Submission from Cystic Fibrosis Ireland on the Retention of Cards used in the National Newborn Screening Programme

June 2013

Note: The Cystic Fibrosis Association of Ireland shortened its name to Cystic Fibrosis Ireland in 2013.
Introduction and Summary

The primary rationale for this submission is to seek to preserve the integrity and public confidence in the National Newborn Screening Programme (NNBSP) in Ireland and in particular in relation to screening for Cystic Fibrosis (CF).

Cystic Fibrosis is one of the 6 diseases that are part of the NNBSP. This submission is written in the context of the Government’s recent suspension, pending review, of its decision to destroy archived NNBSP cards that are more than 10 years old.

As part of our role as the national patient group for Cystic Fibrosis, Cystic Fibrosis Ireland (CFI) is active and has a long track record in funding and supporting medical research. CFI also works closely with colleagues in other medical and patient charities in promoting research and in supporting progressive health policy.

CFI is aware of the sensitivities raised by the potential destruction of archived NNBSP cards; however we are also cognisant of the need to preserve the integrity and our members’ confidence in the NNBSP. CFI is also cognisant of the difference in opinions among clinicians on this issue, including those involved in diagnostics at a national level in the NNBSP programme in Temple Street and the National Centre for Medical Genetics. This difference of opinion also extends to individual clinicians and representative bodies. This submission is from a patient group perspective.

CFI contends that the possible use of NNBSP cards for non-screening purposes must always remain secondary to the primary purpose of the cards, which is the screening for and concomitant early/essential treatment of particular metabolic/genetic diseases, including CF.

We realise, and are sensitive to, the potential genetic material in archived NNBSP cards for therapeutic interventions in other conditions and we further understand the general interest of those in the research community, some of whom may be seeking to access NNBSP cards for the purposes of furthering general medical research.

In principle, CFI is supportive of archived cards being used for therapeutic and possibly medical research purposes, provided that the integrity of the NNBSP is not compromised. Broadening access to NNBSP cards for non-screening purposes must not be at the (unintentional) cost of undermining of the NNBSP itself.

There are serious and potentially insurmountable hurdles that need to be acknowledged and overcome before this ‘broadening out’ could be considered. There are major gaps and weaknesses in our legislative framework, particularly arising from the continued absence of a Human Tissue Act in Ireland (originally planned for 2009). There are also major operational deficits, to ensure that they are stored properly, made accessible to bona fide interests and not misused.

This would likely require significant investment that should be met through public funding and conversely should not be supported by private/commercial interests for obvious reasons of transparency and public confidence. CFI is concerned that such public resources would not be forthcoming at this time.
There are numerous international conventions, national data protections and ethical principles for medical interventions and research involving human subjects, including those related to the principle of informed consent. These Conventions, Acts and Codes have already been invoked by litigants in relation to the retention and storage of NNBSP cards. Failure to deal with the storage and use of archived cards in a way that complies with these standards and protections may open the Department of Health to legal action by the general public, with concomitant costs to the State and with significant collateral reputational damage to the NNBSP. The chances of this litigation taking place would increase if the broadening of access to NNBSP cards is without informed consent and is perceived as the first stage in an incremental process in developing a national DNA database.

Some of the best arguments against retention of archived NNBSP cards, in particular in relation to the informed consent issue, have already been made by the Minister for Health, Dr James Reilly T.D. in a letter to CFI (see Annex One). If policy on the retention and use of screening cards is to change, it would be incumbent upon the Government to explain why circumstances have changed so greatly in such a short period of time.

The retention of NNBSP cards was considered by an HSE Review Group that reported in 2011. After careful consideration the 2011 Review Group concluded that archived cards more than 10 years old should be destroyed, but parents should be given the opportunity to claim their own card (Annex 2).

In the wake of this report, it is somewhat disappointing that the HSE made little determined efforts to advise parents of this choice, which naturally invoked widespread criticism The CFI would be concerned if the concerns and outcomes identified in this report might now be disregarded without adequate reason or in the absence of the safeguards identified in this submission being put in place.

