‘Access to health information held by the department for the purpose of research’
Ethical Principle – Respect (NS)

Researchers and their institutions should respect the privacy, confidentiality and cultural sensitivities of the participants and, where relevant, of their communities. Any specific agreements made with the participants or the community should be fulfilled (1.11).
Waiver of Consent - NS 2.3.5:

Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information. Other review bodies may grant waiver of consent for other research.
Guidance for the conditions of waiver

(a) involvement in the research 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);
(d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;
Guidance for the conditions of waiver

(e) There is sufficient protection of their privacy;
(f) there is an adequate plan to protect the confidentiality of data;
(g) in case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media);
Guidance for the conditions of waiver

(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.
State Legislation that has relevance to confidentiality

- The *Health Services Act 1991* (62c & q)
  Allows disclosure of confidential health information for QH staff to access and disclose patient information for the purpose of initially screening for potential research candidates with a view of ultimately obtaining their consent.

- The *Public Health Act 2005* (Chapter 6: Health Information Management, Part 4: Research: Division 2 Health information held by the department for research).
  Sets out the legislative provisions for accessing QH health information for the purposes of research when accessing confidential information without patient consent.

- The *Information Privacy Act 2009* (Chapter 2 Part 1)
  Deals with collection and handling in the public sector environment of personal information, the right of access to, and amendment of, personal information in the government’s possession or under the government’s control. These provision have no relevance in terms of access and use of confidential information for research.
When is a *Public Health Act* application required?

**Pathways**

- **Screening for CT**
  - Intention to consent
    - Health Services Act (62 c& q) – no application required
  - Intention not to consent

- **Accessing patient charts for study without patient consent**
  - Intention not to consent
    - Public Health Act Application required
Data held by Queensland Health vs. data held by the C’wealth or the private sector

• All confidential health information held in the private sector or by the Commonwealth is dealt with under the Privacy Act 1988 (C’Wealth) and subject to the National Privacy Principles (NPPs), found in Schedule 3 of the Act and administered by the data custodian in the private sector e.g. ABS, AIHW.

• Queensland Health has no jurisdictional authority or administrative responsibility for private sector health information data.
Research Specific Provisions

Public Health Act (Part 4 Division 1, s280-292)

Key elements of the PHA Research Provisions

• Definition of research (s280)
• Application requirements (s282)
• Decision about application (s284)
• What the notice must state (s285)
• Notification of change of persons being given information (s286)
• Establishment of a Register (s288)
Avoiding the pitfalls and anxieties!!

• Discuss with the data custodian your data requirements e.g.- do they have the data fields you require?
• Make sure that the research hypothesis /questions and data requirements are congruent.
• Understand the resource implications, and how this may influence your data release requirements.
• Be open to negotiating release process with custodians.
Where to apply for access to health information held by QH and what will facilitate timely processing?

- Ensure you discuss your data requirements with the data custodian
- You must include your HREC approval letter
- Use the checklist attached to the application before submitting
- E-mail your application to: regu@health.qld.gov.au
  Turn around time 10 working days

Forum Summary

• Dynamic and changing administrative environment for research ethics and governance – keep informed & use the resources of REGU Web pag

• Single ethics review process
  ➢ Upload all your support documents on the on-line form site
  ➢ Use the electronic authorisation
  ➢ Submit a protocol with your On-line form
  ➢ Make the National Statement your friend

• Central Coordinating Service – watch the www for our new 1300#
  ➢ If in doubt phone Us
Forum Summary....

• Anticipate any post HREC approval requirements PHA, QCAT and CaSS
• Site Specific Assessment
  ➢ For MCR – you will need a SSA for each site
  ➢ Start early
  ➢ upload documents
  ➢ your obligations to provide a budget – even it is ‘in kind’
• Watch out for the publication of the “THE MATRIX”
• Watch out for DORA
• CRC@health.qld.gov.au
How can you contact REGU?

E: regu@health.qld.gov.au

T: 07 32340034

REGU URL:

Office of Health and Medical Research URL: