, the Data Protection Act 1998 is a UK-wide statute with no Scottish variations. Thus, to the extent that the Scottish collection involves both human samples *and* personal data the legal framework is a complicated network of domestic and UK-wide provisions. From a policy and procedural perspective, however, Scotland has a wide degree of autonomy and discretion in its approach to storage and use of the collection. We discuss the legal status of the collection in Chapter 4.

### ***Is informed consent to the collection required?***

2.13 The Scottish collection began at a time when medical matters were subject to a lot less oversight than happens today. In particular, consent from patients or relatives was not the norm, as it has since become. Consent to Guthrie card collection, storage and use became the norm in Scotland in 2003 for all newborns and is now routine; this nonetheless means that the majority of the existing collection is held without explicit consent from the persons to whom it relates or from their parents if they are still children. If the continued holding of the collection were to be contingent on explicit consent this would raise a plethora of ethical, practical and economic problems. But is this what the law or good practice requires? Would it be practical or desirable? We discuss the role of consent in Chapter 5.

### ***What can the collection be used for?***

2.14 This report comes at a time when there is both increased interest in the value of public collections such as Guthrie cards and well as increased scrutiny of their very existence, let alone their continued storage and use. As interest in use grows, so too does the number of associated ethical, legal and social issues and potential challenges. Whereas the original purposes for the taking of samples is, and always has been, determinedly the health interests of the child, Guthrie collections around the world can and are put to an increasingly wider range of purposes and uses going beyond individual health interests; among others, these extend to societal health interests and other so-called public interests such as (health) research more

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<sup>23</sup> In March 2004, a public consultation on “Telling parents about the heel-prick test” was undertaken by Stewart, Hargreaves and Oliver, report available at: <http://newbornbloodspot.screening.nhs.uk/cms.php?folder=2488>; another consultation was held in 2005 on the “Storage and use of newborn babies blood spot cards: a public consultation” (Oliver, S, Stewart, R, Hargreaves, K and Dezateux, C. London: Social Science Research Unit, Institute of Education, University of London); however, the report of this consultation is not yet available.

<sup>24</sup> Freedom of Information (Scotland) Act 2002. In the rest of the UK the law is contained in the Freedom of information Act 2000.

generally, and the detection and prosecution of crime. Police access has been granted in the past, for example, for identification of deceased persons (see Chapter 6 below). Recently, there has been an increase in requests from research groups interested in gaining access to cards in the Scottish collection. The legitimacy and lawfulness of granting access for a wide range of purposes or uses is discussed in Chapter 6 below.

### **Who is responsible for the collection and what does this mean?**

2.15 Scotland has a robust mechanism of research governance and ethical approval but the governance framework for the collection is complex and multi-levelled. We have seen above the arrangements for custodianship of the Guthrie card resource and how this implicates local, regional and national bodies. Matters are complicated further as the transformative potential of such a biomedical collection becomes stronger. For example, it is well-recognised that the full promise of these resources will only be realised through national and international networks of data and sample sharing.<sup>25</sup> In governance terms, this means that no collection stands alone and those seeking access must engage with a range of mechanisms. For example, as well as a sophisticated system of local and multi-centre research ethics committees, the Privacy Advisory Committee (PAC) operates in Scotland under the auspices of NHS National Services Scotland (NSS) to advise the Information Services Division of NHS Scotland (ISD) and National Records of Scotland (NRS) on requests for research access to data in the Scottish Medical Record without explicit consent and/or if linkage of data which might pose an increased risk to patient privacy. As a body operating under NSS (in the same way as the National Screening Laboratory) there may be a role for PAC in delivering good governance for the Guthrie Card collection. That said, the remit of PAC does not extend to access to samples (as opposed to patient data) nor does it cover resources held exclusively within health boards. It would only be in circumstances where there was a proposal to link Guthrie data with ISD or NRS data that PAC would have a say. This suggests a fragmented regulatory landscape. At the international level, questions arise about whether data and samples can or should be sent abroad, under what conditions, and with which responsibilities. We discuss possible governance mechanisms in Chapter 7 below.

### ***What does the public think? Should the public be involved more?***

2.16 Public perceptions and attitudes have an important and growing role to play in the development of robust and acceptable policies within the healthcare setting. Whereas once consent was the exception rather than the rule, today the converse is true. Moreover, law and public perception do not necessarily coincide so that what is lawful might nonetheless be unacceptable to a majority or vocal minority of the Scottish public. There is no need to rehearse the sensitivities that surround the (mis)handling of patient information or samples, but equally it is essential to consider whether and how public opinions can inform health policies and the operation of biomedical resources now and in the future. We discuss public attitudes in Chapter 8 below.

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<sup>25</sup> See, for example, J. Kaye, 'From single biobanks to international networks: Developing e-governance' (2011) 130(3) *Human Genetics* 377-382.

## What lessons can we learn from other countries?

2.17 The practice of retention of newborn screening cards has been commonplace in many countries since the 1960s. The phenomenon began at a time when social and ethical expectations were very different to those of today. These have changed considerably over time. Furthermore, the potential value of these collections has also grown over the decades both with advances in genetic analysis and also with the prospect of effective linkage to medical and other records.<sup>26</sup> This means that the nature and balance of the sum total of interests has shifted – as the public interest in these collections has increased, so too has the interest of private citizens in the secure and robust retention of their data and samples. A failure to appreciate and respond to these changing social circumstances has left the status of many collections in a legal and ethical limbo.<sup>27</sup> In some cases, a failure to engage families and publics about the existence and possible uses of such resources has resulted in numerous high-profile destructions of entire collections.

2.18 The most high-profile example of destruction comes from Texas. The state of Texas collected 5.3 million card samples from children between 2002 and 2009 and these were used, among other things, for anonymised research in 8350 cases and always with ethics committee approval. Research projects, including investigations into genetic causes of deafness, were published on the Department of State Health Service website. In a very small number of cases – 200 out of 5.3 million – identifiable research was carried out but this was always with the consent of parents. Notwithstanding these arrangements, the Texas Civil Rights Project brought a class action against the state of Texas for alleged violation of federal constitutional rights, notably that the unconsented use was an illegal search and seizure.<sup>28</sup> The state lost its motion to dismiss, i.e. – the court held that there were legitimate legal interests in play – and the state finally settled out of court before any action was given a full hearing.<sup>29</sup> The state agreed to destruction of the entire collection, despite its recognised research value. Any hope of reprieve was lost when it emerged that 800 samples had been sent to a federal Armed Forces mitochondrial database to assist in the ethnicity categorisation of remains of missing persons. Crucially, freedom of information documentation revealed that although the state had contemplated publishing the details of this agreement, it decided not to do so because of concerns about public reaction. This significant failure in transparency signalled the final end of the resource.<sup>30</sup> Similar law suits have been brought in the US state of Minnesota<sup>31</sup>

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<sup>26</sup> J. Couzin-Frankel, „Newborn blood collections. Science gold mine, ethical minefield“ (2009) 324 (5924) *Science* 166-8 and J. Wilkinson, „Analysis of Guthrie cards could provide insight into epigenome at birth“ (2012) 4(5) *Epigenomics* 480-1.

<sup>27</sup> See, M. Carmichael, „Newborn screening: a spot of trouble“ (2011) 475 *Nature* 156-158, doi:10.1038/475156a, and M.H. Lewis, A. Goldenberg, R. Anderson, E. Rothwell and J. Botkin, „Blood samples: State laws regarding the retention and use of residual newborn screening blood samples“ (2011) 127 *Paediatrics* 703-712.

<sup>28</sup> *Beleno v Tex. Dept. of State Health Services*, (2009); For commentary, see K. Drabiak-Syed, „Legal regulation of banking newborn blood spots for research: How Bearder and Beleno resolved the question of consent“ (2011) 11 *Houston Journal of Health Law and Policy* 1-46.

<sup>29</sup> For selected docket material from the case and reference to the settlement agreement, see here: <http://iucb.wordpress.com/2010/02/26/newborn-blood-spots-biobanks-the-law-research-ethics-in-the-news/>

<sup>30</sup> For an account of the circumstances, see:

and in the Canadian province of British Columbia,<sup>32</sup> both on grounds of alleged violation of privacy by retention and use of sample and data. There is no uniformity in North America as to the regulation of Guthrie collections.<sup>33</sup>

2.19 It is important to note that these law suits only reveal that the legal status of newborn screening collections is unclear in the particular jurisdictions where the disputes have arisen. Thus, in the Minnesota example the Supreme Court recognised the lawfulness of the existence of the collection but noted that the applicable law restricted many uses to consent-only circumstances, e.g. for research. In the British Columbia (BC) situation, the validity of the legal basis for the plaintiff's claims was in question and the government argued that there was no genuine issue for trial. The Supreme Court of the province held that there was no such genuine issue either with respect to the taking of the samples or their retention for medical purposes. The court suggested that, on an objective view, a reasonable person in the circumstances of the plaintiff would have consented to such storage.<sup>34</sup> As to uses for medical research, this had happened on two occasions with the BC collection on an anonymised basis. Here the court did hold that there was a case to answer: "...it is the use of a sample for purposes other than promoting the health of the infant from whom it was obtained that raises a genuine issue for trial in this case."<sup>35</sup> However, because of the way that the case had been pled to the court, it was not possible for the judge to determine the issue. Instead, it recognised that a case *could* be made and gave the plaintiffs thirty days to amend their claim. To date, no subsequent action has been successfully brought.

2.20 Similar concerns about the legal status of Guthrie collections have arisen in Europe. Despite the existence and operation of collections around the European Union, the Irish Health Service Executive issued a notice of destruction in 2009<sup>36</sup> because it was concerned about breaches of European data protection legislation for want of explicit parental consent for retention and use of the resource. However, in a last minute reprieve, the Minister for Health issued a statement in March 2013 in which he announced a further review of the collection, and in particular an assessment of the legality of other European collections and the implications for Ireland. Minister James Reilly "...communicated his deep concern to the HSE that no action should be taken in relation to the destruction of Guthrie cards until an expert

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<http://www.genomicslawreport.com/index.php/2010/03/16/the-texas-newborn-bloodspot-saga-has-reached-a-sad-and-preventable-conclusion/>

<sup>31</sup> S. Hu, 'Minnesota Supreme Court hears whether the Genetic Privacy Act protects newborn blood spot samples obtained under the state's newborn screening statutes--Bearder v. State of Minnesota.' (2012) 38(1) Am J Law Med 225-7.

<sup>32</sup> See L.D. (Guardian ad litem of) v. Provincial Health Services Authority (2011) BCSC 628.

<sup>33</sup> M.H. Lewis, A. Goldenberg, R. Anderson, E. Rothwell and J. Botkin, 'State laws regarding the retention and use of residual newborn screening blood samples' (2011) 127 Paediatrics 703-712. For an argument for harmonisation of guidance, see: B.L. Jr Therrell, W.H. Hannon, D.B. Jr Bailey, E.B. Goldman, J. Monaco, B. Norgaard-Pedersen, S.F. Terry, A. Johnson, and R.R. Howell, 'Committee report: Considerations and recommendations for national guidance regarding the retention and use of residual dried blood spot specimens after newborn screening' (2011) 13(7) Genetic Medicine 621-4.

<sup>34</sup> Note 32, at paras 51-55.

<sup>35</sup> Id., at para 58.

<sup>36</sup> See, R. McGreevey, "Calls for 'priceless resource' of heel prick test results to be saved", The Irish Times, 5 February 2013, available at: <http://www.irishtimes.com/news/health/calls-for-priceless-resource-of-heel-prick-test-results-to-be-saved-1.1254279>

group can meet and that the group considers how these cards could be archived and maintained in a manner that meets the data protection commissioner's concerns".<sup>37</sup>

2.21 Part of the concerns in Ireland were motivated by development in New Zealand and Australia. For example, while in New Zealand the retention and use of the blood spot collection is authorised by law, any population research on samples older than June 2011 can only be done with explicit consent. Importantly, however, other kinds of research do not necessarily require consent so long as there is appropriate ethical approval.<sup>38</sup> In Australia, the governance of collections is state-based albeit that there is no specific legislation in any single state and recommendations for national guidance have not been developed.<sup>39</sup> In Victoria, a Review Committee recommended that consent be the basis for future collection and use,<sup>40</sup> while in Western Australia police access to the Guthrie collection to investigate an alleged case of incest led to a policy of destruction of all cards older than two years.<sup>41</sup>

2.22 The lessons to be learned for Scotland are:

- The importance of determining the legal status of the collection
- The need to determine current and future uses of the resource
- The relative role and importance of consent in governing the collection
- The considerable value of transparency in all processes
- The vital importance of public engagement in determining the future of the collection.

2.23 The next chapter outlines the considerations which are in play in this discussion and offers a framework to approach the particular issues outlined above.

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<sup>37</sup> See, M. Houston, "Reilly does U-turn ordering HSE not to destroy newborn blood samples - Heel prick cards to be retained until expert group reports", *The Irish Times*, 26 March 2013, available at: <http://www.irishtimes.com/news/health/reilly-does-u-turn-ordering-hse-not-to-destroy-newborn-blood-samples-1.1338666>.

<sup>38</sup> See Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 (SR 1996/78), Right 7(10), and for a lay explanation The NZ National Screening Unit: <http://www.nsu.govt.nz/current-nsu-programmes/2917.aspx>.

<sup>39</sup> Australian Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia* (2003), chapter 19.

<sup>40</sup> Victorian Newborn Screening Review Committee, *Final Report for the Minister for Health* (2006), available at: [https://www.privacy.vic.gov.au/privacy/web2.nsf/files/victorian-newborn-screening-review-committee-final-report/\\$file/report\\_08\\_06.pdf](https://www.privacy.vic.gov.au/privacy/web2.nsf/files/victorian-newborn-screening-review-committee-final-report/$file/report_08_06.pdf)

<sup>41</sup> See D.M. Bowman and D.M. Studdert, 'Newborn screening cards: a legal quagmire' (2011) 194(6) *Medical Journal of Australia* 319-322, at 319 quoting Office of the Victorian Privacy Commissioner, *Submission to the Forensic Procedures Review Committee on its review of Part ID of the Crimes Act 1914 (Cth)*. (2002) Melbourne: Privacy Victoria.

## **CHAPTER 3 - CORE CONSIDERATIONS FOR THIS REPORT: PERSONS, PURPOSES AND PROCEDURES**

3.1 It is important to identify the core concerns associated with the collection, storage and use of Guthrie cards in Scotland in order to inform adequately the discussion and recommendations in this report and the future policies applied to the collection. We suggest that the core considerations relate to: Persons, Purposes and Procedures.

### **Key questions to ask of the collection are:**

- **Which persons are affected by the collection and how?**
- **What purposes are envisaged for the collection, now and in the future, and how legitimate are these purposes?**
- **What procedures are required to respect persons and to legitimate purposes?**

### **Key messages from this chapter are:**

- 1. It is essential to consider the full range of people affected by the collection. Different people might be affected in different ways and different legal rules might apply to them.**
- 2. It is essential to consider the full range of purposes for which the collection might be used, both now and in the future. Although a range of purposes might be justified, the case for each use must be clearly made. The justifications must be all the stronger as the use becomes more about the public interest and less about each person's health interest.**
- 3. It is essential that clear, transparent and robust policies are in place for every aspect of the collection from initial taking of consent and samples, to storage, quality assurance, access and contingency planning.**

## **DISCUSSION**

### ***Persons***

3.2 We have already indicated that the long-term nature of this collection in Scotland and its prospective expansion raise particular issues and it may not be the case that a one-size-fits-all approach is possible or desirable. From the perspective of persons affected by their inclusion in the collection, we suggest that there are at least five (5) discrete categories of persons to consider. These are:

1. Persons who are now adults and for whom consent was never given (1965-1997)

2. Persons who are still children but for whom consent was never given (1997-2003)
3. Persons who are still children and whose parental consent has been given (2003-now)
4. Persons who have died since the collection began
5. Future persons and whether and how their samples should be obtained and retained.

3.3 The relevance of this categorisation turns around the crucial date of 2003 when informed consent procedures were introduced. It does not necessarily follow, however, that because consent is now obtained that it should be sought from all of those for whom consent was never sought or who might now be in a position to consent for themselves. The relevance of death is also legally significant, for example, because the requirements of the Data Protection Act 1998 do not apply to deceased persons (although the common law duty of confidence continues after death). Furthermore, as regards future persons it may be the case that current consent procedures can be improved. Overarchingly, while explicit consent might not be necessary or practicable, it is nonetheless important to offer an opt-out system for all who would choose it. This is now provided for by NHS Research Scotland National Guiding Principles for Governance of NHSScotland Tissue for Research.