CFI is concerned that granting access to NNBSP cards for purposes other than screening and for which no consent has been provided and in the absence of a rigorous legal and ethical framework, has the potential to undermine confidence in the integrity of the NNBSP to the extent that some parents might even refuse to participate in the NNBSP. Equivalent programmes in some other countries and States in the USA have now become mired in controversy.

The potential use of NNBSP cards for DNA profiling or genetic fingerprinting linked to security or forensic/crime purposes is not far-fetched. In Britain NNBSP cards are already accessed by the police in certain circumstances for forensic purposes. The potential for security and other agencies seeking to trawl NNBSP cards in the UK in future is a real possibility and may already be happening. These include circumstances where existing data protections are suspended in a national emergency or on grounds of the greater ‘public good’, the definitions of which are both subjective.

CFI is in principle supportive of use of NNBSP cards for therapeutic and possibly medical research purposes provided the Irish Government brings in an adequate legislative and operational framework and if the legal quagmire on the consent issue is resolved. In the absence of these being provided, there can unfortunately be no alternative other than a) put the archived cards into sealed storage until such a time that this legislative framework and facilities become available or b) to destroy the archived cards.
Perhaps an interim mechanism could be found to allow the use of archived cards to be used only for screening and other therapeutic reasons and this could include Sudden Infant/Adult Death Syndrome. This possibility should be actively investigated through the current review process.

**Why the integrity of newborn screening is crucial to Cystic Fibrosis**

In 1966, Ireland was one of the first countries in Europe to commence a National Newborn Screening Programme which has rightly been heralded as one of the most important developments in paediatric health in this country.

Ironically after this head start on many of our neighbours, Ireland is also one of the last countries in Europe to include Cystic Fibrosis in the range of conditions screened at birth.

The person most closely associated with and implementing the Irish national newborn screening programme is Dr Seamus Cahalane. Speaking at the centenary celebrations for Temple Street Hospital in 1972, Dr Cahalane stated,

> ‘The ultimate idea would be to attempt to detect every inheritable disease at pre-clinical level and prevent its manifestations. I would like to see Cystic Fibrosis screened for’

Unfortunately people with CF and their families had to wait for almost 40 years before Dr Cahalane’s wish was fulfilled when the NNBSP was finally extended to cover CF in Ireland in July 2011. This is not to diminish the efforts made by clinicians and patients over many years to highlight the CF screening deficit for newborn children in Ireland. The findings of a working group that reported in 2004 for example, were all but ignored by Government.

The delay in extending the NNBSP to CF is even more perplexing given that Ireland has the highest incidence of CF in the world, some three times the incidence in the rest of the European Union and the United States. Further the positive impact of newborn screening in CF has been well documented for many years.

**Why newborn screening makes a difference**

Early diagnosis for CF as a consequence of newborn screening allows for immediate intervention and treatment. Early interventions have been shown to result in improved height, weight, and cognitive function, help maintain healthy respiratory function, and may reduce hospitalizations and increase life expectancy. Ultimately, newborn screening leads to longer, healthier lives.

Conversely, without newborn screening, irreversible damage to the lungs and digestive system may have already occurred at the time of diagnosis. By that time, parents and families will have endured months or years of anguish trying to understand their child’s health condition before cystic fibrosis is finally diagnosed.

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What are the factors that could undermine confidence and participation in newborn screening in Ireland?

The factors that could undermine confidence and participation in the NNBSP could include one or both of the following:

- Publicity and related legal action undertaken by an aggrieved member of the public because of their lack of informed consent and use of the screening card for non-screening purposes.
- The incremental drift towards NNBSP becoming in effect a national DNA database and use of information for the purpose of DNA profiling and fingerprinting for security or even commercial purposes.

The result would be the undermining or compromising of the present NNBSP in general and the CF paediatric care strategy.

The Consent Issue

Key international conventions and codes related to consent and medical research/care include:

- Nuremberg Code, 1947
- Helsinki Declaration, 1964 and subsequent addendums: Ethical Principles for Medical Research Involving Human Subjects
- Council for International Organisations of Medical Science Guidelines, 2002
- Universal Declaration of Bioethics and Human Rights 2005
- Also European Convention on Human Rights and Biomedicine (1997)
- Clinical Trials Directive (2001/20/EU)
- GCP Directive 2005/28/EC
- European Paediatric Regulation 2007

Consent and Newborn Screening for CF in Ireland

Since 2011, parents must give their consent for newborn screening and this is indicated by a signature on the back of all NNBSP cards. To date, parents are still not asked to give their consent for the use of NNBSP cards for any purpose other than screening. If this policy is changed, parents should be given a choice as to whether their cards can be used for non-screening purposes.

