

# CONFIDENTIALITY AND DATA LINKAGE

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# Researcher Use of Confidential Information

- Use legislation to enable this release
- Expect that researchers will protect the confidential information given to them.
- Consider the views of a HREC
- We also conduct an independent assessment of public interest in disclosure and how data will be secured.
- Security breaches are disturbing

# A Disturbing Breach!



- Red Cross Blood Service admits to personal data breach affecting half a million donors (reported 28 October 2016).
- Red Cross Blood Service chief executive Shelly Park said "due to human error" the unsecured data had been posted on a website by a contractor who maintains and develops the Red Cross website.
- We all need to actively manage the risk of security breaches because.....

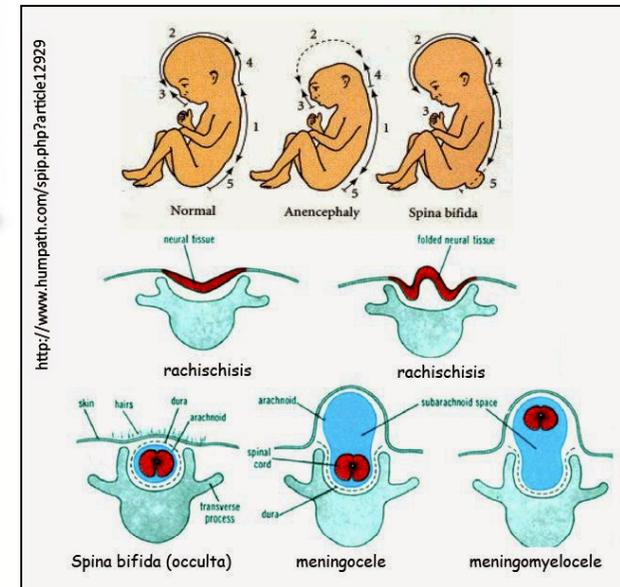
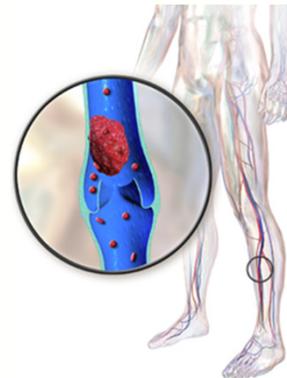
# Researcher Access to Data is a Strategic Priority

- We know researcher access to data is a key enabler to improve health outcomes

The Senate Select Committee on Health - Sixth interim report  
May 2016 ***Big health data: Australia's big potential***

# Data Linkage is a Strategic Priority

- Data integration improves people's health.



# Productivity Benefits of Data Integration

- Increases use of existing information (collected for other purposes) and reduces the duplication of information collection.



The screenshot shows the Australian Government Productivity Commission website. The page features a navigation menu with links for Home, Inquiries, Research, About the Commission, and News, Media and Speeches. A search bar is prominently displayed with the text "Search site and publications". Below the search bar, a list of draft reports is shown, including "Data Availability and Use Draft Report", "Human Services Preliminary Findings Report", and "Migrant Intake into Australia". The background of the page is decorated with a digital-themed image of binary code and server racks.

# Using Information without Consent

- Under Part 7 *Hospital and Health Boards Act 2011* confidential information may be disclosed without consent in certain limited circumstances, for example if permitted by law.

# *And that law is...*

## *Public Health Act 2005*

- The PHA requires researchers to apply to the Director-General of Queensland Health or his/her delegate, for access to health information held by Queensland Health.
- The Director-General may grant access to health information for the purposes of research only if satisfied that the giving of health information held by the department is in the public interest: s.284 (2) and (3).



# Why is our Act is the best of the bunch?



## *Public Health Act 2005 (Qld)*

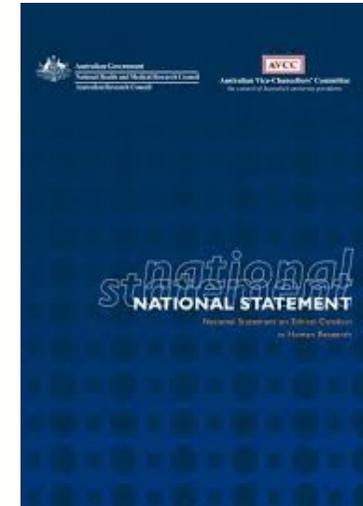
- Applies to all health information held by Qld Health
- ‘research’ – widely defined to include health & well being
- Expressly given precedence over other statutes and common law ...it tops everything!
- Specifies information to be given to Chief Executive (D-G Qld health) and the criteria for decision
- Specifies conditions that may be applied
- Requires CE to give reasons for refusal

# *Public Health Act 2005*

- Applications for the release of confidential information for the purposes of research under Section 280 of the *Public Health Act 2005* must include:
  - Copy of **approval letter from a HREC**
  - Evidence of authorisation from the relevant Queensland Health data custodians

# HRECs and Researchers

- **Research Framework:**
- National Statement on Ethical Conduct in Human Research (2007), (The National Statement)
- Australian Code for the Responsible Conduct of Research (The **Code**).



# Ethics review & approval of data linkage research projects\*

- Some projects involve individual consent to access data, e.g. MBS, PBS, that is then linked to other data collected from participants
- In other projects, access to data for linkage is sought without consent
- National Statement:
  - permits approval of use for linkage without consent
  - provides criteria for an HREC to approve a waiver of the requirement for consent

\*National Statement

# National Statement Public Consultation

- Chapters 3.1 Ethical Considerations Specific to Research Methods or Fields
- Chapter 3.5 (Human Genetics)
- Section 5: Processes of Research Governance Ethics review and also changes to 3.3 – clinical trials are currently under revision.
- Much more guidance on data linkage.