### ***Purposes***

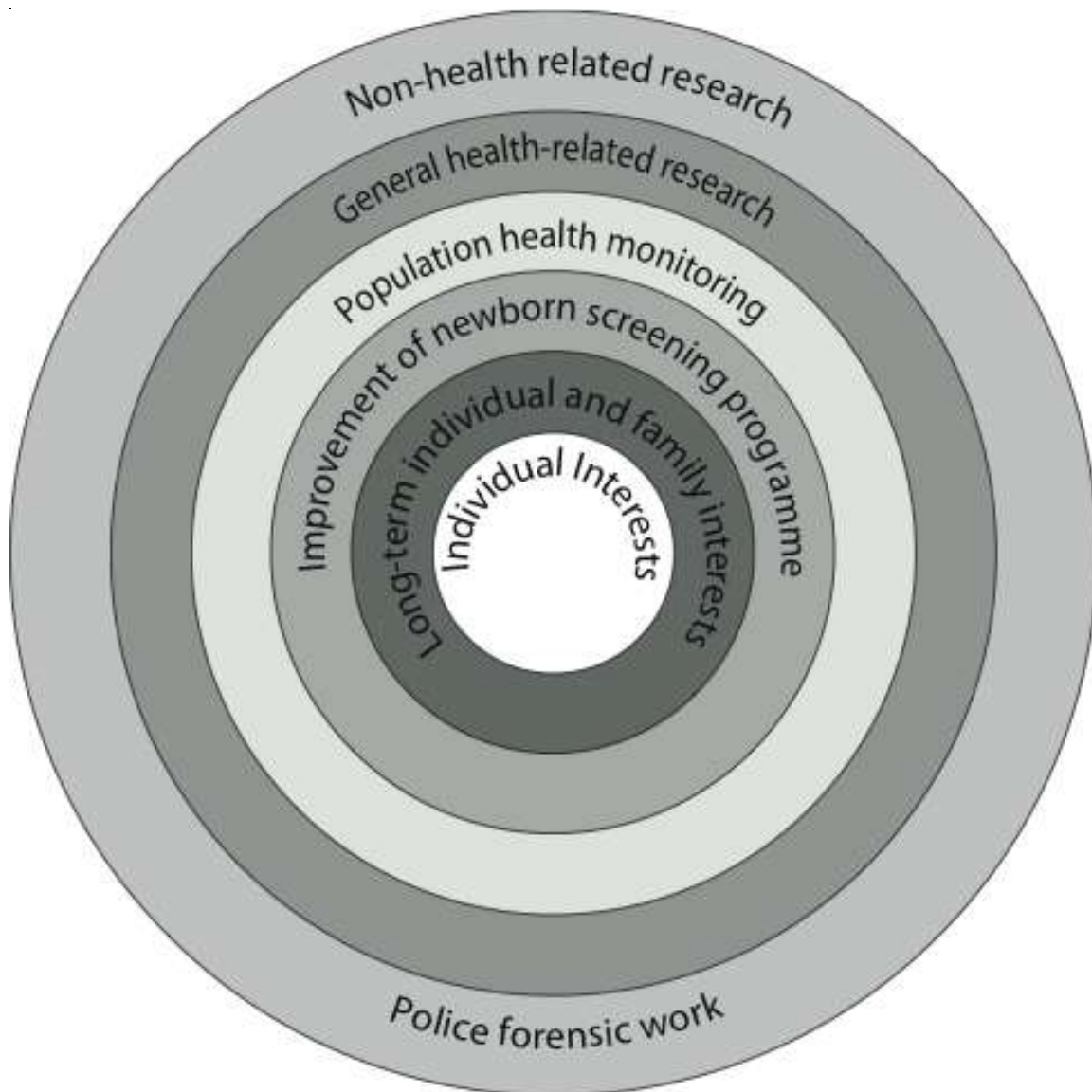
3.4 It is important to consider current and future purposes of the resource because legal and ethical legitimacy of the collection is framed around the purposes for which samples are taken, stored and used.<sup>42</sup> Different purposes will have a different impact on different categories of persons. What, then, is the range of current purposes and what are future purposes likely reasonably to be? What possible impact might these various purposes have on different categories of persons and their interests?

3.5 It is helpful to consider the range of purposes in the form of a series of concentric circles, with the individual and his or her health interests at the centre of that circle – indicating what should be the primary focus of our attention - and wider societal interests occupying the outer circles - indicating that as we move further away from the individual stronger justification of purposes is required.

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<sup>42</sup> The UK Newborn Screening Programme Centre's website sets out the various uses of the stored blood spots: 1. To monitor and improve the newborn screening programme; 2. To directly benefit individuals and their families; 3. To monitor the health of the general population; 4. To answer questions about specific health problems; 5. To develop new equipment and tests; 6. For police forensic work. See: <http://newbornbloodspot.screening.nhs.uk/FAQs>.

Figure 1:



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3.6 The list of current purposes includes:

- the immediate health benefit of the child (PKU etc.)
- the longer-term interests of individuals and their families (e.g. causes of infant or childhood death or disease; the identification of familial genetic conditions; the identification of deceased persons)
- the monitoring and improvement of the newborn screening programme (i.e., for the interests of newborns and families generally)
- the monitoring of the health of the general population (e.g. rates of HIV infection, genetic markers in childhood diseases etc).

The list of possible future purposes includes:



- Health-related research generally (which might include linkage to other information leading to, or increasing the risk of, identifiability of specific individuals)
- Non-health related research, e.g., proposals for access by insurers or employers (should this ever be contemplated)
- Forensic police work: There are two broad purposes under this category: (i) the identification of dead or missing individuals, (ii) the detection and prosecution of crime.

3.7 Factors which might complicate the issues surrounding these purposes include the prospect of access by those with commercial interests, e.g. research undertaken by large-scale pharmaceutical companies. While this is a reality, it could raise broader concerns. For example, some public attitude surveys suggest a degree of discomfort among some sectors of the public when public health resources are used to generate excessive private profit.<sup>43</sup>

3.8 While the importance of an individual's interests is fundamental, those interests, or indeed their individual rights, are rarely (if ever) absolute. That is, while individuals can claim certain rights, such as the right to respect for private life, it is often the case that exceptions exist and rights can be interfered with so long as just cause is shown. In the language of human rights, for example, interference with the individual's right to respect for private life is justifiable if that interference is *necessary, proportionate* and is reasonably likely to further other legitimate social ends. These include: "...the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."<sup>44</sup>

3.9 The core lesson here from a legal perspective is that likely interferences with individual rights must be fully explained and justified. The same is true from an ethical perspective, viz, purposes, policies and procedures must be robust and defensible even if they are not necessarily accepted by all persons affected. Furthermore, for those persons who disapprove of particular purposes it is prudent, and indeed necessary, to offer an opt-out system which at the same time as respecting their individual choice does not necessarily undermine the public interest in the resource itself (see now the NHS Research Scotland Guiding Principles).

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<sup>43</sup> G. Haddow, G. Laurie, S. Cunningham-Burley and K.G. Hunter, 'Tackling community concerns about commercialisation and genetic research: A modest interdisciplinary proposal' (2007) 64 Soc Sci & Med 272-282.

<sup>44</sup> See Article 8(1) and 8(2) of the European Convention on Human Rights as incorporated in the Human Rights Act 1998.

## Procedures

3.10 It is important to consider procedures because transparency, accountability and trust can, in large part, be built around well thought-through and well-executed processes for decision-making, quality assurance, governance and public engagement. Central to this is the value of Standard Operating Procedures (SOPs). Which exist? How fit for purpose are they? Which need to be introduced? Why and how?

3.11 The UK Newborn Screening Programme Centre (UK NSPC) has a range of existing procedural documents covering many aspects related to initial taking and storage of blood spots. For example, these include information about communicating with parents, ensuring high quality blood spots, laboratory quality assurance guidelines and implementation and reporting guidance with respect to UK-wide policies on newborn screening.<sup>45</sup>

3.12 In August 2008, the Centre produced updated *Standards and Guidelines for Newborn Blood Spot Screening*, and stated that: “Central to the development of policies are standards that underpin the performance management of the blood spot screening programme. Their purpose is to assure the quality of the screening process and ensure that babies who may have one of the conditions for which screening is offered receive timely medical treatment.”<sup>46</sup> These were subject to a recent consultation exercise, the report on which was published in March 2013.<sup>47</sup> 133 responses were received, including from parents, parent representative groups, health professionals and professional bodies. Scotland was included in the recent consultation.

3.13 NHS Quality Improvement Scotland has developed *Clinical Standards for Pregnancy and Newborn Screening (2005)*<sup>48</sup> reflecting the above and which require in particular that “All women/parents/carers receive clear information (written or in other formats) to help them to make an informed decision about newborn bloodspot screening” [Statement 4b].

3.14 These procedures focus, rightly, on the health interests of each infant and the quality of the samples and data collected. As we have seen, however, longer-term storage for a wider range of purposes have different impacts. First and foremost, these impact on the quality of the consent that is obtained and the degree and quality of information given to parents. Both England and Scotland have documentation available to parents which mention (in superficial detail) the possibility of research but not the possibility of police access;<sup>49</sup> and while the range of possible uses is contained in the UK NSPC 2005 Code of Practice and on its website, it is not entirely clear how well lines of communication between health professionals and parents join up in practice. The UK NSPC Health Professional Handbook 2012 details procedures

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<sup>45</sup> See further: <http://newbornbloodspot.screening.nhs.uk>

<sup>46</sup> <http://newbornbloodspot.screening.nhs.uk/standards#fileid10827>

<sup>47</sup> Available at: <http://newbornbloodspot.screening.nhs.uk/standards-consultation-2012-13>

<sup>48</sup> Available at:

[http://www.healthcareimprovementscotland.org/previous\\_resources/standards/pregnancy\\_and\\_newborn\\_screen.aspx](http://www.healthcareimprovementscotland.org/previous_resources/standards/pregnancy_and_newborn_screen.aspx)

<sup>49</sup> See the leaflet on newborn blood spot screening at:

<http://newbornbloodspot.screening.nhs.uk/languages>; and NHS Scotland, Your Guide to Newborn Screening Tests, available at: <http://www.healthscotland.com/uploads/documents/20214-YourGuidetoNewbornScreeningTests.pdf>

to discuss and record decisions about research, but again makes no mention of police or commercial access/uses.<sup>50</sup> Robust procedures can address this.

3.15 More broadly, the contemplation of other purposes beyond individual health interests need both to be articulated and communicated clearly and to be handled appropriately. This turns on procedures with respect to access. In research terms, there already exist detailed governance frameworks within the health service which can be deployed to guide researchers in seeking access to the resource and which also could act as a safeguard for patient rights and interests. The NHS Research Scotland Guiding Principles mentioned in para 2.2 are a suitable locus for details on access terms and conditions.

3.16 In police terms, it can matter very much whether the Guthrie collection is seen as part of the medical record in Scotland or is sui generis (of its own kind). Different procedures might apply depending on whether the request for access is to “information” or to a physical object (e.g. a blood sample). Finally, as for future un-contemplated requests for access – for example, non-health related research - clear procedures and lines of authority and accountability can help to ensure that these are dealt with timeously and appropriately and can provide decision-makers with guidance as to the relevant factors and considerations to be taken into account in making a final decision. A commitment to openness about these procedures and any uses that are made of the collection can also help to dispel concerns as well as facilitate an opt-out option for those who wish to use it.

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<sup>50</sup> [newbornbloodspot.screening.nhs.uk/getdata.php?id=10953](http://newbornbloodspot.screening.nhs.uk/getdata.php?id=10953)

## CHAPTER 4 – THE LEGAL BASIS OF THE COLLECTION

### Key questions addressed by this chapter are:

- Is it lawful to continue to hold the collection when consent has not been obtained from the majority of people whose cards are kept?
- Which laws apply to the collection, who is responsible, and what are their obligations?

### Key messages from this chapter are:

- Different legal regimes govern the Guthrie collections in England and in Scotland. In England, the collection would appear to be treated as ‘tissue’, and therefore subject to the Human Tissue Act 2004. This Act does not apply to Scotland, with the notable exception of section 45 (criminal offence of non-consensual DNA analysis). In Scotland, the collection appears to be treated as part of the health/medical record and is, therefore, subject to the provisions of the Data Protection Act 1998, which must also be read with the common law of confidentiality.
- The lawfulness of continued retention and use of the collection depends on compliance with the Data Protection Act 1998, the relevant provision of the Human Tissue Act 2004 (section 45), and the common law of confidentiality. Professional guidance and prior commitments made to the Scottish public might also constrain future retention and use.
- For the avoidance of doubt and to protect the full range of individual interests at stake, the Guthrie collection should be treated as both personal information and human tissue for the purposes of robust governance.
- Consent to use is not an absolute requirement of the law but should not be departed from lightly.
- Anonymisation can remove some legal obligations but not all obligations; moreover, it is not a complete answer to the challenges thrown up by the collection.
- Human rights are a consideration across all areas of law. All mechanisms, policies and procedures should be tested for human rights compliance.

## DISCUSSION

4.1 The legal authority for the existence and continued retention of the Guthrie collection in Scotland is complicated. As an initial and broad consideration, all laws and practices must be viewed through the lens of human rights and all practices with respect to the collection must respect individuals’ human rights. When considering which specific laws might apply to the collection, there are practical and jurisdictional

variations within the United Kingdom which complicate the situation and the overarching influence of European law must also be considered. Practically, the cards contain both physical blood/DNA samples and personal information. We must therefore ask: is the blood spot collection itself a “thing” or information or both or something different altogether? This is not a trivial consideration. It matters very much how these collections are viewed because different legal regimes apply to information as opposed to tissues (and sometimes no specific laws apply at all).<sup>51</sup>

4.2 Further complications arise when we compare the position in England and Scotland. Whereas in England blood samples would appear to be regarded as human tissue, and therefore covered by the Human Tissue Act 2004,<sup>52</sup> in Scotland they appear to be treated primarily as medical records; that said, a single but important provision from the 2004 Act also applies in Scotland and must also be considered (see 4.26-4.32 below).

4.3 For the purposes of discussion, then, we must consider whether the collection should be regarded as (a) information, (b) tissue, or (c) both. The pros and cons of each approach are considered below. All of this is subject to human rights considerations.

### ***The collection as information***

4.4 If the collection is seen as personal information, then the applicable laws are found, in the first instance, in the Data Protection Act 1998 which has application throughout the United Kingdom. The Act is the implementation by the UK government of the terms of the Data Protection Directive that is applicable across all 27 member states.<sup>53</sup> To the extent that the collection as a whole contains information relating to living persons, for example, names, addresses, medical and health data etc, and from which persons can be identifiable, then the provisions of the Data Protection Act 1998 apply to the storage and processing of these data. It is unclear, however, whether a sample such as that containing DNA is *in itself* also personal information for the purposes of these laws. On the one hand the Article 29 Working Party has observed that:

Human tissue samples (like a blood sample) are themselves sources out of which biometric data are extracted, but they are not biometric data themselves (as for instance a pattern for fingerprints is biometric data, but the finger itself is not). Therefore the extraction of information from the samples is collection of personal data, to which the rules of the

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<sup>51</sup> For comment on this fragmented approach to legal regulation of tissue and data, see G. Laurie and S.H.E. Harmon, ‘Through the thicket and across the divide: Successfully navigating the regulatory landscape in life sciences research’ in M Pickersgill and E Cloatre (eds), *Knowledge, Technology and Society: Interrogating the Nexus*, (2013), Routledge.

<sup>52</sup> The HTA 2004 applies primarily in England, Wales and Northern Ireland (except certain sections including section 45, which also applies to Scotland, see further below).

<sup>53</sup> Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281, Nov. 23, 1995.

[EU Data Protection] Directive apply. The collection, storage and use of tissue samples themselves may be subject to separate sets of rules.<sup>54</sup>

4.5 More recently, however, in a ruling against the United Kingdom in the context of the National forensic DNA Database and indefinite retention of DNA samples of persons not convicted of a crime, the European Court of Human Rights ruled that the retention of DNA profiles and cellular samples constitute 'personal data' under the law.<sup>55</sup>

4.6 There is, therefore, powerful legal support for the view that, as a minimum, the entire collection should be treated as 'data'. This means that we should be concerned with personal information held together with the blood samples *and* information derived from those samples *as well as* the samples themselves. The consequence of this is that the entire collection and its uses are subject to data protection law, and we discuss the implications of this in the paragraphs that follow. If this position is not adopted, and rather a distinction is drawn between the physical samples themselves and information derived from the samples or kept with the samples, then the legal position in Scotland is complex because, as we discuss in the next section – *The collection as tissue* – there is very little direct legal authority for this position and this creates uncertainty about the obligations of those responsible for the resource and the rights of people whose tissue are kept as part of the resource.

4.7 There is support in Scotland for the view that the collection should be treated as information. The Guide to the required standards of practice in the management of records for those who work within or under contract to NHS organisations in Scotland (2012) includes newborn screening records and blood spots as health records.<sup>56</sup> The Health Records Retention Schedule draws a distinction between neonatal screening records (presumably for the health interests of the patient) and prescribes a minimum retention period of 25 years, while it provides that newborn blood spot screening cards should be retained for a minimum of 5 years for quality assurance purposes, but that longer retention is recommended in keeping with the Code of Practice of the UK Newborn Screening Programme Centre (2005).<sup>57</sup> Thus, the Guide links purposes and time periods with procedures for justifying on-going retention, although the justification for the periods chosen is less obvious. Unfortunately, helpful instructions from the last version of the document in 2008 – to the effect that parents should be alerted to the possibility of contact from researchers after the minimum period and

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<sup>54</sup> The Article 29 Data Protection Working Party is a group of experts established by the European Commission to advise member states on the implementation and interpretation of the Data Directive which is the basis of the UK's Data Protection Act 1998. See, *Opinion 4/2007 on the concept of personal data*, 20<sup>th</sup> June 2007, (01248/07/EN WP 136). On "separate sets of rules" the Working Party recommends considering the Council of Europe Recommendation No. Rec (2006) 4 of the Committee of Ministers to Member States on research on biological materials of human origin, 15 March 2006.

<sup>55</sup> *S and Marper v United Kingdom* (2009) 48 EHRR 50, para 68.