Prior to 2011 no written confirmation of consent for screening or other use of NNBSP cards was sought. The use of cards for any other purpose other than screening potentially opens the Department of Health to legal action and concomitant negative publicity surrounding the newborn screening programme.

The potential use of the NNBSP cards for the purposes of DNA fingerprinting

Newborn screening cards potentially constitute the only comprehensive and archived national DNA base in Ireland. Perhaps the most extreme risk for undermining the integrity of newborn screening cards is for the purposes of DNA profiling also referred to as DNA fingerprinting, including for example for the purposes of national security; serious crime and the identity of deceased people.
Sceptics of this possibility may point to sufficient protections being provided through the Data Protection Acts to prevent this happening in Ireland. However it should be noted that in the United-kingdom, newborn screening cards are already being accessed by the police for forensic reasons:

‘In certain unusual situations the police can apply for a court order to allow them access to the blood spot cards of specified dead or missing individuals for forensic purposes. This happens very rarely. Current guidance is that samples from specified individuals who are alive and not missing can only be released with a court order for this purpose. This is because living individuals can provide another sample’.  

At present the police in the UK are only allowed to apply for a court order to access blood spots for specific named persons, however in times of national security there is concern among civil liberty bodies that security forces might seek to wish to ‘trawl’ through a collection of blood spots in the hope of identifying someone.

**In Conclusion**

CFI is in principle supportive of use of NNBS cards for therapeutic and medical research purposes provided:

1. The possible use of NNBS cards for non-screening purposes must always remain secondary to the primary purpose of the cards, which is the screening for and concomitant early/essential treatment of particular metabolic/genetic diseases.
2. The integrity of the NNBS is not undermined through their use for non-screening purposes.
3. The non-screening use of cards must be clearly defined in legislation and parents must be asked to give additional informed consent for the broadened use of cards.
4. That the use of NNSBP cards for genetic profiling, genetic finger-printing, commercial purposes and for police forensics must be explicitly outlawed through legislation.
5. Comprehensive and detailed safeguards for the retrieval, archiving, and use of cards must be included under the long delayed Human Tissue Bill.
6. A dedicated facility is developed to store and make available the cards for the above lawful purposes. The security and confidentiality of all aspects of this facility should be a paramount consideration
7. Perhaps a pragmatic mechanism that could be found to allow the use of archived cards in the short term is limiting them for screening and other therapeutic reasons, including for example Sudden Infant/Adult Death Syndrome. This should be investigated through the review process.
8. The Office of the Attorney General and the Data Protection Commissioner would indicate that these arrangements fully comply with national and international law, including on the issue of consent.

*John Coleman, Chairperson, Cystic Fibrosis Ireland

Philip Watt, CEO, Cystic Fibrosis Ireland*

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2 NHS Website [http://newbornbloodspot.screening.nhs.uk/faqs#3c](http://newbornbloodspot.screening.nhs.uk/faqs#3c) accessed 17 June 2013
April 2012

Mr Philip Watt
Chief Executive Officer
The Cystic Fibrosis Association of Ireland
CF House
24 Lower Rathmines Road
Dublin 6

Dear Philip

I wish to thank you for your recent letter concerning Newborn Screening Cards.

In late 2009, a complaint was made by a member of the public to the Data Protection Commissioner in relation to the retention of Newborn Screening Cards. The basis of the complaint (which was upheld) was that the cards should not be retained indefinitely as this constituted a breach of the Data Protection Acts 1998 and 2003. In 2010, following meetings between the Deputy Data Protection Commissioner, the Department of Health, the HSE and Cork University and Temple Street Hospitals, a policy was agreed with the Data Protection Commissioner to address both the legislative and ethical requirements of the National Newborn Screening Programme, which included disposal of archived NSC’s older than ten years.