The screenshot shows the NHMRC website with the following content:

- Australian Government** and **National Health and Medical Research Council** logos.
- NHMRC** logo.
- Navigation menu: Home, Public Consultations, Submission Guidelines, Log In.
- Header: VISIT NHMRC WEBSITE # and WORKING TO BUILD A HEALTHY AUSTRALIA.
- Breadcrumb: YOU ARE HERE: Home > Public Consultation on Section 3 (Chapters 3.1 & 3.5), G.
- Public Consultation on Section 3 (Chapters 3.1 & 3.5), Glossary and Revisions to Section 5 National Statement on Ethical Conduct in Human Research, 2007**
- Closes on Wednesday, 21 December 2016, 11:59pm (AEST)**
- The National Health Medical Research Council (NHMRC) is proposing a revision of Section 3 of the *National Statement on Ethical Conduct in Human Research 2007* (the National Statement).
- The National Statement provides guidelines for researchers, Human Research Ethics Committees (HRECs) and others conducting ethical review of research, and emphasises institutions' responsibilities for the quality, safety and ethical acceptability of research that they sponsor or permit under their auspices.
- The Australian Health Ethics Committee (AHEC) is overseeing the development of this review with the advice of an expert group with expertise from different research disciplines, the Australian Research Council and Universities Australia.
- Scope of the public consultation**
- Comments are invited on the content of Section 3 of the National Statement, which includes new introductory language, new and revised chapters 3.1 and 3.5, consequential changes to Section 5 and additions to the Glossary.
- In particular, feedback is sought on whether the drafts:
  - provides sufficient guidance to address the key ethical issues in relation to human research
  - is presented and written in a manner that is appropriate for the target audience (researchers, HRECs).

# National Statement criteria for waiver of consent



HREC must be satisfied that:

- (a) Involvement carries no more than low risk to participants;
- (b) the benefits from the research justify any risks of harm associated with not seeking consent;
- (c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);

# National Statement criteria for waiver of consent

(d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;

(e) there is sufficient protection of their privacy;

(f) there is an adequate plan to protect the confidentiality of data;



# National Statement criteria for waiver of consent

(g) if results have significance for the participants' welfare there is, where practicable, a plan for making that information available to the participants;

(h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled;

(i) the waiver is not prohibited by State, federal, or international law.

# Preserving Privacy & Confidentiality

- Commonwealth Advice
- Queensland Advice



# High Level Principle for Data Integration Involving Commonwealth Data for Statistical and Research Purposes



## **PRINCIPLE SIX- Preserving Privacy & Confidentiality**

- Operational, administrative and personal identifiers should be removed from datasets as soon as they are no longer required.
- Where identifiers need to be retained, for example for longitudinal studies, they should be kept separate from the integrated dataset.

## **PRINCIPLE SIX**

### **Preserving Privacy & Confidentiality**

- Access to potentially identifiable data for statistical and research purposes, outside secure and trusted institutional environments should only occur where: legislation allows; it is necessary to achieve the approved purposes; and meets agreements with source data agencies.

**Right of Veto...Researcher  
Data Custodian Tension**

# PRINCIPLE SIX

## Preserving Privacy & Confidentiality

- Once the approved purpose of the project is met, the related datasets should be destroyed, or if retained, the reasons for and necessity of retention documented, and a review process set up.
- If such retention was not part of the initial approval process, re-approval of the decision to retain is required.
- Archiving of statistically integrated data sets should be restricted to confidentialised datasets.

<http://nss.gov.au/nss/home.nsf/NSS/7D9DAD8A0C6D1649CA2577E4001AD3D3?opendocument>

# Queensland Health Advice

- The use of publicly available systems such as **Gmail, Dropbox or USBs** to transfer personal or confidential information presents **high risks** to Queensland Health and **is not recommended**.
- In general, if all parties have QH ICT system accounts (ie considered internal staff) then **use internal QH ICT systems** to transfer the data (ie QH email, databases, shared folders etc.).

# How does someone access the Secure Transfer Service?

- External parties do not have QH ICT system accounts (External Access Team's services)
- The transfer of information should be done via secure QH external access systems (eg. STS)
- This can provide one-time transfers of information or a long term solution for two-way information sharing.

# Network Transmission Security Assurance Framework

- NTSAF refers to the Queensland Government's Network Transmission Security Assurance Framework which is a component of the broader Queensland Government Enterprise Architecture (QGEA); which defines whole of government ICT standards.
- The NTSAF clarifies government agencies' requirements in transmission of government information.
- However, even with secure release, data release has risks....

# Someone has worked backwards with Medicare data to identify a provider!

**Amendment to the *Privacy Act 1988* to further protect de-identified data (28 September 2016)** to improve protections of anonymised datasets that are published by the Commonwealth government.



<https://www.attorneygeneral.gov.au/Mediareleases/Pages/2016/ThirdQuarter/Amendment-to-the-Privacy-Act-to-further-protect-de-identified-data.aspx>

# In Summary

- We have a robust framework for the release of confidential information for research purposes.
- Researchers have obligation to protect the confidential information given to them.
- We know researcher access to data is a key enabler to improve health outcomes.

# EOM

- **Contact Melissa Hagan @  
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