<sup>56</sup> The Scottish Government, A guide to the required standards of practice in the management of records for those who work within or under contract to NHS organisations in Scotland, [NHS Code of Practice: v2.1.] (2012) p.66. Available at:

<http://www.scotland.gov.uk/Resource/Doc/366562/0124804.pdf>

<sup>57</sup> *Ibid.*

that there should be a record of their consent to contact response – have been removed.<sup>58</sup> **Best practice suggests strongly that these be reinstated.**

4.8 The consequences of treating the entire collection as information are that it becomes subject to the Data Protection Act 1998. This in turn means that the ‘data controller’ – being Greater Glasgow & Clyde Health Board and (possibly also) National Services Scotland - is responsible for compliance with the provisions of the 1998 Act. This includes, for example, that the data are held lawfully and fairly; that the data are processed only for the original purposes for which they were obtained; that the data are not kept longer than necessary to meet those purposes; and that they should not be transferred to any other country which does not have similar levels of privacy protection.

4.9 A potential complicating factor is that much of the Scottish collection is not held in a systematic format; rather many cards are merely stored in boxes arranged by year. Normally, for the Data Protection Act to apply personal data must be held in a ‘relevant filing system’, that is, in an ordered and accessible way. There are, however, two reasons why no attempt should be made to rely on this as a means to evade the Data Protection Act. First, the data contained in the collection relate to the health of individuals and were collected for health purposes; as such, they constitute an ‘accessible record’ which automatically qualifies for legal protection under the 1998 Act. An additional consideration is the fact that the data are held by a public authority meaning that they are ‘Category E’ data<sup>59</sup> and also deserving of protection (albeit that not all provisions of the 1998 Act apply). In each case, the way in which nature of the holding is irrelevant.

### ***The importance – or otherwise – of consent***

4.10 Contrary to popular belief, it is not the case that the consent of the individual is necessarily required for the processing of his or her data; rather information about processing and purposes thereof must be available; moreover, certain exceptions apply to the processing of data. These include processing that is necessary for the protection of the vital interests of the individual, or for the prevention or detection of crime. Importantly, the Data Protection Act does not apply to data relating to deceased persons or to data which have been adequately anonymised, i.e., from which an individual cannot likely reasonably be identified. In all cases, a lawful basis for processing personal data must exist, but consent is only one of a range of possible lawful bases.

4.11 Section 33 of the Data Protection Act provides for the so-called ‘research exemption’. This can be applied where the processing of personal data is only for research purposes, and where the following conditions are met:

- The data are not processed to support measures or decisions relating to particular individuals; and
- The data are not processed in such a way that substantial damage or substantial distress is, or is likely to be, caused to any data subject.

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<sup>58</sup> Scottish Government, Records Management: Code of Practice (Scotland) Version 1.0, Annex D ‘The Management, Retention and Disposal of Personal Health Records’, July 2008, p.88.

<sup>59</sup> ‘Category E’ data are those held by public authorities in non-electronic or un-filed records.

4.12 Three important consequences of the application of the research exemption are:

- (a) personal data may be kept indefinitely;
- (b) personal data may be processed for purposes other than those for which it was originally obtained; and
- (c) data subjects need not be given access provided that they cannot be identified from results of the research.

This having been said, the arbitrary retention of records with the abstract hope that they might have a future research value is not acceptable. The Information Commissioner's Office has made it clear that: '[t]he exemption may only be used...if research is actually being carried out or there is a firm intention to use the records for that purpose.'<sup>60</sup> Data subjects should normally be informed of the prospect of this research use of their data. If, however, patients cannot be contacted without disproportionate effort then this requirement need not be met. The Information Commissioner's Office advises that this fact should be recorded.<sup>61</sup> What constitutes 'disproportionate effort' is a matter of facts and circumstances in each case and the advice of the Information Commissioner's Office should be sought if there is any doubt. This does not preclude an effective and sustained public awareness campaign about the existence and use of a resource such as the Guthrie collection, as indeed was recommended by the Confidentiality and Security Advisory Group for Scotland in 2002.<sup>62</sup>

4.13 Apart from the Data Protection Act 1998 and the NHS Guide, a number of other laws and policy documents affect record keeping arrangements in NHS organisations.<sup>63</sup> In particular, legal and professional obligations must be complied with (arising from the common law duty of confidentiality and the NHS Scotland Confidentiality Code of Practice), including the role of Caldicott Guardians.<sup>64</sup> Caldicott Guardians play a very important role within the NHS as officers responsible for maintaining oversight of legal and ethical propriety of information flows with respect to patient confidentiality. A recent review has confirmed their central role in information governance, emphasising not only the enduring and vital importance of protecting confidentiality, but also now that "The duty to share information can be as important as the duty to protect patient confidentiality."<sup>65</sup> Prior professional

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<sup>60</sup> Information Commissioner's Office, *Use and Disclosure of Health Data* (2002), chapter 3.

<sup>61</sup> *Ibid.*

<sup>62</sup> CSAGC, *Protecting Patient Confidentiality – Final Report* (2002), paras 6.5-6.8, available at: <http://www.sehd.scot.nhs.uk/publications/ppcr/ppcr.pdf>

<sup>63</sup> As the Guide points out, "NHS organisations need robust records management procedures to meet the requirements set out under the Data Protection Act 1998, the Freedom of Information (Scotland) Act 2002 and the Environmental Information (Scotland) Regulations 2004. In addition they will be required to produce and implement a records management plan under the terms of the Public Records (Scotland) Act 2011." (para 17).

<sup>64</sup> <http://www.knowledge.scot.nhs.uk/ig.aspx>

<sup>65</sup> Dame Fiona Caldicott, *Information: To share or not to share? The Information Governance Review*, March 2013, available at:

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/192572/2900774\\_InfoGovernance\\_accv2.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf). Note that this report is directed only at England but the comment is made that "...there is much in our report which should prove useful in all the jurisdictions of the United Kingdom.", p.7.



undertakings to the public must also be taken into account especially if a shift in policy or approach is being contemplated.<sup>66</sup>

4.14 The relevance of the common law duty of confidence is that this complements and in some ways goes beyond the requirements of data protection, most notably that the duty of confidence extends after death (albeit not indefinitely).<sup>67</sup> Thus, from the perspective of management of the collection, although data protection safeguards no longer apply to deceased persons, this does not give *carte blanche* for the use of records without considering the requirements of the common law. These include that disclosure must be justified on one or more of a limited number of grounds as laid out in the Human Rights Act 1998, that is, "...in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."<sup>68</sup> We discuss the full implications below.

4.15 Thus, conclusions to note about the collection as information are:

- As a matter of current practice, it would seem that the Guthrie collection is treated in Scotland as part of the health record; this has implications for retention periods and the legal regimes that apply;
- As a matter of law, the most relevant provisions are found in the Data Protection Act 1998 and the common law duty of confidence, both of which must be read in light of the Human Rights Act 1998;
- Individual rights of privacy over personal information are not absolute nor do they require as a strict matter of law the consent of the person; while consent is one means to legitimate processing of personal data, other justifications are possible but individuals should be able to know the purposes for which their data are being processed;
- Anonymisation of data can greatly minimise the privacy risks and, by association, the privacy claims of individuals; indeed appropriate anonymisation of data means that the Data Protection Act does not apply;
- There are merits in treating the sample *in itself* as personal information for the purposes of regulation although – as we discuss in the next section - other legal regimes must also be considered.

### ***The collection as tissue***

#### ***England***

4.16 In England, blood samples (and, thus, newborn blood spot screening cards) are covered by the Human Tissue Act 2004 (HTA 2004), which provides a legislative

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<sup>66</sup> For example, the NHS Scotland Code of Practice on Protecting Patient Confidentiality sets expectations against relying on exemptions in the Data Protection Act 1998, s.33 with respect to research.

<sup>67</sup> This position has been laid down by the UK Information Commissioner, and upheld by the Information Tribunal in *Bluck and The Information Commissioner and Epsom & St Helier University NHS Trust*, 17 September 2007, EA/2006/0090.

<sup>68</sup> The House of Lords has confirmed that the common law of confidentiality must be read in terms of the Human Rights Act 1998, see *Campbell v Mirror Group Newspapers Ltd.* [2004] 2 AC 457, [2004] 2 All ER 995.

framework for regulating the storage and use of human organs, tissues and cells from both living and deceased persons<sup>69</sup> for certain “scheduled purposes”.<sup>70</sup> Part 1 of the Act regulates the removal, storage and use of “relevant material” for the purposes outlined in Schedule 1 of the Act, including “research in connection with disorders, or the functioning, of the human body”. “Relevant material” is defined as material that has come from the human body, which consists of or includes human cells. Embryos outside the human body are excluded, but blood is included.<sup>71</sup>

4.17 Part 2 of the Act made provision for the establishment of the Human Tissue Authority (HTA), which oversees and licenses organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions, and gives approval for organ and bone marrow donations from living people.<sup>72</sup>

4.18 The HTA’s Codes of Practice cover the main aspects of the removal, storage and disposal of human organs and tissue. The Codes make clear that material may be taken from the living in a variety of circumstances, for example:

- in the course of a diagnostic procedure (e.g., blood sample, biopsy)
- specifically for the purposes of research (e.g., a blood sample taken as part of a population screening programme)

4.19 This would seem to put beyond doubt that Guthrie Card collections in England are regulated by the HTA 2004 and the Human Tissue Authority.

4.20 The Code on Consent also notes that: “Under the HT Act, consent from the living is not needed for storage and use of tissue for:

- clinical audit
- education or training relating to human health (including training for research into disorders, or the functioning, of the human body)
- performance assessment
- public health monitoring
- quality assurance”<sup>73</sup>

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<sup>69</sup> The Human Tissue (Scotland) Act 2006 regulates only the use of human organs, tissue and samples from the deceased, which are removed post mortem, and subsequently used for research purposes. It does not regulate the use of human tissue from the living for research.

<sup>70</sup> MRC Regulatory Support Centre, Research and Human Tissue Legislation Series, “Research and the Human Tissue Act 2004 –DNA Analysis”, October 2007. Updates available here: <http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/Useofhumantissue/index.htm>

<sup>71</sup> MRC Guide, Clarification p.4.

<sup>72</sup> <http://www.hta.gov.uk/aboutus.cfm>. A review of fundamental functions of the HTA will be conducted in 2013, to report to government in April of that year.

<sup>73</sup> HTA Code of Practice 1: Consent, September 2009, para 114 . Available at: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm>

4.21 However, consent is normally required to store tissue from the living for:

- obtaining scientific or medical information about a person which may be relevant to any other person (now or in the future)
- public display
- research into disorders, or the functioning, of the human body and
- transplantation.

4.22 More specifically on research, the relevant Code of Practice states: “Tissue that was taken from the living for diagnosis and subsequently stored in a diagnostic archive can be valuable for use in research in connection with the disorders, or the functioning of, the human body. Diagnostic tissue can only be released for research under the following circumstances:

- When the patient has given consent for use of their tissue in research (the preferable scenario); or
- When the tissue will be released to the researcher in a non-identifiable form; and
- When the tissue will be used in a project that has approval by a recognised research ethics committee (for more information on ethics committees see the National Research Ethics Service (NRES): <http://www.nres.nhs.uk/>)<sup>74</sup>

4.23 The HTA 2004 applies only to England, Wales and Northern Ireland EXCEPT certain sections, including section 45 – Non-consensual DNA analysis - which also applies to Scotland, and this is discussed further below.

### ***Tissue in Scotland***

4.24 If the collection/the physical samples are seen as “tissue” then the legal position in Scotland is less clear. As stated above, the Human Tissue Act 2004 does not, in the main, apply in Scotland, with the notable exception of section 45 (see below). Moreover, the equivalent legislation for Scotland – the Human Tissue (Scotland) Act 2006 - does not extend to the Guthrie card collection because it is concerned only with material taken from deceased persons or from living persons for transplantation purposes. It may therefore be the case that a lacuna in the law exists with respect to tissue from the living generally. The common law, that is, judge-made law, is of little assistance.<sup>75</sup> Almost all of the cases relate to material taken from deceased persons<sup>76</sup> or are concerned with the criminal law, for example, theft of

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<sup>74</sup> HTA Code of Practice 9: Research, September 2009, para 26, available at: [http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm?faAre a1=customwidgets.content\\_view\\_1&cit\\_id=757](http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm?faAre a1=customwidgets.content_view_1&cit_id=757)

<sup>75</sup> As McLean *et al* have commented, “when the retention of tissue from the living [is] considered the law [becomes] unclear”, see S McLean *et al*, „Human tissue legislation: A benefit or a burden?” (2006) 8(1) *Medical Law International* 1-21 at 11.

<sup>76</sup> For an in-depth discussion of the position in Scots law see N Whitty „Rights of Personality, Property Rights and the Human Body in Scots Law” (2005) 9 *Edin LR* 194 and more recently *Stevens v Yorkhill NHS Trust and another* 2006 SLT 889; 2007 SCLR 606; (2007) 95 BMLR.

human material.<sup>77</sup> It might be possible to argue that the physical samples are owned by those who have created and hold the collection – on an old rule about ownership going to those who exercise labour and skill to create something new – but there is no direct modern Scottish authority on this point.<sup>78</sup>

4.25 On questions of property, it is important to be aware of an important decision of the Court of Appeal in England in which it was held that men who deposited sperm in a fertility clinic and which perished because of negligent storage had a property claim against the NHS Trust for resulting emotional harm.<sup>79</sup> The influence of this in Scotland is open to question because (a) decisions of the English Court of Appeal are not binding on Scottish courts, (b) this is an unprecedented decision with unclear legal basis, and (c) the decision itself was contingent on the circumstances, that is, sperm was deposited with the express expectation that it be returned to the donor at some future date. This having been said, two points should be taken from this turn of events: (1) it may signal a shift in judicial attitudes towards property-type claims in human material, and (2) there might be an analogy with Guthrie spots, viz, one purpose for retention is the longer-term health interests of the individual and therefore a connection or continuing claim might remain between an individual and his or her sample.<sup>80</sup>

4.26 The only statutory provision of direct relevance to the Guthrie collection in Scotland is Section 45 of the Human Tissue Act 2004 (Non-consensual DNA Analysis). This in effect creates an offence of 'DNA theft'. It is concerned with DNA analysis only, not with the holding of tissue per se. The basis for this legislation is consent, reflecting the cultural and attitudinal shifts which have occurred in the last few decades with respect to biomedical collections and practices. That said, while consent is now the norm to legitimate actions done with or to biomedical collections is not required in all circumstances.

#### *Lawfulness of continued retention*

4.27 Section 45 of the Human Tissue Act 2004 came into force on 1 September 2006. Its effect is to create a criminal offence of non-consensual DNA analysis, albeit with exceptions, but it does not create a statutory legal basis for the holding of human tissue in Scotland. It is, in fact, difficult to find a clear positive legal entitlement for continued retention. Arguably, however, in such cases an old maxim of the law applies: *nulla poena sine lege* (no penalty without law). Put another way, 'that which is not illegal is legal'. It does not follow, however, that the Guthrie collection can be used freely because wider ethical considerations must also be borne in mind, as should the possibility of the criminal offence of non-consensual DNA analysis.<sup>81</sup> Moreover, there is an important distinction to be drawn between hard and soft law.

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<sup>77</sup> *R v Rothery* [1976] RTR 550, (1976) 63 Cr App R 231 and *R v Welsh* [1974] RTR 478.

<sup>78</sup> For English authority on this point see *R v Kelly* [1998] 3 All ER 741.

<sup>79</sup> *Yearworth v North Bristol NHS Trust* [2009] EWCA Civ 37; [2009] 2 All ER 986; [2009] 3 WLR 118; (2009) 107 BMLR 47. For commentary on this ruling and its likely implications, see S.H.E. Harmon and G.T. Laurie, 'Yearworth v. North Bristol NHS Trust: Property, principles, precedents and paradigms' (2010) 69 Cambridge Law Journal 476-93.

<sup>80</sup> For discussion of possible ramifications and the on-going uncertain legal nature of any consent that is provided, see G. Laurie and E. Postan, 'Rhetoric or Reality: What is the Legal Status of the Consent Form in Health-related Research?' (2012) *Medical Law Review* 44pp, doi: 10.1093/medlaw/fws031

<sup>81</sup> See Human Tissue Authority, *Code of Practice 1: Consent*, 2009. paras 152-156.

Hard law, such as Acts of Parliament or case law, is a more formal expression of the legal system and political will. Soft law, in the form of guidance or governance arrangements, can be equally and sometime more effective. It is certainly the case that NHS Scotland has a robust system of research governance procedures. NHS Scotland has brought the collection within the remit of these procedures to help to ensure appropriate oversight. We assess these measures in chapter 7.

### ***Lawfulness of use – section of the 45 HTA 2004 (Non-consensual DNA analysis)***

4.28 Section 45 of the Human Tissue Act 2004 provides that a person commits a criminal offence<sup>82</sup> if he has any bodily material<sup>83</sup> intending that any human DNA in the material be analysed and (a) there is no consent to such analysis, or (b) the results of the analysis are not for an ‘excepted purpose’ as prescribed by the law. These purposes include the prevention or detection of crime, conduct of a prosecution and purposes of national security.

4.29 This provision of the law has two important qualifications of relevance to the Guthrie Collection. First, the legal position regarding ‘existing holdings’, i.e., material held prior to the section coming into force (1 September 2006), and, second, the research exemption which relates to material taken from living persons after that date.

4.30 As regards existing holdings, DNA analysis is lawful for a finite list of purposes even if the samples are identifiable and even if no consent has been obtained. This list includes clinical audit, research in connection with disorders, or the functioning, of the human body, and obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person).

4.31 As regards the research exemption, the results of DNA analysis may be used for research in connection with disorders, or the functioning, of the human body without consent, providing that:

- the bodily material concerned is from a living person; and
- the research is ethically approved in accordance with regulations made by the Secretary of State; and
- the researcher is not in possession, and not likely to come into possession of information that identifies the person from whom it has come.

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<sup>82</sup> Pursuant to section 45(3), a person found guilty of an offence under this section is liable on summary conviction to a fine, or on indictment to imprisonment for a term not exceeding 3 years, or a fine, or both.

<sup>83</sup> “Bodily material” is defined in section 45(5) as “material which has come from the human body [living or deceased] and consists of or includes human cells”. This definition covers human blood, as it ‘consists of or includes human cells’; it does not, however, cover extracted DNA or RNA where no whole cells remain. This definition, thus, covers newborn blood spot screening cards.

4.32 In other words, scientifically sound, ethically approved and adequately anonymised research for human health purposes is lawful under the 2004 Act.

The Human Tissue Authority provides advice on the application of this section of the 2004 Act to Scotland.

4.33 Conclusions to note about the collection as tissue:

- There is no clear legal basis in Scotland to regulate the collection as tissue, with the exception of section 45 of the Human Tissue Act 2004;
- This section merely concerns DNA analysis and creates an offence for which exemptions apply;
- The existence of the collection as an existing holding does not require specific consent but careful attention is required to questions of access and use;
- As with data protection, anonymisation of the collection for use can elide a number of legal concerns (see further below under Consent, Chapter 5)
- Appropriate ethical oversight of the collection is required in order to conform with the provisions of section 45 of the 2004 Act.

### ***The human rights dimension***

4.34 All laws and practices must respect the human rights of UK citizens. Thus, in order to obtain the complete legal picture with respect to the Guthrie collection it is essential to consider the human rights dimensions.

4.35 The ruling of the European Court of Human Rights in *Marper*, see above, has cast some light on these dimensions with respect to DNA collections (albeit in a forensic setting). It was held in that case that the blanket policy of the UK to retain DNA profiles and samples indefinitely when taken from persons without their consent and who had not been convicted of a crime was an unjustified breach of their human rights. Indeed, it held that the mere retention of DNA, even without use, was an interference with the right to respect for private life because of the possible implications that future uses could have for individuals. This might raise obvious questions for elements of a Guthrie collection for which current explicit consent is not operating, i.e., the historical collection. But it does not follow that long-term retentions must cease; it might mean, however, that the procedures for governance should be strengthened.

4.36 Human rights law seeks balance and even interference with individual rights can be lawful so long as it is justified. Justification is a three-prong test:

#### ***1. In accordance with the law***

This means that measures must have a basis in domestic law; the law must be adequately accessible and foreseeable and with sufficient precision for individuals to know how it operates; and there must be sufficient protection from arbitrary decisions and clarity of the scope of discretion. Whether these criteria are met depends on all circumstances in a given context. As has been demonstrated, there is an absence of any specific hard law basis for taking and retaining blood spots in Scotland. This places all the more emphasis on

the soft law conditions attached to, and arrangements for, the storage and use of the collection. This issue was of particular concern for the European Court of Human Rights in *Marper* and suggests that robust, transparent policies and procedures are essential. We return to this below.

## **II. Legitimate aim**

This means that the measure must further one of the aims mentioned above. The health of individuals and others, social welfare and the prevention of disorder or crime are all legitimate aims; but these are further qualified by the final criterion.

## **III. Necessary in a democratic society**

This means that the measure must show that it addresses a “pressing social need”, that its operation is proportionate and that the reasons advanced for its existence are “relevant and sufficient”. It is the obligation of authorities to demonstrate that they meet these criteria.

### 4.37 Conclusions to note about the human rights dimension.

- All laws and practices must be compliant with human rights
- To test human rights compliance, we must ask if (1) a measure is in accordance with the law, (2) pursues a legitimate aim, and (3) is necessary in a democratic society. If this test can be met then a measure is lawful *even if* it engages individual human rights.
- In the context of DNA collections, the *Marper* case held that it was the blanket and indiscriminate nature of the policy which was unjustified.
- The fact that consent provisions have been introduced to the regulation of the Guthrie collection indicates that no such charge could be levelled in the current context. But the question of the historical collection remains as this affects persons in categories 1, 2 and 4 in Chapter 3.

The options for the future of the collection include:

(a) complete destruction,

(b) attempts to obtain informed consent for people whose cards are held as part of the collection,

(c) a clear, well-publicised, accessible and efficient opt-out system.

**In deciding between options the guiding parameters are whether the ultimate decision embodies a proportionate and justifiable policy.**

## **POINTS TO CONSIDER AND RECOMMENDATIONS FROM CHAPTER 4**

- **The Guthrie collection should be treated as both personal information and human tissue for the purposes of robust governance.**
- **The existing collection is not unlawful but careful attention must be paid to matter of governance, especially those concerning future use and access.**
- **Consent to use is not an absolute requirement but should not be departed from lightly.**
- **Anonymisation can remove some legal obligations but not all obligations; moreover, it is not a complete answer to the challenges thrown up by the collection.**
- **Human rights are a consideration across all areas of law. All mechanisms, policies and procedures should be tested for human rights compliance.**



## CHAPTER 5: CONSENT AND ANONYMISATION

### Key questions addressed by this chapter are:

- Should specific consent be sought from all persons whose samples and information are held as part of the Guthrie collection?
- What are the arguments for and against this approach?
- What does the law and good practice require?
- What are the alternatives?
- Can the collection be kept and used if the cards are anonymised?
- Is it possible or practical to do so?
- What are the pros and cons of anonymisation?

### Key messages from this chapter are:

- The law does not require that specific consent be sought from all persons whose samples or data are held in the Guthrie collection; it is for consideration none the less, whether such consent should be sought as a matter of good practice.
- If specific consent is not sought, there must be a robust system of opt-out to respect persons whose samples/data are contained in the collection.
- Because people consent to inclusion in the collection on the basis of broad consent, attention should be given to how they will be kept up-to-date with uses of the resource as and when these occur.
- It is for consideration whether a system of 'consent for consent' should be considered to facilitate access to the Guthrie collection for research purposes; caution should be exercised, however, about adopting a presumed consent approach.
- Specific consent should be sought from individuals if access is contemplated for non-standard purposes, e.g. non-health-related research.
- It is for consideration whether mature minors should be allowed to opt-out of the collection.

- **Transparent procedures should be developed for circumstances where access will be given without consent but subject to suitable authorisation.**
- **Transparent procedures should be developed to decide whether and how access will be granted if neither consent nor anonymisation is possible.**
- **Consideration should be given to scrutiny mechanisms authorising access even when anonymisation is contemplated.**
- **A policy should be developed on whether and how feedback of individual results will be given.**
- **A decision should be taken on Open Access to the resource or results from the resource.**
- **A Privacy Impact Assessment should be carried out on the Guthrie collection.**

## **DISCUSSION**

### ***Consent: the issues***

5.1 This section discusses the function of consent, ethically and legally, and raises some issues for the collection. The next section addresses the most viable alternative, namely, anonymisation.

5.2 The purposes for which the Guthrie collection is maintained, the role of consent and the requirements of the relevant legal regimes are inextricably linked. The introduction of an informed consent system addresses many of the ethical, legal and social issues surrounding the collection but it is not a panacea nor should it be considered as such. Even for those who have given consent there are questions about the degree to which this was sufficiently informed (for example in relation to current procedures for police requests for access, and as yet untested applications by commercial interests such as pharmaceutical companies – see Chapter 6). These matters could clearly be addressed for the future. More difficult issues relate to the elements of the collection relating to persons for whom specific consent was not given, either those who are now adults or those who are still children. If consent were thought to be the ‘best practice’ option this would raise a plethora of social and economic issues and would bring with its own set of ethical concerns.

### ***The function of consent***

5.3 Consent is merely a device to show respect to persons, it is not an ethical value in its own right. Moreover, there are many different models of consent which are in use.

5.4 The lingua franca of modern medicine is *informed* consent, and this works best in the context of treatment or clinical trials when individuals can be fully informed

*before* committing to a course of action about what will happen, the consequences, risks and alternatives. This model does not work for collections like the Guthrie collection. Equally, while *presumed* consent can be inferred from individuals' actions, this only has a very narrow sphere of legitimate operation – for example when a patient offers his or her arm for blood to be taken. In particular, it is not at all clear that consent can be inferred from non-action. This raises questions about the information material given to parents. The section on research states: “If you do not want the stored blood spot card to be used for research, please ask the midwife to write ‘no research’ in the comments box on the blood spot card.”<sup>84</sup> Can it be inferred from a blank box that consent has been given? **Matters would be clearer if a positive assent to research was recorded.**

5.5 The approach with the Guthrie collection is one of *broad* consent whereby individuals are presented with a broad proposition and asked to agree to participate. Clearly all future uses, research or otherwise, cannot be explained before consent is given. None the less, arguably the ethical (and legal) obligation is to keep people informed of uses as and when they occur. If this does not happen people might lose trust in the system if they discover uses of which they would not have approved. The experience of Texas, para 2.18 above, is a clear example of this.

5.6 Existing projects that rely on broad consent, such as UK Biobank,<sup>85</sup> always provide an opt-out or withdrawal mechanism. Keeping people informed about the uses of a collection, e.g. via regular updates on a website, can help to ensure transparency and give meaning to a right to withdraw. Moreover, human rights would suggest that the onus is on those responsible for the collection to demonstrate and justify the continued need for, and value of, its retention. It will be recalled from para 4.12 that arbitrary retention of records with the abstract hope that they might have a future research value is not acceptable. A clear commitment to a research purpose and demonstrate utility is required.

5.7 The ethical imperative in all dealings with patients is to respect them. There may be many ways to respect individuals, their rights and their interests which do not require consent. It is essential, therefore, to identify which interests or rights are at stake for people with respect to the Guthrie collection. Two stand out as having paramount importance: privacy and autonomy (freedom of choice).

5.8 Assuming the lawfulness of the existing collection in terms of continued storage, the next question is whether specific consent for on-going use should be sought. We make no comment here about the resource implications of such a policy or the procedures that this would involve. Consent could operate in a variety of ways with respect to future use of the resource. We can consider the following questions.

5.9 **Should “consent for consent” be sought in the context of research use?** There is on-going contemporary discussion about the need for, and utility of, seeking “consent for consent” with respect to use of health data for research purposes. It is argued in some quarters that individuals should be actively approached, or at least informed, about the prospect of their medical data being used for research and given

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<sup>84</sup> NHS Scotland, Your Guide to Newborn Screening Tests, (2012), p.20.

<sup>85</sup> See the details of the UK Biobank Ethics and Governance Framework here: <http://www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf>

the opportunity to consent to being contacted for specific consent at some future date, or alternatively, to refuse any such approach. There are serious practical and economic consequences of adopting this approach, but its application to the Guthrie collection raises no novel issues not already being discussed in the wider community.

**5.10 Should specific consent be sought only for specific purposes, e.g., a specific research project?** The logistics of this would be considerable if it were to occur for every research use. It might, however, be used for research uses which reasonable persons would not consider to be within the original purposes of a collection such as Guthrie cards. An example of such a use might be non-health-related research.<sup>86</sup>

**5.11 What is the role of opt-out/on-going obligations of keeping the public informed about issues of use and access?** We suggest that given the nature of consent that has been obtained since 2003 (broad consent) and the absence of consent before 2003, there is an imperative to keep people informed about the collection and the uses to which it is put and, ideally, to involve them in processes for deciding future policy. This does not necessarily mean that every individual should be contacted individually.<sup>87</sup> Furthermore, given the interest in freedom of choice, this supports a robust opt-out mechanism.

**5.12 What is the position with respect to the mature minor/minor assent?** The law recognises that children can be sufficiently mature to take health-related decisions about their own care before they are 16.<sup>88</sup> In keeping with the spirit of this law, there is a strong case for arguing that mature children should be able to opt-out of the collection should they choose to do so. A counter argument to this is that their continued inclusion in the collection might be a necessary part of their own medical record. In the event of any dispute about whether to retain or destroy a mature minor's sample and data, the guiding legal principle would be best interests to be resolved by a court in the ultimate resort.

**5.13 Is consent required at all if, all things considered, risks are minimal or non-existent?** In the absence of any expression of choice by a person or their representative to opt-out, the remaining serious risk is to privacy. We suggest, in keeping with other ethical models of biomedical governance, that if privacy risks can be shown to be minimal and ethical approval for access has been granted by a relevant and authorised body or person (such as a Caldicott Guardian), then access can be granted without prior consent. The mechanics of this are best dealt with under *Governance*, below. The most likely privacy protection mechanism in such cases is anonymisation, and it is to a consideration of that issue that we now turn.

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<sup>86</sup> M.T. Lysaught *et al*, 'A Pilot Test of DNA-based analysis using anonymized newborn screening cards in Iowa', in R.F. Weir ed., *Stored Tissue Samples: Ethical, Legal and Public Policy Implications* (University of Iowa Press, 1998).

<sup>87</sup> This is accepted by bodies such as Genewatch. See: 'Keeping blood spots from newborn babies', January 2006, available at: <http://www.genewatch.org/pub-507666>, p. 3, citing J. Kaye, (2004) Abandoning informed consent: the case of genetic research in population collections; S. Weldon, (2004) 'Public consent' or 'scientific citizenship'? What counts as public participation in population-based DNA collections? Both in: R. Tutton and O. Corrigan (eds) *Genetic databases: socio-ethical issues in the collection and use of DNA*. London, Routledge.

<sup>88</sup> See the Age of Legal Capacity (Scotland) Act 1991, s.2(4) although it is unclear if this extends to refusals.

## **Anonymisation: the issues**

5.14 It should be clear from the previous section that while consent has a role to play in legitimating actions which might otherwise be illegal, it is not the only means to do so. Information can be processed without consent to promote recognised public interests, such as the prevention or detection of crime, and/or because other safety mechanisms can be used to protect individuals' interests and which do not require specific consent. Anonymisation is the paradigm example of this and is frequently used in research ethics to protect participants' privacy. Both data protection laws and human tissue legislation envisage a role for anonymisation.<sup>89</sup> Thus, anonymisation can serve in protecting privacy interests while seeking to maximise the use of the resource.<sup>90</sup> As with consent, however, anonymisation is not a solution to all challenges thrown up by all uses of the resource. Specific issues to consider include:

### ***I: Anonymisation is not always possible from the privacy perspective***

There is considerable debate about what 'anonymisation' actually means.<sup>91</sup> For example, is it *absolute anonymity* that is required such that no person can ever be identified from information/material?, or is it *relative anonymity* such that it is not reasonably likely that the person will be identified? It has been increasingly demonstrated that the former is not possible in the context of genetic material and other personal data,<sup>92</sup> while the latter is probably all that is required by law.<sup>93</sup> More recent contributions to the Scottish Guthrie collection are reversibly anonymised, but this is not true for the majority of the collection where personal information and the sample are held together on the same card. **This has implications for what people are told about the risk to their privacy.**

Expectations couched in terms of guarantees of privacy protection should be avoided; expectations must be realistic and the reality is the *any* use of personal data, even anonymised data, increases privacy risks. **To appropriately assess the range of privacy risks, we recommend a regular Privacy Impact Assessment of the Guthrie collection in Scotland.** Details are available from the Information Commissioner's Office<sup>94</sup> and the Information Services Division in NHS Scotland has already conducted such exercises.

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<sup>89</sup> The effect of anonymisation for data protection and human tissue regulation purposes is that those processing anonymised data/tissues do not have to comply with the provisions of the legislation, for example, researchers receiving suitably anonymised samples/information. This, however, clearly does not absolve the custodians of the collection from complying with the relevant laws since they hold both the collection and personal data from which specific individuals can be identified.

<sup>90</sup> See further, W. Lowrance, *Privacy, Confidentiality and Health Research* (2012).

<sup>91</sup> W. Lowrance and F.S. Collins, 'Identifiability in Genomic Research' (2007) 317:5838 *Science* 600-602.

<sup>92</sup> For discussion, see J.K. Mason and G.T. Laurie, *Law and Medical Ethics*, 9<sup>th</sup> ed, 2013, chapter 6.

<sup>93</sup> This point of law was not ultimately determined by the House of Lords in *Common Service Agency v Scottish Information Commissioner* [2008] UKHL 47, 2008 SLT 901. For comment see G. Laurie and R. Gertz, 'The worst of all worlds? *Common Services Agency v Scottish Information Commissioner*' (2009) 13 *Edin LR* 330.