Soon after I was appointed Minister, I requested the HSE to conduct a review of the decision. The review examined both the legal and ethical basis for retention of NSC's and the potential use of existing cards for research purposes. In order to meet both our legal and ethical obligations, I have accepted the recommendation of the HSE review group to provide members of the public an opportunity to secure their or their children’s “Guthrie card” prior to any destruction of cards more than 10 years old.

Retention of newborn screening cards for a period of ten years means they are available for second opinion, medico-legal reasons, long-term clinical follow-up and re-examination of samples with the most recently developed techniques to further refine the initial diagnosis. This is standard practice in many countries and extends a potential benefit to the child and is ethically and legally justifiable as it directly relates to the initial purpose for which the sample/data was originally collected. Moreover, quality control remains an integral part of delivering the clinical service.

I am aware that recent advances in biomedical and genetic technologies have significantly increased the scientific value of archived human biological material stored in institutions in this country and around the world. Nonetheless, the potential benefits from such research have to be balanced against the rights of the donors of that material. In the case of the newborn screening archive, parents did not give consent for retention of the material/data and almost certainly did not conceive of secondary purposes of the material, including research.
Informed consent represents the standard for adequate protection of all participants in biomedical research. This standard is affirmed in international legal and ethical documents. The Nuremberg code (1947), the Helsinki Declaration in its various iterations, Council for International Organisations of Medical Science Guidelines (2002) and the Universal Declaration on Bioethics and Human Rights (2005) all state that informed consent must be central to the ethical undertaking of all scientific experimentation involving human biological material. This has been further reinforced by enshrining informed consent into legal instruments including The European Convention on Human Rights and Biomedicine (1997), the Clinical Trials Directive 2001/20/EU, the GCP Directive 2005/28/EC and the European Paediatric Regulation 2007. Indeed, at the national level, the proposed draft Human Tissue Bill requires consent for the removal, retention and use of human tissue for research.

More specifically, with respect to archival human biological material for which no or limited consent exists, the international consensus clearly favours seeking the individuals consent for use of previously collected material for research purposes. The Canadian Tri-Council Policy Statement states that when investigators wish to use previously collected identified material for research purposes “researchers shall seek to obtain informed consent from individuals, or from their authorized third parties, for the use of their previously collected tissue”. The Council of Europe has adopted a similar stance in Recommendation 2006(4) on the use of archived human biological materials in biomedical research . Article 14 stipulates that research on human biological material and personal data should only be undertaken if this is done in conformity with appropriate information and consent procedures and in the case where no consent exists, “reasonable efforts should be made to contact the person in order to obtain consent to the proposed use”. In its 2005 report on The Irish Council for Bioethics recommended that where identified or coded material could be traced back to an individual, consent should be sought from that individual (or their representative) to use their biological material for research purposes.

In relation to the suggestion that a legal framework should be provided for the maintenance of the archive, using provisions in the European Directive on Data Protection (95/46/EU), it should be noted that this is also problematic. In the case of processing sensitive data, Article 8.2 (a) requires the explicit consent of the data subject. While Article 2.4 provides for Member States, for reasons of substantial public interest, to lay down additional exemptions by national law, this would be in the context of having met the other provisions of the Directive, including fair processing at the time of collection. In the case of the newborn screening archive, the Data Protection Commissioner indicated that fair processing requirements were not met. It would be inappropriate to seek to legitimise that action by introducing new exemptions and legally doubtful if this could be applied retrospectively.

On a related issue, the suggestion to rely on “implied consent” in terms of retaining the newborn screening cards is at odds with the requirement of explicit consent. Furthermore, for consent to be valid, in accordance with the Directive, it should be indicated. It is questionable whether the absence of any behaviour, or passive behaviour could be interpreted as an indication. Other elements of the definition of consent, and the additional requirement in Article 7(a) for consent to be unambiguous , support this interpretation. Moreover, the draft EU Regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data, published in January 2012, makes clear that in Article 25, that consent should be given either by a statement or clear affirmative action and that “silence or inactivity should not therefore constitute consent”. Interestingly, a recent
representative national survey in the US found that three quarters of parents, if asked, were willing to permit use of the Newborn screening samples for research. This figure plummeted to 28.2% if permission were not obtained, indicating a clear preference of behalf of parents to have an explicit say in the fate of the material collected from their children. The results of the 2010 eurobarometer survey on European citizens’ attitudes to biotechnology are interesting in that, 59% of Irish citizens surveyed expressed the view that scientists should seek consent every time new research is to be carried out involving material stored in a biobank, while 22% felt that consent for research should be on a once off basis, with only 7% expressing the view that consent was not required for research using biobanked material.

