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Report on the Newborn Screening Card Archive Forum

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Screening Card Archive Forum**

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Appendix 1: Participants in the Forum

ATTENDEES at the NEWBORN SCREENING CARD FORUM 27 OCTOBER 2016

SURNAME	FIRST NAME	TITLE	POSITION	ORGANISATION
Baker	Mona	Ms	Chief Executive Officer	Temple Street Children's University Hospital
Barron	Marian	Ms	Newborn Screening Liaison	Rotunda Hospital
Barry	Ray	Dr	Consultant Paediatrician Dean Council Member	Faculty of Paediatrics, Royal College of Physicians of Ireland
Beattie	Carol	Dr	Consultant in Public Health, Lead for Newborn Bloodspot Screening Programme	Public Health Agency, Northern Ireland
Bedford	Declan	Dr	Chairman	Board, Health Research Board
Bonner	Colette	Dr	Deputy Chief Medical Officer	Department of Health
Bracken	Suzanne	Dr	Programme Officer	Molecular Medicine Ireland
Brosnan	Mary	Ms	Director of Midwifery and Nursing	National Maternity Hospital, Holles Street
Browne	Fidelma	Ms	Head of Programmes and Campaigns Communications	Health Service Executive
Carroll	Tomás	Dr	Chairperson	Irish Platform for Patients Organisations, Science and Industry
Crushell	Ellen	Dr	Consultant Metabolic Paediatrician Member	Board of the Faculty of Paediatrics, Royal College of Physicians of Ireland
Denyer	Seán	Dr	Health and Wellbeing Specialist	Department of Children and Youth Affairs Office
Doran	Peter	Dr	Chairperson Board Member	Molecular Medicine Ireland Health Research Board Clinical Research Coordination Ireland
Egan	Tracy	Ms	Information and Support Manager	Irish Heart Foundation
Galvin	Joe	Dr	Consultant Cardiologist Council Member	Family Heart Screening Clinic, Mater Private Hospital and Royal College of Physicians of Ireland
Greene	Andrew	Prof	Director	Department of Clinical Genetics , Our Lady's Children's Hospital, Crumlin
Janning	Pia	Ms	Human Rights Policy and Research Officer/ Project Manager	Irish Council for Civil Liberties

Jennings	Phil	Dr	Director of Public Health, Health and Wellbeing Division	Health Service Executive
Kenny	Louise	Ms	Assistant Principal Officer	Department of Health
Lennon	Peter	Mr	Assistant Principal Officer	Department of Health
Loftus	Gerry	Prof	Chairman	Irish Health Research Forum
Love	Graham	Dr	Chief Executive Officer	Health Research Board
Macey	Chris	Mr	Head of Advocacy	Irish Heart Foundation
Maguire	Teresa	Dr	Principal Officer	Department of Health
Mayne	Philip	Prof	Director	National Newborn Bloodspot Screening Laboratory, Temple Street Children's University Hospital
Murray	Aveen	Ms	Member	Board of Directors, Temple Street Children's University Hospital
Naughton	Clare	Ms	Solicitor	Irish Council for Civil Liberties
O'Brien	Maeve	Ms	Assistant Principal Officer	Department of Health
O'Connor	Robert	Dr	Head of Research	Irish Cancer Society
O'Grady	Loretta	Ms	Chief Scientist	National Newborn Bloodspot Screening Laboratory, Temple Street Children's University Hospital
Pye	Virginia	Ms	National Lead - Public Health Nursing	Health Service Executive
Ryan	Bernie	Ms	Principal Officer	Department of Health
Sheehan	Seán	Mr	Chairman	Board of Directors, Temple Street Children's University Hospital
Smyth	Kieran	Mr	Principal Officer	Department of Health
Sugrue	Sheila	Ms	National Lead - Midwifery	Health Service Executive
Walsh	Olivia	Ms	Clinical Liaison Officer	National Newborn Bloodspot Screening Laboratory, Temple Street Children's University Hospital
Walsh	Seán	Dr	Clinical Director	Our Lady's Children's Hospital, Crumlin

Ward	Deirdre	Dr	Co-Director, Centre for Cardiovascular Risk in Young Persons	Tallaght Hospital
Watt	Philip	Mr	Chief Executive Officer	Cystic Fibrosis Ireland
Wynne	Mary	Ms	Interim Director, Office of Nursing and Midwifery Services Clinical Strategy and Programmes Division	Health Service Executive

Appendix 2: Programme



NEWBORN SCREENING CARD ARCHIVE

FORUM

Date: Thursday, 27 October 2016

Time: 11.30 - 16.30hrs

Venue: The Stephen's Green Hibernian Club, 9 St Stephen's Green, Dublin 2

PROGRAMME

11.00 - 11.30 **REGISTRATION** (Refreshments available)

11.30 - 11.35 **Welcome**

Dr Siobhán O'Sullivan, Department of Health

11.35 - 11.45 **Opening Address**

Mr Simon Harris TD, Minister for Health

11.45 - 12.10 **Neonatal Screening: storing dried bloodspots in the Netherlands**

Professor Martina Cornel (Professor of Community Genetics and Public Health Genomics, VU University Medical Centre, Amsterdam and Chairperson, Neonatal Heelprick Screening Programme Committee, Netherlands)

12.10 - 12.35 **Research Biobanking and genetic testing: what are the issues in 2016?**

Dr Anne Cambon-Thomsen (Lead, European Common Service ELSI (Ethical, Legal and Social Implications) of BBMRI-ERIC and Emeritus Director of Research at CNRS (National Centre for Scientific Research, France)

12.35 - 13.00 **Biobanking: lessons in reflexive governance**

Professor Graeme Laurie (Chair of Medical Jurisprudence, University of Edinburgh, Director of the JK Mason Institute for Medicine, Life Sciences and Law and Wellcome Trust Senior Investigator in Medical Humanities)



13.00 - 13.15 Questions /discussion

13.15 - 14.15 **LUNCH**

14.15 - 14.25 **Preparation for group discussions**

Ms Mary Godfrey, Project Lead Newborn Screening Card Archive,
Department of Health

14.25 - 15.15 **Group discussion**

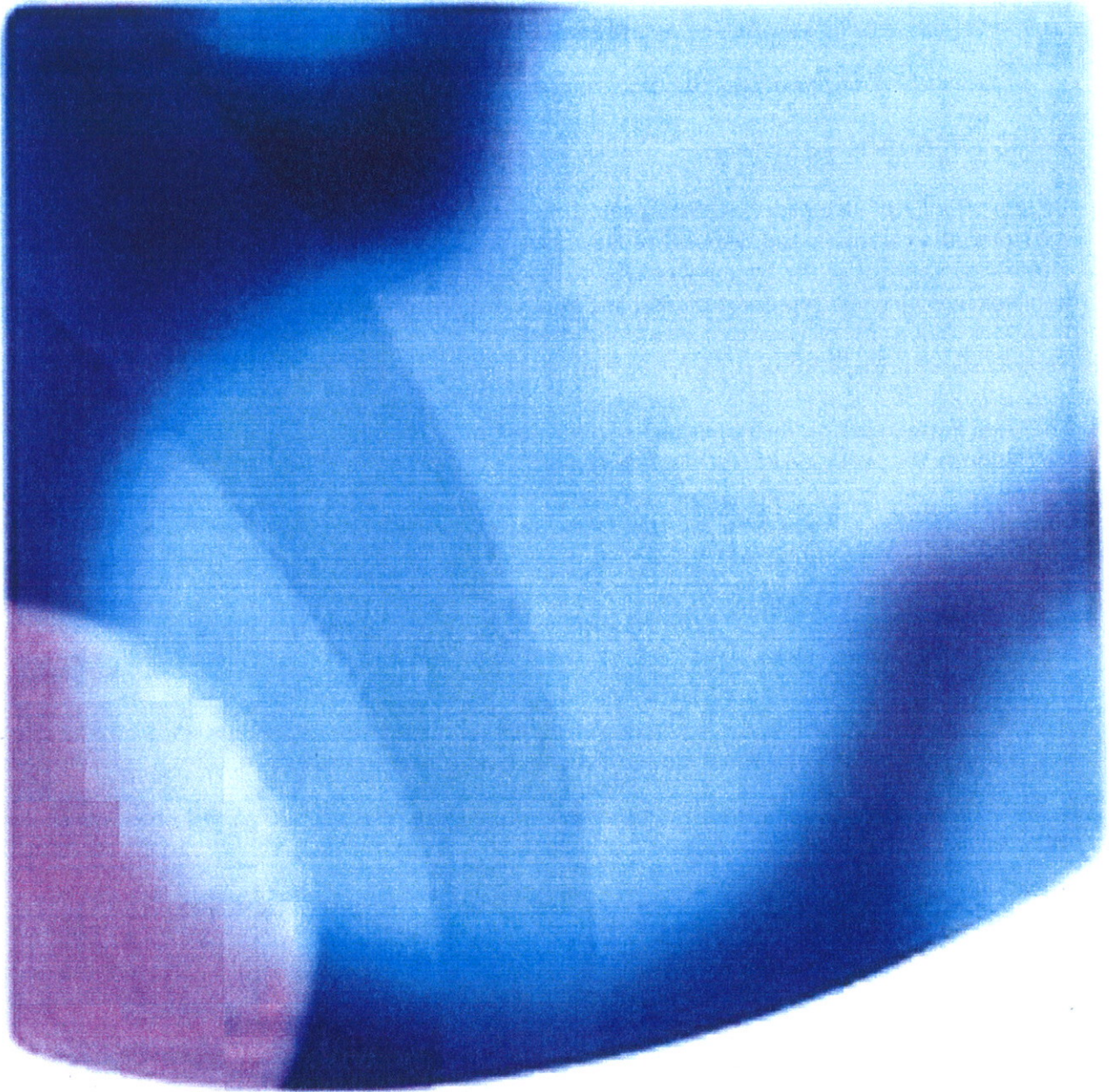
15.15 - 16.15 **Feedback from groups and general discussion**

16.15 - 16.30 **Closing remarks**

Ms Mary Godfrey, Project Lead Newborn Screening Card Archive,
Department of Health



Appendix 3: Review of Current Policy for the Retention of Newborn Screening Cards



**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 NNBSF 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 2003¹, 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 1st 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 NNBS. It is extremely important that the NNBS 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 NNBS 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.

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- NNBS, 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.