<sup>94</sup> [http://www.ico.org.uk/for\\_organisations/data\\_protection/topic\\_guides/privacy\\_impact\\_assessment](http://www.ico.org.uk/for_organisations/data_protection/topic_guides/privacy_impact_assessment)

## ***II. Anonymisation is not always possible from the research perspective***

Some kinds of research are not possible using anonymised data, i.e., identifiable or potentially identifiable data are required in order for the research to be carried out.<sup>95</sup> While the possibility of seeking specific consent remains, in many cases it is not reasonable or practicable to pursue this route. In other countries, legislation has been introduced which allows a designation body to authorise uses of information without consent when use would otherwise be unlawful, e.g., a breach of confidence. The Ethics and Confidentiality Committee performs this role for England & Wales under the auspices of the Health Research Authority<sup>96</sup> and operates on a statutory footing.<sup>97</sup> A similar, although not identical function is performed in Scotland by the Privacy Advisory Committee (PAC) but this body does not have a statutory basis. PAC exists to advise the institutions that set it up, being the NHS National Services Scotland (NSS) and National Records of Scotland (NRS). It considers applications for linkages of identifiable data from any datasets held under the auspices of these bodies. The Guthrie collection is not such a collection as such – it is held under the auspices of the Greater Glasgow and Clyde Health Board. PAC would only have a role with respect to any requests to *link* data from the collection to other datasets held by NSS or NRS. Therefore, PAC has no direct remit over the Guthrie collection per se. This means that requests merely to access the Guthrie collection without other linkage to other datasets must be governed by other means. The operation of the Caldicott Guardians system is integral to these mechanisms in the United Kingdom. As stated previously, these Guardians are responsible for protecting patient confidentiality and exist in each of the Scottish Health Boards. Thus, the Greater Glasgow and Clyde Guardian will have a responsibility for the Guthrie collection and can play a vital role in decisions about access and use. **The point to note here is that the traditional approach of „consent or anonymise“ is not always possible for all kinds of research. Authorisation is another valid route.** We return to consider this in the section on *Governance*, below.

## ***III: Anonymisation can lead to potential harm to other individual interests***

What are the obligations that exist between researchers and research participants and how are these affected by anonymisation? For example, is there a duty to feedback results if health-relevant information is generated as a result of research? How would this be possible if anonymity is to be preserved? This is a difficult issue in the research community on which opinion is currently divided.<sup>98</sup> It is important to compare and contrast, however, two situations in the context of the Guthrie collection: (i) monitoring infection rates in women/children, which is the confirmation of a specific diagnosis and

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<sup>95</sup> D.R. Karp *et al.* „Ethical and practical issues associated with aggregating databases“ (2008) 5 PLoS Med. e190.

<sup>96</sup> <http://www.hra.nhs.uk/>

<sup>97</sup> National Health Service Act 2006, ss251-252.

<sup>98</sup> See: S.M. Wolf, „The challenge of incidental findings“ (2008) 36 J. Law Med. Ethics, and the other articles in this symposium edition. Cf, F.A. Miller, R. Christensen, M. Giacomini and J.S. Robert, „Duty to disclose what? Querying the putative obligation to return research results to participants“ (2008) 34(3) Journal of Medical Ethics 201-13.

therefore of direct significance to someone's health,<sup>99</sup> and (ii) the creation of generalisable knowledge on a population level which is only statistically significant at that level, that is, the chances of saying something about an individual's health status is very slim. Either way, **what, if any, feedback policies are in place with respect to the uses of the Guthrie spot collection? Has this issue been considered? How would it be managed and what are the implications of any given policy? We are not aware of any consideration of these issues and therefore recommend that attention be given to the subject.**

#### ***IV: Anonymisation and the specifics of genetic information***

It is trite to confirm that every individual's genetic data are unique to them (absent the case of homozygous twins); in terms of anonymisation and identifiability, therefore, it suggests that genetic data/samples always point to a particular individual (or pair of individuals). This reality can impact significantly on the deliberate balance between access policies and privacy protection.<sup>100</sup> A recent experience illustrates the point well. The U.S. National Institutes of Health and the Wellcome Trust hurriedly revised their policy of open access to genome-wide association materials after it was shown statistically how individuals could be identified from aggregated data available on the public site.<sup>101</sup> **There is serious doubt about attempts to make genetic or genomic data available on an open access basis, even if it is thought that anonymity has been achieved;** once again, it has implications for access policies as we discuss below.

#### ***V. Anonymisation and authorisation***

Given the comments above, and in keeping with conclusions about consent, we suggest that consideration should be given to whether appropriate authorisation of access should be given *even if* a proposal for access is for anonymised use of samples/data. This is not only to address concerns about individual's privacy but also because there might be wider, social impacts of (research) access depending on the purposes for which access is sought. This is particularly the case for the Guthrie collection due to the coverage of the collection and the potential for the collection to be misrepresented as a de facto "DNA database" for the Scottish population born since 1965.<sup>102</sup>

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<sup>99</sup> K.M. Boyd, Institute of Medical Ethics: working party report: 'HIV infection: the ethics of anonymised testing and of testing pregnant women' (1990) 16 J. Med. Ethics 173-178. Cf – A.J. Pinching, 'The ethics of anonymised HIV testing of pregnant women: a reappraisal' (2000) 26 J. Med. Ethics 22-24.

<sup>100</sup> M.J. Taylor, *Genetic Data and the Law: Critical Perspectives on Privacy Protection* (2012).

<sup>101</sup> N. Homer *et al* 'Resolving individuals contributing trace amounts of DNA to highly complex mixtures using high-density SNP genotyping microarrays' (2008) 4 PLoS Genet. e1000167.

<sup>102</sup> See: M.T. Lysaught *et al*, 'A pilot test of DNA-based analysis', p. 23, where the authors comment: "...the trend toward seeing newborn screening labs as DNA databanks which can provide samples for secondary purposes has fundamentally altered the nature or status of the blood-spot filter card. Previously, one could have argued that newborn screening was simply one of a series of diagnostic assays performed under the umbrella of general parental consent to actions promoting neonatal health. But now the blood-spot filter card has become a commodity, an item with "value", to be used for purposes unrelated to the health of the individual newborn. In this new context, it will be increasingly difficult to justify conducting newborn screening in the absence of informed consent."

## **POINTS TO CONSIDER AND RECOMMENDATIONS FROM CHAPTER 5:**

- **The law does not require that specific consent be sought from all persons whose samples or data are held in the Guthrie collection; it is for consideration none the less, whether such consent should be sought as a matter of good practice.**
  - **If specific consent is not sought, there must be a robust system of opt-out to respect persons whose samples/data are contained in the collection. Robust in this context means that clear and detailed information be publicly available both about the existence of the collection and any uses to which it is put. Citizens must be able to access procedures for opt-out easily and have their wishes respected in a timely fashion.**
  - **Because people consent to inclusion in the collection on the basis of broad consent, attention should be given to how they will be keep up-to-date with uses of the resource as and when these occur.**
  - **It is for consideration whether a system of ‘consent for consent’ should be considered to facilitate access to the Guthrie collection for research purposes; caution should be exercised, however, about adopting a presumed consent approach. The parent information and consent leaflet should be revised to make consent for research an explicit option.**
  - **Specific consent should be sought from individuals if access is contemplated for non-standard purposes, e.g. non-health-related research.**
  - **It is for consideration whether mature minors should be allowed to opt-out of the collection.**
  - **Transparent procedures should explain in accessible format the circumstances in which access will be given without consent but subject to suitable authorisation.**
  - **Transparent procedures should explain whether and how access will be granted if neither consent nor anonymisation is possible.**
  - **A policy should be developed on whether and how feedback of individual results will be given.**
  - **A decision should be taken on Open Access to the resource or results from the resource.**
  - **A regular Privacy Impact Assessment should be carried out on the collection.**
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## CHAPTER 6: STORAGE AND ACCESS

### Key questions addressed by this chapter are:

- What kinds of uses should the collection be put to and which are lawful?
- Should access be allowed for health research?
- What other non-health research access is currently possible, and who is likely to request future access?

### Key messages from this chapter are:

- The need for a clear, robust and transparent access policy for the Guthrie collection in Scotland is non-negotiable in terms of ethical and legal requirements; this must cover all current and foreseeable future uses of the resource;
- This policy should include guidance for decision-makers on relevant factors to take into account. This might include:
  - scientific or public value of the project;
  - ethical concerns both for individuals and society;
  - the pressing social need for the access;
  - whether consent can and should be sought for access;
  - any consequences of access for the resource; e.g. use of depletable samples, and
  - ways to minimise any adverse impact of the access.
- There should be some mechanism for prioritising research requests;
- A written protocol for the release of samples and information to the police be developed and made publicly available;
- Personnel within the NHS should act as gatekeepers with respect to access requests, and most notably and ideally Caldicott Guardians should be involved in all decisions;
- Given the existence of an opt-out system, consideration should be given to the mechanism for adequately informing people about withdrawing consent if the person no longer wants the blood spot card to be used for research or other purposes;
- Consideration should be given to the specific role of any Access Committee and/or oversight body in this regard (see further Chapter 7);
- Those responsible for the collection must clearly define the purposes of the collection and link these to justifiable periods of retention.

- **Consideration needs to be given to the appropriateness of the physical environment in which the collection is held and the way in which it is archived.**

## DISCUSSION

6.1 There is a growing awareness that Guthrie card collections are potentially valuable sources of DNA for genetics research, and requests for access to the collections are increasing. Access to Guthrie cards for secondary uses raises numerous ethical issues, including privacy, confidentiality and genetic discrimination; these are compounded by the potential for requests for commercial access and access by non-health motivated parties, such as employers or insurers.

6.2 Storage and access are, of course, connected to issues of consent and anonymisation, which were discussed in the previous chapter. This chapter will focus on some of the ethical and practical considerations with regard to storage and access, and will make offer a number of points for consideration to improve current procedures.

### ***A range of possible uses***

6.3 As noted in Chapter 3 Figure 1, Guthrie cards are currently used for a number of purposes and might be used for other purposes in the future.

6.4 There are both practical and ethical issues to consider in terms of storage of, and access to, the Guthrie collection. One of the central concerns is that the indefinite or permanent retention<sup>103</sup> of the blood spots creates in effect, what could be viewed as, a *de facto* DNA database. This raises questions about how decisions are made regarding research access, how people's rights and privacy are protected, and how the involvement of commercial interests is taken into account in access decisions. Beyond this, concern lies with public perception of currently tightly controlled police access. (see Chapter 9 below).

### ***Storage periods***

6.5 The question of the legitimacy of retention periods for samples in the collection is important. In particular, it is noted that the current initial retention period of 1 year in Scotland – as detailed in the parental information leaflet<sup>104</sup> - is at odds with the UK NSPC guidance which suggests 5-years retention for quality assurance purposes. Data protection, in turn, requires that data are kept only so long as necessary for the original purposes for which they were gathered. **This means that those responsible for the collection must clearly define the purposes of the collection and link these to justifiable periods of retention.** What, for example, justifies one year and not a longer or shorter period of time? Clearly, different purposes can justify different retention periods, but as noted above, as the purposes move further away from individual health interests, the justification required is stronger.

<sup>103</sup> The 2005 Consultation on the 'Storage and use of newborn babies blood spot cards', raised the issue of permanent retention of the cards.

<sup>104</sup> NHS Scotland, Your Guide to Newborn Screening Tests, (2012), p20.

## **Practical considerations**

6.6 If the collection is to be retained indefinitely and is to be available for health-related research or indeed any other purposes, then it must be fit-for-purpose(s). **Consideration thus needs to be given to the appropriateness of the actual physical environment in which the collection is held and the way in which it is archived.** In this regard the importance of the NHS Scotland Guide on Records Management contains guidance on archiving collections. Also, the designation of the Guthrie collection as a national research collection means that it comes under NHS Research Scotland Guiding Principles for Governance of NHS Scotland Tissue for Research. Such collections have NHS Research Ethics Committee approval to operate as a generic research tissue bank, and this means giving approval for research studies using human tissue. It should also be kept in mind that the European Court of Human Rights has indicated that the storage and use of cellular material interferes with an individual's right to respect for private life and that **suitable mechanisms for storage and use must be in place** (see Chapter 4 above).

## **Access**

6.7 Requests for access to the Scottish Guthrie collection have been handled in the past on an ad hoc basis. However, with increased requests for access for a range of purposes, the potential for requests for commercial use of the collection, and increased attention to biomedical governance, **it is imperative that robust mechanisms, policies and procedures are in place that are in accordance with the law<sup>105</sup> and in line with national guidance.** This is important both for the protection of individuals whose samples/information are held as part of the collection, but also to assist the NHS Greater Glasgow & Clyde Biorepository staff in making decisions about requests for access to the collection. As we discuss in the next chapter, these decisions might involve the appropriate Caldicott Guardian and/or a suitable authorising body. The status of the Guthrie collection as a national research collection now means that any researcher who wants access must follow the nationally-agreed Access Policy. This includes provisions on ensuring that data are anonymised, that some of the bloodspot is retained for patient and family health screening, and that researchers share the data collected so that it can be used in future studies. In other words, there is a commitment to benefit sharing.

## **Considerations for access:**

6.8 Research using Guthrie Cards for secondary purposes should not only be scientifically sound, but should also produce some “useful information” or clear health-related “benefit” even if this is to a broad (and/or future) category of persons.<sup>106</sup>

6.9 In all likelihood, most interest in access to the Guthrie collection will be for genetic research as it represents a potentially very valuable resource. The use of the collection for genetic research is contested, however, because the actual benefits of any research using such a resource remain unproven and because of the spectre of

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<sup>105</sup> See Chapter 4 above on human rights requirements.

<sup>106</sup> Lysaught *et al*, ‘A pilot test of DNA-based analysis’, p.25.

discrimination for groups of persons on genetic grounds.<sup>107</sup> There are also fears about the collection being seen as *de facto* National 'DNA Database'.<sup>108</sup> All of these issues are potentially exacerbated by the prospect of requests for commercial interests, as we discuss in the next section.

6.10 Considerations are different depending on whether access is sought to information or samples. While information is an inexhaustible resource, the same is clearly not true for physical samples. Issues of prioritisation must be addressed. Moreover, while information might readily be subject to anonymisation processes, the same is not possible for a DNA sample which points to a single individual. In other words, privacy risks vary depending on the types of access sought. Indeed, even if consent for research is thought to be necessary, for example because the sample card will be accessed or the research is non-health related, it is vital that approaches to individuals and their families are handled in a sensitive and ethically appropriate manner. **All of these considerations and more need to be considered in any access policy.**

### ***I: Commercial interests***

6.11 The Newborn Blood Spot Screening Code of Practice for the Retention and Storage of Residual Spots, states that:

Newborn screening laboratories may not sell, or grant exclusive access to, residual newborn blood spots to commercial organisations. Some commercial partnerships may be required to develop screening methods that may benefit the screening service and public health more generally. These arrangements will be subject to scrutiny by the Programme Centre Board and will be documented in the Programme Centre's annual report.

6.12 The Code does not, however, address commercial access for research, and leaves it to the Board of each Centre to scrutinise arrangements for commercial partnerships individually. The proposed access provisions for the Scottish Guthrie collection envisage an Access Committee or Governance Board that would address such issues. The NHS Research Scotland guidelines make it clear that: "tissue should be made available to all legitimate researchers including commercial entities. Access should be as broad as possible."

6.13 Lysaught *et al* have commented that commercial use "is an area that has received the least attention".<sup>109</sup> They note that commercial access raises issues of ownership and profit-sharing, and suggest that release for commercial purposes could only be justified "in the context of an investigation explicitly designed to benefit public health, particularly the goals of newborn screening (i.e., diagnosis of conditions for which treatment will make a difference)".<sup>110</sup> This in turn, however,

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<sup>107</sup> See: B. Almond, 'Genetic profiling of newborns: ethical and social issues' (2005) 7 Nature Reviews Genetics 67-71.

<sup>108</sup> Genewatch, 'Keeping blood spots from newborn babies'.

<sup>109</sup> Lysaught *et al*, "A pilot test of DNA-based analysis", p.27

<sup>110</sup> *Ibid*.

raised issues of conflicts of interest,<sup>111</sup> which requires robust policies and procedures to monitor.

6.14 The involvement of commercial interests, while a reality, has raised public concern. One of those concerns is that “research funded or undertaken by commercial companies is likely to give priority to potential profits and to what can be patented than to public health.”<sup>112</sup>

6.15 In the 2005 Public Consultation on the *Storage and use of newborn babies blood spot cards* (Oliver et al, IOE London) (final report not publicly available), commercial access to the UK blood spot collection was included as a question: Do you have any comments about commercial companies using blood spot cards to develop equipment or tests? Interestingly, there was no question about commercial access for research purposes.

6.16 Evidence of public disquiet already exists. Dixon-Woods et al<sup>113</sup> and Haddow et al<sup>114</sup> have found that the attitudes of groups towards commercialisation can depend on their experience of ill-health. In particular, there can be marked differences between groups suffering from disease and their healthy counterparts both with respect to attitudes towards property claims and towards the prospect of others profiting from their contributions. Understandably, groups which have experienced ill-health are usually very supportive of research and can be more tolerant of its commercial aspects than healthy groups. **The prospect of profit might not be a stumbling block in itself, but rather the idea of excessive profit; this raises a further concern about exploitation – or perceptions of exploitation – all of which should be considered in robust access policies before any access is granted.**

## ***II: Police Forensic Work***

6.17 There is also public concern in some quarters about the prospect of police access/use to genetic resources. The human rights ruling in *S and Marper v UK* is a case in point. Notwithstanding, it should be noted at the outset that the police can get access to any form of evidence, held in a medical context or otherwise, so long as lawful procedures are followed. The Guthrie collection is no different in this regard. It does not follow, however, that the prospect of police access should not be discussed or communicated openly with patients. **We suggest that information material and access policies with respect to the police make this clear.**

6.18 Guthrie cards have been used by the police for two distinct purposes: to identify remains/deceased persons and for crime investigation. Two examples of the former use of Guthrie Cards are the identification of missing persons in the wake of

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<sup>111</sup> GeneWatch, ‘Keeping blood spots from newborn babies’.

<sup>112</sup> Ibid., citing A. Harrison and B. New (2002), *Public interest, private decisions: health-related research in the UK*. London, The King’s Fund.