The HSE review group did examine the operation of the newborn screening programmes in both New Zealand and Australia, neither of which has specific legislation underpinning their programmes. In June 2011, in response to similar concerns about their newborn screening archive, the New Zealand Government’s National Screening Unit published the Newborn Metabolic Screening Policy Framework. Section 9 of the policy stipulates that residual blood spots collected prior to June 2011, require written consent for research use for each individual blood spot sample from the person authorised to give consent. Ethics committee approval is also required for use in research prior to consideration by the Newborn Metabolic Screening Programme (NMSP) Governance Team and the Ministry. The use of residual blood spot samples is also subject to the New Zealand Standard NZS 8135:2009 Non-therapeutic use of human tissue and the Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (Ministry of Health, 2007). This Standard ensures that where a person has given consent to the use of human tissue for non-therapeutic purposes, correct processes are followed for the collection, storage, use and return/disposal of tissue. New Zealand, are not however constrained by EU Data Protection legislation. In Australia, newborn screening programmes operate in each state and territory, with substantial variation across programmes in the number and type of disorders screened, card storage periods and the nature of entities responsible for storing and controlling access and use. No jurisdiction in Australia has enacted legislation specifically designed to govern operation of its newborn screening programme. Newborn screening programmes in all Australian jurisdictions are bound by the informed consent doctrine which emanates chiefly from common law. As I am sure you are aware, that in response to unauthorised secondary use of the newborn screening material in Western Australia and following a report by the Office of the Victorian Privacy Commissioner, all cards older than two years were destroyed. A subsequent report from the Victorian Newborn Screening Review Committee recommended that written consent for the long term retention and subsequent use of cards for research purposes should be introduced.

The newborn metabolic screening programme is not intended as a DNA biobank. It has not been designed in this way and does not have the processes and safeguards in place to be used in this manner. A key focus of biobank governance is to ensure that the rights and well-being of prospective research participants prevail over any research interests, a principle which has been enshrined in specific legislation.

The National Newborn Screening Programme tests thousands of children annually to identify medical conditions that, if untreated, result in severe physical, mental, or developmental harms, and offers the opportunity to intervene and dramatically alter a child’s life course. A transparent approach, based on parental written consent for use of material for uses unrelated to the screening should serve to protect the integrity of the programme. The course of action I have endorsed seeks to ensure public confidence, trust, and a continued willingness to
participate in the National Newborn Screening Programme, one of the country’s most successful public health initiatives.

I trust that this clarifies the matter for you.

Yours sincerely

[Signature]

Dr James Reilly
Minister for Health
Review of Current Policy for the Retention of Newborn Screening Cards
1. INTRODUCTION

Dr James Reilly, Minister for Health requested the Health Service Executive to review the policy regarding the retention and disposal of Newborn Screening Cards (NSCs). The NSCs are an integral component of the National Newborn Bloodspot Screening Programme (NNBSP). The Minister had received representations concerning the archived NSCs stored by the National Newborn Bloodspot Screening Laboratory (NNBSL) at the Children's University Hospital, Temple Street (CUH, T/S).

The Data Protection Commissioner had also received a complaint from a member of the public in relation to the retention of NSCs in late 2009. The basis of the complaint (which was upheld by the Data Protection Commissioner) was that the NSCs should not be retained indefinitely without consent as this was breaching the Data Protection Acts 1998 and 2003.

2 POLICY DEVELOPMENTS

The current policy was developed to correct this breach. During 2010, a number of meetings were convened with the Deputy Data Protection Commissioner and representatives of the HSE, the DoHC and CUH, T/S. A policy was agreed in conjunction with the DPC to address both the legislative and ethical requirements of the NNBSP and provides that:

1. the blood portion of the Newborn Screening Card (NSC) be retained for 10 years and disposed of during the child's 11th year;

2. parents/guardians receive specific information on the retention of the NSCs with regard to their use and specifying the duration the NSC would be retained;

3. space be provided for a signature for written, explicit consent from the parent/guardian at the time the sample is taken;

4. a proposal for the disposal of the archived NSCs within an agreed timeframe be developed.

2.1 Rationales underpinning the Policy

The decision to retain the NSCs for 10 years is based on the fact that there is no agreed practice standard internationally with regard to retaining NSCs. In Europe, this varies considerably from 1 month to indefinitely. Retaining the NSCs for 10 years precludes the issue of having to seek consent from a mature minor to dispose of their NSC, when consent was originally obtained from his/her parent/guardian. Retaining the NSC provides a facility for healthcare professionals to undertake a review of the sample which may be required for the purpose of confirming an initial diagnosis should this be deemed necessary.
If such a request is submitted, then informed consent must be obtained from the child’s parents/legal guardians. In the event of the child’s sudden death, permission must be sought from the Coroner if further testing is required.

2.1.1 Meeting Data Protection Requirements

Data Protection legislation safeguards the privacy rights of individuals in relation to the processing of personal data, in both paper and electronic format. The objective of EU and national data protection instruments is to protect the fundamental human rights of persons and in particular their right to protection of personal data. The role of consent is explicitly recognised in the EU Charter of Fundamental Rights (which became legally binding as part of the Lisbon Treaty) in dealing with the protection of personal data. Article 8(2) states personal data can be processed “on the basis of the consent of the person concerned or some other legitimate basis laid down by law”.

Similarly, Section 2A - (1) of the Data Protection Acts 1988 and 2003 (the “Data Protection Acts”) (Ireland) states that personal data shall not be processed unless the data subject has given his or her consent to the processing or, if the data subject, by reason of his or her physical or mental incapacity or age, is unable to appreciate the nature and effect of such consent, it is should be given by a parent or guardian. Thus, consent is recognised as an essential aspect of the fundamental right to the protection of personal data.

Prior to July 1st 2011, there was no formal policy for seeking consent from parents/guardians to obtain blood samples from newborns for bloodspot screening; parents/guardians were not asked to consent for the long-term retention and storage of the Newborn Bloodspot Screening samples. By extension, there was no consent for the processing of sensitive personal data, and thereby the process was in breach of EU and national data protection legislation. Article 8 of the European Directive 1995, clearly states that for processing of special categories of data (including health information), the data subject must give explicit consent.

By extension, then there was no consent either for the processing of sensitive personal data, and thereby is breaching EU and national data protection legislation. Article 8 of the European Directive 1995, clearly states that for processing of special categories of data (including health information), the data subject must give explicit consent.

Data should only be obtained for one or more specified, explicit and legitimate purpose(s); should not be further processed in a manner incompatible with that purpose or those purposes and should not be kept for longer than is necessary for that purpose.

Given that the primary purpose for obtaining NSCs is for newborn bloodspot screening, under the Act it is unlawful to retain them beyond the period for which they might reasonably be used for that purpose or to retain them for any other purpose, such as research or further testing unrelated to newborn screening. Furthermore, as the current archive of NSCs samples stored since 1984 were obtained without explicit written consent for the primary purpose, that is newborn screening in the first instance and this is a wrong, the prospect of these NSC samples
being used for any secondary purpose compounds only further that initial wrong. Hence, the concerns expressed in relation to the storage and potential secondary use of archived NSCs is reasonable as they relate principally to the issue of consent and confidentiality. Therefore, it is essential that this archive of NSCs is disposed of as a matter of urgency as outlined in the proposal developed by the HSE Working Group on NSCs.

2.1.2 Meeting Ethical Obligations

The changes to the NNBSP since 1st July 2011 bring about compliance with both national and EU data protection legislation, uphold ethical principles and meet ethical obligations with regard to consent, privacy and confidentiality.

With respect to archived human biological material for which limited or no consent exists, the international consensus clearly favours seeking the individual’s consent for use of previously collected material for research and other purposes. The Council of Europe outlined in Recommendation 2006(4) on the use of archived human biological materials in biomedical research. Article 14 stipulates that research on human biological material and personal data should only be undertaken if this is done in conformity with appropriate information and consent procedures and in the case where no consent exists, “reasonable efforts should be made to contact the person in order to obtain consent to the proposed use”. In 2005 The Irish Council for Bioethics recommended that where identified or coded material could be traced back to an individual, consent should be sought from that individual (or their representative) to use their biological material for research purposes. This is to have the proper regard for an individual’s autonomy, thereby affording the individual from whom the material originated due respect.