<sup>113</sup> M. Dixon-Woods et al, ‘Tissue samples an ‘gifts’ for research: a qualitative study of families and professionals’ (2008) 9 *Medical Law International* 131-150.

<sup>114</sup> Haddow et al, ‘Tackling community concerns’.

the tsunami in Sri Lanka,<sup>115</sup> and the identification of deceased persons.<sup>116</sup> While these uses are relatively uncontroversial, of greater concern is the use of Guthrie Cards for evidential purposes in crime detection and prosecution. Indeed, the 2003 murder of Anna Lindh, Minister for Foreign Affairs in Sweden, in which a newborn blood spot card was used to positively identify the person suspected of the murder, created massive media attention and controversy.<sup>117</sup> Similar police use led to the destruction of cards in Western Australia (para 2.21 above). In these instances, ethical considerations about protecting individual privacy often conflict with the provisions of the law; it is for this reason that procedures for police access need to be clear, and readily available to the public as well as those managing the resource. Once again, the distinction between the collection as information and the collection as tissue might have a bearing on the legal position.

### **III: Obtaining information from health records for police use**

6.19 If Guthrie cards in Scotland are regarded as health records then guidance developed by the Scottish Government with the Association of Chief Police Officers on 'Information sharing between NHS Scotland and the Police'<sup>118</sup> is relevant. In terms of access to information in a patient's records, the Guidance provides the following:

Type of request	Action by Police	Action by NHS Staff
Written request for information from a patient's medical record	Police officer will provide: <ul style="list-style-type: none"> <li>▪ Section 29 form to NHS or</li> <li>▪ Signed 'consent' form completed by subject of the inquiry</li> </ul>	NHS will provide information requested and retain Section 29 form, consent document
Procurator Fiscal Request	Procurator Fiscal will provide letter delivered by Police or Recorded Mail	NHS will provide requested information and retain PF letter and completed incident reporting form in accordance with local procedures
Sheriff Court Warrant	Court will provide Sheriff's Warrant delivered by Police or recorded Mail	NHS will provide requested information and retain Warrant and completed incident reporting form in accordance with local procedures

<sup>115</sup> S.O. Hansson and B. Björkman, 'Bioethics in Sweden' (2006) 15 Cambridge Quarterly of Healthcare Ethics 285-203 at 287.

<sup>116</sup> See: 'Privacy fears over method used to take Vicky's DNA', *The Herald*, 3 December 2008, p.16.

<sup>117</sup> Hansson and Björkman, 'Bioethics in Sweden', p.286.

<sup>118</sup> [http://www.sehd.scot.nhs.uk/mels/CEL2008\\_13.pdf](http://www.sehd.scot.nhs.uk/mels/CEL2008_13.pdf)

6.20 The role of the 'Section 29' form in this procedure is, in effect, to make an official request for information.<sup>119</sup> The police are not entitled to this information without an official warrant from a court of law, but the effect of the guidance is that it operates as an agreement on the part of NHS Scotland to accede to requests. This does not mean, however, that scrutiny procedures can be laid aside. **Personnel within the NHS should act as gatekeepers with respects to such requests, and most notably and ideally Caldicott Guardians should be involved in all decisions.**<sup>120</sup> Moreover, in circumstances in which there is doubt as to the legitimacy of a police request, a refusal would mean that a court warrant would have to be sought.

#### ***IV: Obtaining samples for police use***

6.21 If the physical parts of the collection are seen as tissue in Scotland then, under the common law,<sup>121</sup> a warrant would always be required.<sup>122</sup> This reflects the position in England.<sup>123</sup>

6.22 In England, the police require an access order to obtain samples for the purposes of a criminal investigation from existing collections held by third parties. Access orders may be sought by a constable pursuant to s.9(1) of the Police and Criminal Evidence Act 1984 (PACE) (which does not extend to Scotland) for 'human tissue or tissue fluid which has been taken for the purposes of diagnosis or medical treatment and which a person holds in confidence', provided certain conditions are met.<sup>124</sup>

6.23 In Scotland, there is no statutory equivalent to the provisions in PACE for obtaining samples from third parties. Legislation in Scotland, such as the Criminal Procedures (Scotland) Act 1995 (CPA), deals mainly with the taking of samples from arrested, detained or convicted persons (see for example ss.18 & 19 of the CPA). In Scotland, powers of search and seizure are governed by the common law. At common law, the police cannot enter a private premises without a warrant to search for evidence,<sup>125</sup> unless consent has been given or in situations of urgency.<sup>126</sup> The normal procedure is that police officers in Scotland who wish to obtain a search warrant make a report to the Procurator Fiscal who will then prepare the application

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<sup>119</sup> The 'Section 29' form refers to section 29 of the Data Protection Act 1998, which provides that information can be disclosed without consent where failure to gain the information would be likely to prejudice: the prevention or detection of crime, the apprehension or prosecution of offenders, or the collection or assessment of any tax or duty.

<sup>120</sup> In the October 2007 minutes of the UK Council of Caldicott Guardians meeting, it was noted that, while the police in Scotland have a "standard form when requesting information from health organisations... this [does] not negate the need for [the] final decision to be made by the Caldicott Guardian".

<sup>121</sup> See C.N. Stoddart, *Criminal Warrants* (2<sup>nd</sup> edn), (Edinburgh: Butterworths, 1999), p.63.

<sup>122</sup> This was the procedure in the Stephen Kelly case (unreported), in which the police seized personal medical information and a blood sample, which had been taken as part of a research project, with a warrant. For information on the case see: C. Dyer, 'Use of confidential HIV data helps convict former prisoner', (2001) *BMJ* 322:633, and S. Connor, "Police access to medical data 'a threat to research'", *The Independent*, 16 July 2001.

<sup>123</sup> See s.9 (1) of the Police and Criminal Evidence Act 1984 and Schedule 1.

<sup>124</sup> See: J. Kaye, 'Police collection and access to DNA samples', (2006) 2:1 *Genomics, Society and Policy* 16-27.

<sup>125</sup> Stoddart, *Criminal Warrants*, p.63.

<sup>126</sup> *Ibid.*, p.133ff.

for a warrant to the appropriate magistrate, most commonly the Sheriff.<sup>127</sup> Warrants to search premises must be specific as to the articles the search is intended to locate and the place(s) to be searched. A warrant that is too wide and indefinite is illegal.<sup>128</sup> When carrying out a search under warrant in Scotland, police officers should follow what is considered 'appropriate procedure' in their area.<sup>129</sup>

### **V: Missing persons**

6.24 With regard to the identification of missing or deceased persons, current practice in Scotland is that the police will obtain a letter from the Procurator Fiscal for release of the blood spot card.

### **VI: Accessing children, parents and families**

6.25 The above analysis suggests that in the future it will be important to seek consent from parents or persons themselves about uses of the samples or data. Examples include where the proposed use exceed the bounds of what a reasonable citizen would expect, where a research use might be particularly controversial, where the sample or use involves identification of individuals and/or where an access or ethics committee otherwise deems consent to be necessary. In all such cases, the procedures for tracing and contacting people become very important. It is not acceptable, for example, for researchers simply to be given contact details in order to approach people 'out of the blue'. Rather, approaches must be carried out sensitively and be proportionate in relation to the privacy implications. In such cases, it is important to identify a suitably-responsible intermediary to make the approach. This might be a senior official in National Services Scotland or National Registers for Scotland or from the Health Board under whose auspices the collection is held (Greater Glasgow & Clyde). Any approach should first be subject to ethical oversight by a suitable ethics committee or the Privacy Advisory Committee.

## **POINTS TO CONSIDER AND RECOMMENDATIONS FROM CHAPTER 6:**

- **A clear, robust and transparent access policy for the Guthrie collection in Scotland should cover all current and foreseeable future uses of the resource;**
- **This policy should include guidance for decision-makers on relevant factors to take into account. This might include:**
  - **Determining the scientific or public value of the project;**

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<sup>127</sup> Ibid., p.9. See also *R. v. Manchester Stipendiary Magistrate and the Lord Advocate (Appellants) Ex Parte Granada Television Ltd. (Respondent)* (On appeal from a Divisional Court of the Queen's Bench Division) 14 December 1999, House of Lords, in which Lord Hope of Craighead stated that: 'When a constable of a Scottish police force wishes to obtain a search warrant he makes a report to the procurator fiscal, who in Scotland is the public prosecutor. This is because in Scotland applications to the courts of summary jurisdiction in criminal matters are made by the procurator fiscal, not by the police'. Available at: <http://www.publications.parliament.uk/pa/ld199900/ldjudgmt/jd991214/granad-1.htm>

<sup>128</sup> Ibid., p.19.

<sup>129</sup> Ibid., p.69.



- **Assessing ethical concerns both for individuals and society;**
  - **Establishing the pressing social need for the access;**
  - **Deciding whether consent can and should be sought for access;**
  - **Identifying any consequences of access for the resource; e.g. use of depletable samples, and**
  - **Implementing ways to minimise any adverse impact of the access;**
- **There should be mechanisms for prioritising research requests and requiring return of results to the resource in the spirit of benefit sharing;**
  - **A written protocol for the release of samples and information to the police be developed and made publicly available;**
  - **Personnel within the NHS should act as gatekeepers with respect to such requests, and most notably and ideally Caldicott Guardians should be involved in all decisions;**
  - **Given the existence of an opt-out system, consideration should be given to the mechanisms for adequately informing people about withdrawing consent if the person no longer wants the blood spot card to be used for research or other purposes;**
  - **Consideration should be given to the role of any Access Committee and/or oversight body in this regard (see further Chapter 7);**
  - **Those responsible for the collection must clearly define the purposes of the collection and link these to justifiable periods of retention;**
  - **Consideration needs to be given to the appropriateness of the actual physical environment in which the collection is held and the way in which it is archived;**
  - **Appropriate processes must be established for contacting people when seeking consent to use of samples and data.**

## CHAPTER 7: GOVERNANCE

### Key questions addressed by this chapter are:

- Who is (or should be) responsible for the governance of the collection?
- Who is legally liable if things go wrong?
- Can existing oversight bodies, such as research ethics committees or the Privacy Advisory Committee, assist with the governance challenges of the Guthrie collection?
- Can lessons be learned from other countries or other biomedical collections?
- What does *good governance* look like?

### Key messages from this chapter are:

- The relationship between the Glasgow Southern General Hospital – as immediate custodian of the initial sample collections for the first two years - and other entities such as Greater Glasgow & Clyde Health Board, National Services Scotland, NHS Research Scotland, and Health Improvement Scotland should be clarified within lines of accountability and framework for research governance. Ultimately, it is Greater Glasgow & Clyde Health Board that bears the responsibility of management of the collection but the input and influence of national bodies could be explained further.
- Robust and transparent policies should be kept under constant review with respect to all aspects of the resource. Valuable lessons can be learned from the Danish model of research and access governance for newborn blood spot cards.
- It is suggested that models used by UK Biobank and Generation Scotland to provide independent oversight of biomedical collections add considerable value in addressing the challenges of running a long-term resource into an uncertain future and could serve as possible models. Governance mechanisms for the Guthrie collection could learn useful lessons in this regard.
- Governance mechanisms must include policies and procedures for raising awareness of the collection and engaging with the public and other stakeholders, such as the research community.
- It is for consideration whether an education campaign like that envisaged by the Confidentiality and Security Advisory Group for Scotland (CSAGS) should now be undertaken in Scotland.

## DISCUSSION

7.1 Good governance in healthcare has become a topic of significant interest in recent years. In the United Kingdom alone, numerous projects are underway with respect to information governance. Novel models of governance have been instituted for large-scale longitudinal genetic resource projects such as UK Biobank and Generation Scotland; the Scottish Health Informatics Programme (SHIP) has been launched with involvement of NHSScotland; the Ministry of Justice has published a report on Data Sharing and the UK Government has issued its response and Scottish Government has held various consultations on improving research infrastructure in Scotland and which culminated in the publication of its Guiding Principles for Data Linkage.<sup>130</sup> A growing number of examples of good practice are emerging as lessons are learned from experience.<sup>131</sup> In this regard, we should also consider foreign experiences, not just the cautionary such as those outlined in Chapter 2, but also the positive and especially that of the Danish Newborn Screening Biobank. In sum, there is much experience on which to draw when considering the governance challenges of the Guthrie collection in Scotland. This chapter lays out those challenges as identified in this report and makes suggestions as to how these can be met.

### ***Governance challenges***

7.2 The following governance challenges face the Guthrie collection:

- Although the Scottish Newborn Screening Laboratory sits under the auspices of Greater Glasgow and Clyde Health Board and NSS, it would be helpful to clarify how its operation should dovetail with other branches of the work of NSS, such as Privacy Advisory Committee, and how/whether there should be a role for research ethics committees, for example in applications for access. The input from other agencies, such as NHS Research Scotland that has produced tissue research Guiding Principles, and Health Improvement Scotland, which is responsible for monitoring compliance under its Accreditation Scheme, further complicates matters.
- More particularly, the role of the Caldicott Guardian with respect to the collection and the Scottish Newborn Screening Laboratory could be more explicit.
- A Governance Board and/or an Access Committee has been established for the Guthrie collection and this is welcomed. Notwithstanding, its role and relationship to other bodies also needs further elucidation with respect to all of the points raised in previous chapters.

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<sup>130</sup> At the time of writing this can be obtained on written request from [Craig.Gilbert@scotland.gsi.gov.uk](mailto:Craig.Gilbert@scotland.gsi.gov.uk)

<sup>131</sup> As an example from the Scottish Health Informatics Programme, see G. Laurie and N. Sethi, 'Towards principles-based approaches to governance of health-related research using personal data' (2013) 4(1) European Journal of Risk Regulation 43-57.

- Independent oversight will be provided by Healthcare Improvement Scotland in monitoring the Guiding Principles. It is for further consideration whether this is sufficient for all aspects of the resource, especially given its potential high profile and public concerns that we discuss in the next chapter. Other large biomedical collections now benefit from such monitoring and advice.
- There has been little effort to engage the wider public about the collection and its uses. Consideration should be given to the need for consultation.

### ***Learning from experience: Danish Newborn Screening Biobank (NBS-Biobank)***

7.3 This example has been chosen as the most closely analogous to the position in Scotland. Since 1982, residual dried blood spot samples from virtually all newborns in Denmark, Greenland and the Faroe Islands have been stored in the Danish Newborn Screening Biobank (NBS-Biobank). There are approximately 1.8 million samples in the bank.<sup>132</sup> The purpose of the storage is:

- Diagnosis and treatment of congenital disorders including documentation, repeat testing, quality assurance, statistics and improvement of screening methods;
- Diagnostic use later in infancy after informed consent;
- Legal use after a court order;
- The possibility of research projects after approval by the Scientific Ethical Committee System in Denmark, the Danish Data Protection Agency and the NBS-Biobank Steering Committee.<sup>133</sup>

Parents may “opt-out of biobank storage at the time of blood sampling by marking the data card, or at any time later, either by a written letter to the department or by registering in the central ‘Use of Tissue Register’ ([www.Sundhedsstyrelsen.dk/vaev](http://www.Sundhedsstyrelsen.dk/vaev))”.<sup>134</sup>

7.4 New Biobank Regulations were introduced in 2004 and incorporate the terms of the EU Data Protection Directive (which is also the basis of the Data Protection Act 1998 in the UK). A Task Group on biobank regulation determined in 2002 that a biobank may be regarded as a ‘manual register’ and is, therefore, subject to the legislation in data protection. **This provides some support for the Scottish position that Guthrie Cards are “medical records” and the conclusion in this report that they are subject to the Data Protection Act 1998.** The Task Group also made recommendations which led to changes in the law:

- The establishment of a central opt-out register for the use of tissue (the Central Use of Tissue Register), which allows people to opt-out of non-treatment-related use of biological material, and a right to destruction or the conditional surrender of donated biobank material;

<sup>132</sup> See generally, B. Nørgaard-Pedersen and D.M. Hougaard, “Storage policies and use of the Danish Newborn Screening Biobank”, (2007) 30 *Journal of Metabolic Disease* 530-536.

<sup>133</sup> Nørgaard-Pedersen and Hougaard, “Storage policies and use of the Danish Newborn Screening Biobank”, p. 530.

<sup>134</sup> *Ibid.*

- The approval of all research projects using biobank material by a science-ethical committee.<sup>135</sup>

The new regulations on biobanks, published by the Ministry of Health in September 2004, made the following provisions:

1. The biobank and register must be registered and accepted by the Danish Data Protection Agency with information about purpose, operation, data-responsible authority, biobank-responsible person, etc. (Act on processing of personal data). The equivalent in the United Kingdom is the Information Commissioner's Office.
2. Accordance with the Act on Patients' Rights which is concerned with 'self-determination' for a clinical biobank concerning informed consent and the right to 'opt out', to 'destruction' or to 'retrieval' of the biobank material. There is no equivalent Act in Scotland or the United Kingdom, although the general legal position embodies a right to self-determination with a right to refuse.
3. Procedures for use of biobank material for research must always be accepted by the Scientific Ethical Committee System according to the Act on Scientific Committee ([www.cvk.im.dk](http://www.cvk.im.dk)). The Guthrie collection in Scotland currently has no such oversight.
4. According to the Act on Health, the biobank-responsible person(s) is/are responsible according to general rules for personal health care concerning secrecy confidentiality, etc. Complaints concerning biobanks can be directed to the Health Care Patients Complaints Authority, Danish National Board of Health. As established above, the equivalent lines of accountability for the Scottish Guthrie collection lead to NSS within NHS Scotland.<sup>136</sup>

### ***Steering Committee for Scientific Use of the NBS-Biobanks***

7.5 A Steering Committee for Scientific Use of the NBS-Biobank (SCSU) was set up in 2005 to administer the use of the samples for research and, in particular, to prioritise the use of the residual blood spots to ensure that enough blood is left to serve the most important purposes, which are, first, the analysis of the residual blood spots for the benefit of the child and family and, second, the development of new methods for newborn screening analyses.<sup>137</sup>

7.6 Once the proposed project has received approval from the Danish Data Protection Agency and the Scientific Ethics Committee System, the SCSU "evaluates the scientific value of the projects and the appropriateness of the proposed analytical technology", ensuring that "there is always enough blood left of each sample to complete the necessary medical analyses directly related to the original purpose of

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<sup>135</sup> Ibid.