NSCs have identifying information attached which enables them to be linked to healthcare records, and this makes them useful tools for research, particularly epidemiological research. While there is no physical risk to an individual from using their material for research, use of identified/coded archival biological material poses a risk to the individual in terms of unwanted information flow. Unauthorised disclosure of personal information or access to data can place individuals at risk of discrimination, and related groups at risk of stigmatisation. All retained NSCs contain information that could be revealed about an individual or about members of an individual’s family, such as the mother’s name on the NSC that can have serious consequences.

Privacy and confidentiality are assigned substantial value in medical/research ethics because they directly derive from an individual’s autonomy to control his or her own life, and by extension, the uses to which his/her biological material are put. In the context of research or other uses unrelated to the primary purpose, an individual’s right to privacy is generally protected by the right to refuse to participate in research. Privacy issues arise when investigators wish to use identifiable biological material or records without obtaining consent. The principle of confidentiality provides an assurance that personal information will not be disclosed to unauthorised persons, processes, or devices. The principle of confidentiality is
provided for under the Irish Data Protection Acts 1988 and 2003\(^1\), under which personal information must be obtained for a specified purpose, and must not be disclosed to any third party except in a manner compatible with that purpose.

2.1.3 Respectful of All

In order to respect all concerned at this time and in this jurisdiction in which there is no legislative basis for retaining the NSCs indefinitely, a detailed proposal to dispose of the archived NSCs over and above 10 years was developed. The proposal aims to be respectful of all, namely those individuals who were screened without providing written, explicit consent and whose NSCs have been retained. Members of the public will be afforded the opportunity to access their NSCs and have their NSC returned to them or destroyed. This will be achieved by posting a notice in all the national newspapers to ensure that the wider public is made aware and notified of the intention to dispose of the archived NSCs. This aims too strike a balance between those whose cards have been retained without explicit consent and those who wish to access their NSC for the purpose of research or further testing.

3. CONCLUSION

The archived NSCs do not comply with Data Protection Principles. Newborn bloodspot screening samples taken from all newborns prior to 1\(^{st}\) July 2011 are being retained without disclosure and consent to do so. Clearly, this contravenes both EU and national Data Protection legislation.

The proposed course of action of destroying archived NBS samples for which no explicit consent was sought for collection, testing, or retention, let alone any secondary uses, serves to respect the autonomy of the individual themselves and their parents/guardians. The principal of autonomy is being further upheld by offering an opportunity to those who wish to retain material for whatever purpose, to have their own (or their children’s samples) returned to them should they so wish.

Notwithstanding legal obligations, the proposed course of action seeks to ensure public confidence, trust, transparency and a continued willingness to participate in the NNBSP. It is extremely important that the NNBSP must not be undermined or compromised in any way.

Having undertaken this review, the Review group believes that the current policy is correct and that there is a need to protect the NNBSP as a public health measure for children and their families. Furthermore, the group believe that the solution is respectful for all in this jurisdiction, at this time, and in this context and achieve an appropriate balance for all concerned.

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APPENDIX

Review of Current Policy for the Retention of Newborn Screening Cards Group

MEMBERSHIP

Dr Sean Denyer, Director of Public Health and Head of Childhood Screening, Health Service Executive (CHAIRPERSON)

Ms Paula Day, Risk Manager, Children’s University Hospital, Temple Street, Dublin 1.

Ms Mary Godfrey, Project Manager- NNBSN, Health Service Executive

Prof Philip Mayne, Director, National Newborn Bloodspot Screening Laboratory, Children’s University Hospital, Temple Street, Dublin 1.

Dr Siobhan O’Sullivan, Chief Bioethics Officer, Department of Health, Hawkins House, Dublin 2.

Ms Geraldine Roche, Chief Medical Scientist, National Newborn Bloodspot Screening Laboratory, Children’s University Hospital, Temple Street, Dublin 1.