<sup>136</sup> Ibid., p.532

<sup>137</sup> Ibid., p.533.

storage”, that being medical analyses for the benefit of the child and family.<sup>138</sup> **This is a very good example both of priority setting with respect to the use of a depletable resource and of robust mechanisms for assessing the scientific/public value of proposed uses. A further consideration for such a body might be an assessment of the likely privacy impact on individuals of granting any particular application for access and recommendations as to whether this is acceptable or might be minimised.**

7.7 In Scotland, the Greater Glasgow & Clyde Health Board Biorepository Governance Board acting as Access Committee could scrutinise applications in this way. Alternatively, or additionally, a research ethics committee or a body such as the Privacy Advisory Committee in Scotland could have such responsibility or even a wider oversight role. At the time of writing a consultation was underway on the need for a National Privacy Advisory Committee. In this respect, lessons might be learned closer to home from the UK Biobank project and the Generation Scotland project and existing guidelines/principles for tissue collections<sup>139</sup>.

### **Learning from experience: UK Biobank and Generation Scotland**

7.8 The purpose of the UK Biobank project is to build a resource for research in the public good with the specific aim of improving the prevention, diagnosis and treatment of illness and promoting health throughout society. Recruitment took place between 2007 and 2010 and the resource now contains health and lifestyle data and biological samples from over 500,000 individuals aged 40-69 at time of enrolment. Participants give broad consent to participate in UK Biobank and grant permission to UK Biobank to access to their health records, provide some biological samples (e.g. blood and urine) and information about their lifestyle. The cohort will be followed up for decades, capturing all major health episodes and eventual death.

7.9 UK Biobank operates within an Ethics and Governance Framework (EGF). The EGF is a public document which contains the express commitments of UK Biobank to its participants, to the public and to other stakeholders, such as researchers. The EGF affirms the right to withdraw at any time; makes a commitment to protect the confidentiality of both samples and data; confirms the role of UK Biobank as a steward of the resource (albeit, probably also its legal owner); describes the principles which will govern access to the resource and describes the benefit sharing arrangements that will be required of those who use the resource - these include the obligatory publication of findings (including negative results), return of data to UK Biobank, and the accessible storage of findings for future use.

7.10 UK Biobank is monitored by the independent Ethics and Governance Council (EGC).<sup>140</sup> The EGC is a permanent and independent body to oversee the project and to monitor and advise on its operation.<sup>141</sup> Current challenges facing UK Biobank and the EGC are the development of access policy and procedures and the possible

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<sup>138</sup> Ibid.

<sup>139</sup> e.g. SAHSC Bio-repository principles and Bio-repositories - Better Cancer Care.

<sup>140</sup> Laurie, the lead author of this report, was Chair of the Ethics and Governance Council (2006-10).

<sup>141</sup> UK Biobank Ethics and Governance Council: <http://www.egcukbiobank.org.uk/> The Secretariat of the EGC is provided jointly by the Wellcome Trust and the Medical Research Council.

input of the EGC into the work of any Access Committee which might be established by UK Biobank.

7.11 Generation Scotland (GS) has a similar scientific focus to UK Biobank in that it is concerned with gene/environment interaction in the onset of disease; it is entirely complementary, however, in that it seeks to recruit families and not unrelated individuals. GS also has governance parallels with UK Biobank in that it has been overseen by the Generation Scotland Advisory Board which performed a similar function to the UKB Ethics and Governance Council.<sup>142</sup> This was disbanded in due course once the resource was firmly established, albeit the on-going issues continue to arise as access has got underway.

7.12 In both cases, the rationale for an independent advisory body is related to the long-term nature of each project - which could extend for many decades - and the known unknowns surrounding the kinds of research that might be carried out using each resource and the kinds of researchers who will carry it out. Thus, such oversight bodies provide on-going scrutiny and input as the projects develop and change. This role has not been undertaken by any body to date in the UK with respect to life sciences research. Equally, Scotland must not succumb to the vagaries of unwarranted regulatory burden. What is important here is that the *function*, not necessarily the form, of such entities is built into governance arrangements. That is, these functions might be picked up by the Greater Glasgow & Clyde Biorepository Governance Board and there might be no need to establish a new one so long as the key features of this role are discharged.

7.13 A further issue relates to the nature of the consent which is sought from participants and which arguably requires a different approach to that which has traditionally governed the involvement of individuals in research. This is *broad* consent as outlined above. This is used because it is not possible to give people full information *prior* to participation. Rather, the ethical (and legal) obligation is to inform people as the projects progress on matters such as access, research use, benefit sharing, commercialisation etc. In this way consent is constructed far more robustly as a *process* including an on-going obligation to engage with participants throughout the life of the project and not a one-off event prior to launch. Participants have a right to withdraw at any time and for any reason.

The parallels here with the Guthrie collection should be self-evident. They require on-going and robust engagement about the management and use of the Guthrie collection.

### **Public engagement**

7.14 We address specific questions about public attitudes and engagement in the next chapter. Here we simply to point to the numerous junctures in this report, and in the experience of other collections, which suggest that a robust policy of public engagement is valuable and an increasingly essential feature of good governance. The English consultation on Guthrie cards contemplated the possibility of a public

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<sup>142</sup> Laurie served as a member of the Generation Scotland Advisory Board. The Secretariat for the GSAB was provided by the Chief Scientist Office, Scottish Government.

scrutiny panel and regular public consultation exercise.<sup>143</sup> At the time of writing the report remains unpublished. In Scotland, the Confidentiality and Security Advisory Group for Scotland (CSAGS)<sup>144</sup> recommended in 2002 a public education campaign about uses of health information but no such campaign has taken place. **We recommend that this issue be given serious reconsideration.**

#### **POINTS TO CONSIDER AND RECOMMENDATIONS FROM CHAPTER 7:**

- **While it is Greater Glasgow & Clyde Health Board that has the principal responsibility for governance of the Guthrie collection, the relationship with, and influence of, other entities such as National Services Scotland, NHS Research Scotland, and Health Improvement Scotland could be elucidated further.**
- **Robust and transparent policies must be kept under review with respect to all aspects of the resource, especially because access requests are only likely to increase in the future. Valuable lessons can continue to be learned from the Danish model of research and access governance.**
- **It is for consideration whether the Guthrie collection requires its own independent oversight body. The important feature, however, is not the form of this governance but the fact that the key features are incorporated into arrangements. Thus the NHS Greater Glasgow & Clyde Biorepository Governance Board might learn valuable lessons from existing independent bodies such as the UK Biobank Ethics and Governance Council.**
- **Governance mechanisms must include policies and procedures for raising awareness of the collection and engaging with the public.**
- **It is for consideration whether an education campaign like that envisaged by CSAGS should now be undertaken in Scotland.**

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<sup>143</sup> The report on the consultation document has not been made publicly available.

<sup>144</sup> <http://www.sehd.scot.nhs.uk/publications/ppcr/ppcr.pdf>



## **CHAPTER 8: PUBLIC ATTITUDES & PUBLIC ENGAGEMENT**

8.1 This chapter discusses some of the previous work that has been conducted on public attitudes to the storage and use of newborn bloodspots obtained for screening purposes. Prior to 2009, there had been very little empirical work to examine the views of parents and the wider public on the possible research uses of these samples and associated information. However, as the scientific case for the research potential became more compelling, the associated social, ethical and legal issues remained to be characterised and solutions sought. Empirical research exploring public attitudes is central to that endeavour as this will indicate whether or not there is broad public support, what public concerns are articulated and what conditions need to be met to ensure such support and alleviate concerns. Several studies, using both quantitative and qualitative research techniques, conducted in different countries, have helped answer key questions about what the public think about research uses of stored blood spots from newborn screening. The findings from studies in different jurisdictions, utilising different methods and with different participating population groups, while identifying a range of views, demonstrate overall support for the storage and use of these samples for research purposes, with appropriate safeguards and permissions. The results of several of these studies are distilled below and the key themes identified. The chapter then suggests what research, engagement and consultation should be conducted in Scotland to inform policy in this area.

### **Key questions addressed by this chapter are:**

- **What research has been conducted on public attitudes relating to the storage and use of newborn bloodspots?**
- **What are the key findings from such research?**
- **What needs to be done in Scotland to assess views and support public engagement?**

### **Key messages from this chapter are:**

- **There seems to be majority support for the storage and future use of newborn bloodspots for health related research.**
- **However, a minority do not support such use, with some evidence that this may be related to concerns about privacy, discrimination or lack of trust.**
- **Overall, permission/consent was identified as essential for such support, although there are different views on when, how and what type of consent should be sought.**
- **There is a lack of knowledge about retention and future use. Increased understanding was related to increased support in some studies.**
- **Parents and the wider public wish to have information and choice.**
- **Public engagement is likely to enhance trust and support for such biorepositories.**
- **In the Scottish context, there should be a programme of public engagement to explore the public's views and concerns and to identify**

## **ways to promote on-going public involvement and the appropriate mechanisms for information sharing.**

### **Existing research on public attitudes**

#### ***Australia***

8.2 Davey et al (2005)<sup>145</sup> conducted a survey of 600 new mothers in Perth, Western Australia, using a self-administered questionnaire. This represented a response rate of 33%. The majority of women had heard of newborn genetic blood screening and over half were satisfied with the information provided. However, some commented on the need for better information given at a more appropriate time.

8.3 Twenty-nine per cent supported the current 2 year retention period and the same proportion a 3-10 year period. However, the authors note that some women said that they did not know enough to make an informed answer; others thought that two years was enough to meet the primary purpose of the test. Those supported a retention period of longer than 2 years seemed to be more keen on promoting research.

8.4 Most (85%) believed that anonymised samples should be made available for research, with 4% disagreeing and 11% being unsure. More specific questions reaffirmed this commitment and also the strong concern about the need for samples to be de-identified. Additional qualitative comments also identified the need for consent. There was also support for different types of health related research.

8.5 Survey research is of course limited by the questions asked and the scope provided for respondents' answers. Some of the question wording was rather positively framed (for example, respondents were asked the extent to which they agreed or disagreed with the statement: 'I would like to have the opportunity to contribute positively to research through newborn screening cards').

8.6 Muchamore et al (2006)<sup>146</sup> conducted qualitative research using moderated small group discussions in New South Wales. Nine discussions were conducted with a total of 40 participants (24 women and 16 men) including young adults, parents with young children and parents with older children. Each group met twice to allow a deliberative component.

8.7 There was overall support for newborn screening although little specific knowledge. Discussion of the retention and use of samples revealed little understanding that this occurred nor of why it might be useful. The vast majority felt that parents should know that the dried blood spots were stored and could be used for a range of purposes.

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<sup>145</sup> A. Davey, D. French, H. Dawkins and P. O'Leary P, 'New mothers' awareness of newborn screening, and their attitudes to the retention and use of screening for research purposes' (2005) 1(3) *Genomics, Society and Policy* 41-51.

<sup>146</sup> I. Muchamore, L. Morphett and K. Barlow-Stewart, 'Exploring existing and deliberated community perspectives of newborn screening: informing the development of state and national policy standards in newborn screening and the use of dried blood spots' (2006) 3(14) *Australia and New Zealand Health Policy*: doi: 10.1186/1743-8462-3-14

8.8 Use for medical research was seen positively, but in the context of parents being informed and consulted if identifying information was provided. Parental consent was only seen as important by a few in the case of anonymised samples. There seemed to be a misconception that stored specimens might have direct future benefit to families.

8.9 Views were expressed about unacceptable uses (e.g. research into human cloning; research that might lead to discrimination by insurers or employers) and about inappropriate access - some felt concerned about access by pharmaceutical and biotechnology companies because of the profit principle whilst others reflected on the need for such research (such findings resonate with Scottish research on public attitudes to Generation Scotland, Haddow et al 2007; 2008<sup>147</sup>). Overall, the authors note a high level of trust in those representing the public good and therefore a willingness for them to make decisions about appropriate research.

8.10 Most saw value in stored samples being used to identify missing children and most were supportive of police access for solving crime. However, amongst the groups of men, concern was expressed as there seemed to be general distrust of the police. Concerns were also raised about security and privacy.

### ***New Zealand***

8.11 A comprehensive consultation has been undertaken in New Zealand, combining a public consultation with focus group research (Research New Zealand 2007 a and b)<sup>148</sup>. The consultation included closed and open ended answers to questions on information; consent; refusals; repeat sampling/testing; and storage and use. 182 responses were received with 80% of these being from private individuals (68% of whom were women).

8.12 Focussing on the issue of storage, access and use, the consultation found that 55% agreed with current New Zealand Police access to blood spot cards (to help identify a missing or deceased person or for other coronial inquiries within a Memorandum of Understanding between the Newborn Metabolic Screening Programme and the New Zealand Police). A further 21% agreed but with some suggested changes and 19% disagreed with 5% either did not know or had no comment on this issue. Although this suggests majority support, nearly a fifth of respondents did not agree with the current policy.

8.13 Forty-six per cent of respondents said that the blood spot cards should be stored indefinitely, 16% agreed with 21 years and 15% with 10 years. Nineteen per cent suggested other time periods, ranging from three months to the average lifespan.

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<sup>147</sup> G. Haddow, G. Laurie, S. Cunningham-Burley and K.G. Hunter, 'Tackling community concerns about commercialisation and genetic research: A modest interdisciplinary proposal' (2007) 64 *Social Science and Medicine* 272-282 and G. Haddow, S. Cunningham-Burley, A. Bruce and S. Parry, 'Generation Scotland: Consulting publics and specialists at an early stage in a genetic database's development' (2008) 18(2) *Critical Public Health* 139-149.

<sup>148</sup> K. Bendikson et al, 'Newborn Blood Spot Cards: Consent, Storage and Use: A public consultation', Research New Zealand, 18 December 2007.

8.14 Respondents were asked if they agreed or disagreed with the proposed process of approving research requests (formal approval by Ethics Committee and National Screening Unit). Sixty-six percent agreed with the proposed approval process; 22% disagreed and 12% either did not know or had no comment. Areas of concern amongst those disagreeing who provided comments were that the blood spots had not been originally taken for the purposes of research or that they (respondents) did not have enough knowledge of the organisations concerned.

8.15 The focus group research involved seven groups of 37 participants of different ethnicities, including new parents and adults without children. The research aimed to understand people's perceptions and expectations about future storage and use of blood spot cards. The research found support for screening but that attitudes and beliefs varied on some of the other issues. None could recall, where relevant, receiving information about storage and future use. There were a range of views about consent, although consensus about the need for consent. Some felt that there should be consent each time their child's blood spot was being used, others felt that final consent at the time of screening was sufficient, so long as this included specific consent for storage and each possible future use. The need for more information, given at an appropriate time and in an appropriate way, was also noted.

8.16 Participants did not know that the blood spots were stored; this was an emotional issue for some due to the specific cultural meanings of blood amongst the Maori and Pacific peoples. The authors note that only some were comfortable with the idea of indefinite storage and the New Zealand Europeans expressed an attachment to their blood spots.

8.17 Responses were also varied in relation to use of blood spots for research, with some happy about this and the proposed approval process and others concerned about lack of explicit consent or about final consent. Other types of use, for example by police or for audit seemed to generate less concern.

### **Canada**

8.18 Avarad et al (2006)<sup>149</sup> report on a consultative workshop held as part of a review of the social, ethical and legal issues regarding the storage, access and uses of newborn bloodspots. The workshop included a range of participants: policy makers, consumer groups, representatives from provincial NBS laboratories, health professional associations and the research community.

8.19 In relation to uses of dried bloodspots, respondents were supportive of research but less supportive for other purposes, such as special family studies or forensic purposes. It was noted:

*'It was agreed that there may be appropriate and inappropriate secondary uses of newborn dried bloodspots although there was diversity on where to draw the line and how to proceed' (p88)*

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<sup>149</sup> D. Avarad, H. Vallance, C. Greenberg et al, 'Variability in the storage and use of newborn dried bloodspots in Canada: Is it time for national standards?' (2006) 2(3) Genomics, Society and Policy 80-95.

8.20 Important factors raised were that secondary use should not interfere with the primary purposes of NBS; that identifiers must be removed and of course ethical approval gained. However, concern was noted about whether research ethics boards were able to determine appropriate uses. Most felt that future use for forensic purposes was a violation of individual liberties.

8.21 The workshop found no consensus over whether informed consent should be obtained before secondary use for research purposes took place. However, many seemed to think that if samples were anonymised and the research subject to ethical review, then explicit consent should not be required. Further research might help illuminate whether explicit consent should be required or assumed, but that the issue would remain complex. For example, would the primary purpose be negatively affected if consent for future use was required but then would individual autonomy and privacy rights be compromised if explicit consent was not obtained? Participants also noted that parents need to be informed about storage and future use as well as about the screening programme more generally.

8.22 Bombard et al (2012)<sup>150</sup> explored citizens' values about research with stored samples from newborn screening. Focus groups with an educational component, deliberative discussion and a pre and post interview questionnaire were employed. The study focussed on anonymous medical research and linkage to other information, as this reflects the approach in Canada as well as elsewhere.

8.23 The study found overall support for future anonymous research, with 90% (36 participants) agreeing to storing samples for such use and further support identified in the focus groups. Most suggested the need for choice in relation to whether their child's sample should be stored, although some thought that parents' should be required or at least strongly encouraged to allow such storage and use.

8.24 The researchers identified three key themes that underlay these differences: level of trust, concern about harms and where the balance between individual and population interests lay.

8.25 There was strong agreement that parents need to be informed about the secondary use of newborn bloodspots.

8.26 Given the differences between participants in relation to parental choice, the authors conclude that:

*Ultimately, although public engagement exercises may elucidate values, enhance transparency, and inform policy, they may not necessarily provide explicit policy direction (p245)*

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<sup>150</sup> Y. Bombard, F.A. Miller, R. Hayeems et al, 'Citizens' values regarding research with stored samples from newborn screening in Canada' (2012) 129 Pediatrics 239-247.

## **USA**

8.27 There have been several studies in the USA over the past few years exploring public attitudes. These have included different States and diverse methods and populations. The first are a group of publications by a research team including Botkin and Rothwell from the University of Utah.

8.28 Botkin et al (2012)<sup>151</sup> conducted a multi-method study utilising a survey (paper/telephone), focus groups and an internet survey through Knowledge Network panels. A total of 3855 participants were involved in these studies. An educational movie or written information was provided.

8.29 Although the study found strong support for NBS, 30% of survey respondents indicated that they were very concerned about retention. Those with lower concern were more likely to have seen the movie rather than the written information, to be white, a mother of young children, with higher educational attainment and to have been surveyed by telephone.

8.30 However, there was majority support (80%) for potential uses of residual bloodspots whether this was for quality control, research on diseases affecting mothers and children or research on diseases of the general population.

8.31 The survey asked whether an opt-in or opt-out permission model was preferred. 62% supported an opt-in model. The factors that were associated with selecting an opt out model were movie education, older age and higher level of education.

8.32 This study reinforced the importance of providing information; this led to increased support as well as improving knowledge. The authors note that their focus group discussions demonstrated that participants were supportive of retention but wanted more information and that choice was important.

8.33 Rothwell et al (2012)<sup>152</sup> report on the focus group element of the above study. Fourteen groups were conducted across six states, with a total of 128 participants. The groups included ones with the general population, African-American groups, Hispanic groups and mothers with young children.

8.34 The results suggest support for the retention and use of residual blood spots for research. There was a preference for an opt-in approach although some recognition of the logistical issues with this.

8.35 There was general support for research to improve health or provide medical benefit if conducted by university or medical departments rather than pharmaceutical companies.

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<sup>151</sup> J.R. Botkin, E. Rothwell, R. Anderson et al, 'Public attitudes regarding the use of residual newborn screening specimens for research' (2012) 129 Pediatrics 231-238.

<sup>152</sup> E. Rothwell, R. Anderson, A. Goldenberg et al, 'Assessing public attitudes on the retention and use of residual newborn screening blood samples: a focus group study' (2012) 74 Social Science and Medicine 1305-1309.

8.36 Personal control was considered important with participants expressing their right to choose, their need to be informed and to be able to change their minds.

8.37 Rothwell's earlier study (2010)<sup>153</sup> also employed focus group methods, with three groups, an African American group, a Paediatrician group and a Mothers of young children group. They noted that that guidance had tended not to be informed by public input and suggest this is a failure than could become problematic.

8.38 This research identified the need for informed consent on both anonymous and identifiable residual samples, appropriate ethical review, consent for storage, fears of discrimination arising from research and lack of awareness of the programme.

8.39 Duquette and colleagues at Michigan Department of Community Health and University of Michigan report on two studies. The first comprised a set of four questions on the 2008 Behavioural Risk Factor Surveillance System (telephone survey)<sup>154</sup>. These asked about support for the use of dried blood spots for research in general, for specific diseases (general health research, childhood, adult and environmental exposure). The sample was 3018 adults.

8.40 The majority (72.3%) supported the use of dried blood spots for research; those who were female, younger, white, healthy and with at least a high school degree were more likely to say that they were in favour. Only three per cent strongly opposed.

8.39 Support was high for each type of use with little variation across use; indeed it was higher than for the overall question about use. This support was associated with age, education and household income.

8.41 The second study reported by Duquette et al (2010) involved ten focus groups from diverse communities. The discussions explored public views about the Michigan BioTrust for Health, a program for storage and use of residual newborn screening dried blood spots:

*'Community engagement was considered critical for assuring that samples are used in a manner acceptable to the public and to the ultimate success of the MDCH BioTrust initiative' (p147)*

8.42 Four key questions were used focussing on initial thoughts about the BioTrust, types of research that would be acceptable, how consent should be obtained and how you would feel about your own or your child's de-identified blood spots being used for research. Each participant was provided with written information, there was a presentation and a pre and post survey.

8.43 There was very strong support for the idea of a BioTrust, with none saying they were opposed and a consensus being reached. The survey produced consistent results, with 86.4% strongly or somewhat agreeing. There was also broad support for

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<sup>153</sup> E. Rothwell, R.N. Anderson, J. Botkin, 'Policy issues and stakeholder concerns regarding the storage and use of residual newborn dried blood samples for research' (2010) 11(1) Policy, Politics & Nursing Practice 5-12.

<sup>154</sup> D. Duquette, A.P. Rafferty, C. Fussman et al, 'Public support for the use of newborn screening dried blood spots in health research' (2010) 14 Public Health Genomics 143-152.

any type of health research, although participants identifying cloning or cosmetic research as exceptions. The post discussion survey identified increased support. In the survey, support for use by academic institutions was higher than for private sectors, but in the focus groups there was a recognition that distinguishing these two was sometimes difficult and the type of research seemed to be more important than who was conducting it.

8.44 There was a consensus that information was required for informed decision making but different views as to how this might be provided. There was also lack of consensus in the focus groups about whether consent should be opt-in or opt-out. This was reflected in the survey responses also.

8.45 Lastly, there was general agreement about using one's own or one's child's bloodspots in de-identified research. In the questionnaires, willingness increased post discussion. Privacy concerns were expressed by a minority and opinion was divided about the benefit of receiving research results.

8.46 Tarini et al's research<sup>155</sup> comprised an internet survey of a nationally representative sample of parents, with a sample size of 1508. This examined willingness to permit use of their children's newborn samples and to allow storage.

8.47 Overall, 76.2% responded that they were willing or somewhat willing to permit use, with permissions. This dropped to 28.2% if permission was not obtained. Seventy-eight per cent would permit storage; those less willing to permit use were also less willing to permit storage.

8.48 They conclude that it is important to:

*'engage the public in a transparent and informative discussion that also provides parents a forum in which to voice their concerns.'*  
(p129)

8.49 Neidich et al (2010)<sup>156</sup> conducted a survey of women in University of Chicago hospitals who had live infants. 239 women participated, with 82% self-classifying as black. The researchers wanted to explore attitudes to a hypothetical paediatric biobank as a response to ethical concerns about a proposed programme, particularly what additional safeguards might be required and what information beyond the usual consent requirements.

8.50 The results suggested some support for such a biobank, with 48% of women saying they'd be willing to enrol their child and 28% being not sure. Caucasians were the most willing.

8.51 The research also explored why people responded as they did and 58% expressed altruism for societal benefit. Exploring what that benefit might be, the survey contained questions about trust and justice. Understanding of research, trust

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<sup>155</sup> B.A. Tarini, A. Goldenberg, D. Singer et al, 'Not without my permission: Parents' willingness to permit use of newborn screening samples for research' (2010) 13 Public Health Genomics 125-30.

<sup>156</sup> A.B. Neidich, W.J. Josh, C. Ober and L.F. Ross, 'Empirical data about women's attitudes towards a hypothetical pediatric biobank' (2010) American Journal of Medical Genetics Part A: 297-304.



in researchers and a belief that findings would be used fairly all correlated with hypothetical enrolment. The authors conclude that:

*'It is imperative that researchers help ensure that the women's trust and justice beliefs are fulfilled' (p303)*

## **China**

8.52 Gong and colleagues conducted the first survey of Chinese parents regarding the use of newborn screening samples. This was a hospital-based survey to explore attitudes to newborn screening sample storage and permitting use for research (with or without consent). With a 52% response rate, the sample size was 378. The research was conducted in Beijing.

8.53 Sixty-eight per cent of parents would permit infants' samples to be stored but this dropped to 14% if no permission was obtained. This did not seem to be explained by a range of socio-demographic variables, such as gender, education or household income. Those who would not approve of use in those circumstances also reported that they should be given more information:

*'They strongly believed that they – and not merely the researchers – should play a more important role in such research' (p191)*

8.54 Although these authors note similarities between their findings and other research such as that summarised above, they also suggest that there is a basic lack of trust between patients and doctors in China and therefore concern about rights and privacy.

## **Japan**

8.55 Fujii et al (2010)<sup>157</sup> conducted a questionnaire study to examine the attitudes of the public, parents, patient families and health professionals to extended uses of newborn screening and storage of blood spots. They found that awareness of newborn screening was low amongst the general public and they were less likely to be positive about the extended use for the study of health problems. Patient families and health professionals were more positive.

8.56 The open ended comments were analysed through text mining and three concepts were identified: personal data (for example, privacy); consent availability; and progress in medical science. As with other studies, they noted the importance of information.

## **England**

8.57 Research by Hargreaves et al (2005)<sup>158</sup> from the Parent Support Research Team of the UK Newborn Screening Programme Centre touched on this issue. Hargreaves et al conducted a qualitative study involving telephone interviews and

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<sup>157</sup> C. Fujii, Y. Sato, S. Harada et al 'Attitudes to extended use and long-term storage of newborn screening blood spots in Japan' (2010) 52 Pediatrics International 393-397.

<sup>158</sup> K. Hargreaves, R.J. Stewart and S.R. Oliver SR, 'Informed choice and public health screening for children: The case of blood spot screening' (2005) 8 Health Expectations 161-171.

focus groups with 47 parents and 35 health professionals. They found that amongst some parents the need for written consent was heightened when the storage of bloodspots was considered.

### ***Conclusions on public engagement***

8.60 Research across different jurisdictions, using different methods identify overall support for the storage and research use of newborn blood spots. However, some are less supportive and support is contingent on a number of factors. Consent, control, trust and information are all identified as key to maintaining and promoting public support.

8.60 In policy terms, the research is clear about the need for public engagement, not as a one-off consultation to ascertain views but as an integrated component of the on-going relationship between citizens and those who procure, curate and use newborn blood spot collections. This suggests an approach to engagement that embraces awareness raising, consultation and empowerment.

8.61 Research and public engagement should be conducted in Scotland to explore views and attitudes as well as to shape best practice in public involvement in governance.

## **POINTS TO CONSIDER AND RECOMMENDATIONS FROM CHAPTER 8**

- **Although previous research on public and professional attitudes does not suggest widespread distrust or concern about the storage and use of newborn bloodspots, the issues of consent, access, appropriate use and regulation are pertinent and there is a degree of ambivalence about appropriate policies. This needs to be resolved transparently and with public input.**
- **We recommend primary research on public and professional attitudes and concerns about the storage and further use of newborn bloodspots and a programme of public and stakeholder engagement for effective governance.**

## **CHAPTER 9 - SUMMARY OF POINTS, RECOMMENDATIONS AND FUTURE CONSIDERATIONS**

### **General considerations**

- It is essential to consider the full range of people affected by the collection. Different people might be affected in different ways and different legal rules might apply to them.
- It is essential to consider the full range of purposes for which the collection might be used both now and in the future. Although a range of purposes might be justified, the case for each use must be clearly made. The justifications must be stronger as the use becomes more about the public interest and less about each person's health interest.
- It is essential that clear, transparent and robust policies are in place for every aspect of the collection from initial taking of consent and samples, to storage, quality assurance, access and contingency planning. While many aspects of the collection are now covered in this respect, all policies must be kept under regular review given the rapidly changing social and scientific landscape.

### **Legal Basis**

- The Guthrie collection should be treated as both personal information and human tissue for the purposes of legal governance.
- The existing collection is lawful but careful attention must be paid to matter of future use and access.
- Consent to use is not an absolute requirement but should not be departed from lightly.
- Anonymisation can remove some legal obligations but not all obligations; moreover, it is not a complete answer to the challenges thrown up by the collection.
- Human rights are a consideration across all areas of law. All mechanisms, policies and procedures should be tested for human rights compliance.

### **Consent and anonymisation**

- The law does not require that specific consent be sought from all persons whose samples or data are held in the Guthrie collection; it is for consideration none the less, whether such consent should be sought as a matter of good practice.
- If specific consent is not sought, all the more emphasise must be placed on the system of opt-out that exists. This is the principal means to respect persons whose samples/data are contained in the collection. It requires clear

communication to the public about uses of the collection and details about the governance mechanisms in place. Vitally, citizens must be able to know easily how to exercise their right to opt-out and have the respected in a timely fashion.

- Because people consent to inclusion in the collection on the basis of broad consent, attention should be given to how they will be kept up-to-date with uses of the resource as and when these occur.
- It is for consideration whether a system of 'consent for consent' should be considered to facilitate access to the Guthrie collection for research purposes; caution should be exercised, however, about adopting a presumed consent approach.
- Specific consent should be sought from individuals if access is contemplated for non-standard purposes, e.g. non-health-related research.
- It is for consideration whether mature minors should be allowed to opt-out of the collection.
- Procedures should be developed for circumstances where access will be given without consent but subject to suitable authorisation.
- Procedures should be developed to decide whether and how access will be granted if neither consent nor anonymisation is possible.
- Consideration should be given to scrutiny mechanisms authorising access even when anonymisation is contemplated.
- A policy should be developed on whether and how feedback of individual results will be given.
- A decision should be taken on Open Access to the resource or results from the resource.
- A Privacy Impact Assessment should be carried out on the Guthrie collection.

### **Storage and access**

- A clear, robust and transparent access policy should be kept under regular review for the Guthrie collection in Scotland to cover all current and foreseeable future uses of the resource;
- This policy should include guidance for decision-makers on relevant factors to take into account. This might include:
  - scientific or public value of the project;
  - ethical concerns both for individuals and society;
  - the pressing social need for the access;
  - whether consent can and should be sought for access;

- any consequences of access for the resource; e.g. use of depletable samples, and
  - ways to minimise any adverse impact of the access.
- There should be some mechanism for prioritising research requests;
  - A written protocol for the release of samples and information to the police be developed and made publicly available;
  - If an opt-out system is thought to be desirable, consideration should be given to the mechanism for withdrawing consent if the person no longer wants the blood spot card to be used for research or other purposes.
  - Consideration should be given to the role of an Access Committee and/or oversight body in this regard.

## **Governance**

- The relationship between the Yorkhill Centre and NSS should be clarified within lines of accountability and framework for research governance. In particular, what is the relationship with:
  - the Caldicott Guardian,
  - Research ethics committees and
  - Privacy Advisory Committee?
- Robust and transparent policies should be developed with respect to all aspects of the resource. Valuable lessons can be learned from the Danish model of research and access governance for newborn blood spot cards.
- It is for consideration whether the Scottish Guthrie collection requires its own Governance Board and/or Access Committee.
- It is for consideration whether the Guthrie collection requires an independent oversight body. It is recommended that models used by UK Biobank and Generation Scotland add considerable value in addressing the challenges of running a long-term resource into an uncertain future and could serve as possible models.
- Any governance mechanisms that are instituted must include policies and procedures for raising awareness of the collection and engaging with the public.
- It is for consideration whether an education campaign like that envisaged by CSAGS should now be undertaken in Scotland.

## **Public attitudes and public engagement**

- Previous research on public and professional attitudes does not suggest widespread distrust about the storage and use of newborn bloodspots but some degree of ambivalence was expressed by some.

- The issues of consent, access, appropriate use and regulation are relevant to parents and a variety of opinions are expressed about appropriate mechanisms.
- We recommend primary research on public and professional attitudes and concerns about the storage and further use of newborn bloodspots and a programme of public and stakeholder engagement for effective governance and policies.

### **Future considerations**

The essential issue at the heart of all challenges relating to biomedical collections such as the Scottish Guthrie card collection is the question of time. The Guthrie collection was started at a time when ethical and social expectations were very different to those of today. Its potential value has become clearer over time and this forms the basis for arguments in favour of its retention; equally, only time will tell which kinds of request for future uses might arise and whether these will be granted. It is also very likely that public and individual expectations and attitudes will change. It would be unhelpful and unproductive to attempt to respond to speculative Frankenstein futures that can be imagined by the advent of developments such as cloud computing and genome-wide association studies. There is little doubt that the potential of biomedical collections will only increase, but we cannot say today what will be the appropriate responses of tomorrow. Notwithstanding, all of this speaks to the importance of dynamic and robust governance that can respond to near-future challenges of storage, management and use as and when they arise. Given the cross-cultural and wide-ranging disciplinary issues at stake, it will be important to provide ample manoeuvre in developing appropriate responses to technological advances and which take into account the implications for science and society. For these reasons, as **a final recommendation we suggest that jointly-funded AHRC and ESRC doctoral scholarships be pursued to examine the cross-cutting themes.**

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