Engaging in research at GCHHS: a guide for external researchers

Introduction

This information is provided to guide external persons to undertake research at the Gold Coast Hospital and Health Service (GCHHS).

This information applies to all external researchers wanting to engage in research activities, including students and collaborators who are not GCHHS employees, using GCHHS patient data and/or infrastructure.

The Office for Research Governance and Development (ORGD) is the first point of contact for external persons interested in engaging in research with GCHHS. *ResearchGoldCoast@health.qld.gov.au*

Study Design

When considering your research, you will need to consider your study design.

If you plan on using GCHHS patient information you will need to consider how you will obtain the information you require for your study.

- If the information is routinely collected by GCHHS
- If the information is available in QH systems – i.e. IEMR
- If you plan on collecting the information, how you will undertake that collection.

Having a legal permission to be granted access to or to disclose, specified items of confidential information does not mean that access is permitted to the entire information system or database in which those items may be found.

What data do you want to access?

The Queensland Government publishes Queensland Health open datasets which can be accessed through its *Open Data portal*.

Depending upon how data is collected and held by QH, it can be described as from:

- **Single site/centre** – collected from one Hospital and Health Service or Queensland Health organisational unit
- **Multi-site/centre** – collected from multiple Hospital and Health Services or Queensland Health organisational units
- **Statewide** – collected within a statewide information ***application*** or held as a discrete statewide ***data collection***
- **Queensland Health Statistical Data** – the collection, processing, analyses, reporting and dissemination of statistics on the health of Queenslanders and their use of health services.

General information about Accessing Queensland Health information can be found on the QH webpage.

Data Custodians

All requests for Queensland Health data, whether it is for research or non-research purposes require approval from the respective Data Custodian(s). When you have identified which data you would like to access for your project you will need to get formal approval from the Data Custodian(s).

If you have not yet identified the data custodian, you can *search for data collections*, applications and data and application custodians.

Does your research require you to access confidential information?

About patients

Confidential information is information that is acquired by a person, in the capacity of that person's duty, that is about another person. Confidential information must not be disclosed unless there is a legal permission to do so.

Patient data that is held within Queensland Health operational digital information systems is personal and sensitive data and subject to the *Information Privacy Act 2009 (QLD),* the *Hospital and Health Boards Act 2011 (QLD)* and other legislative, regulatory and QH policy, standards and guideline controls. Unless data has expressly gone through a de-identification process controlled by suitably qualified persons data may still be identifiable and therefore subject to the IP ACT.

About QH and HHS confidential information

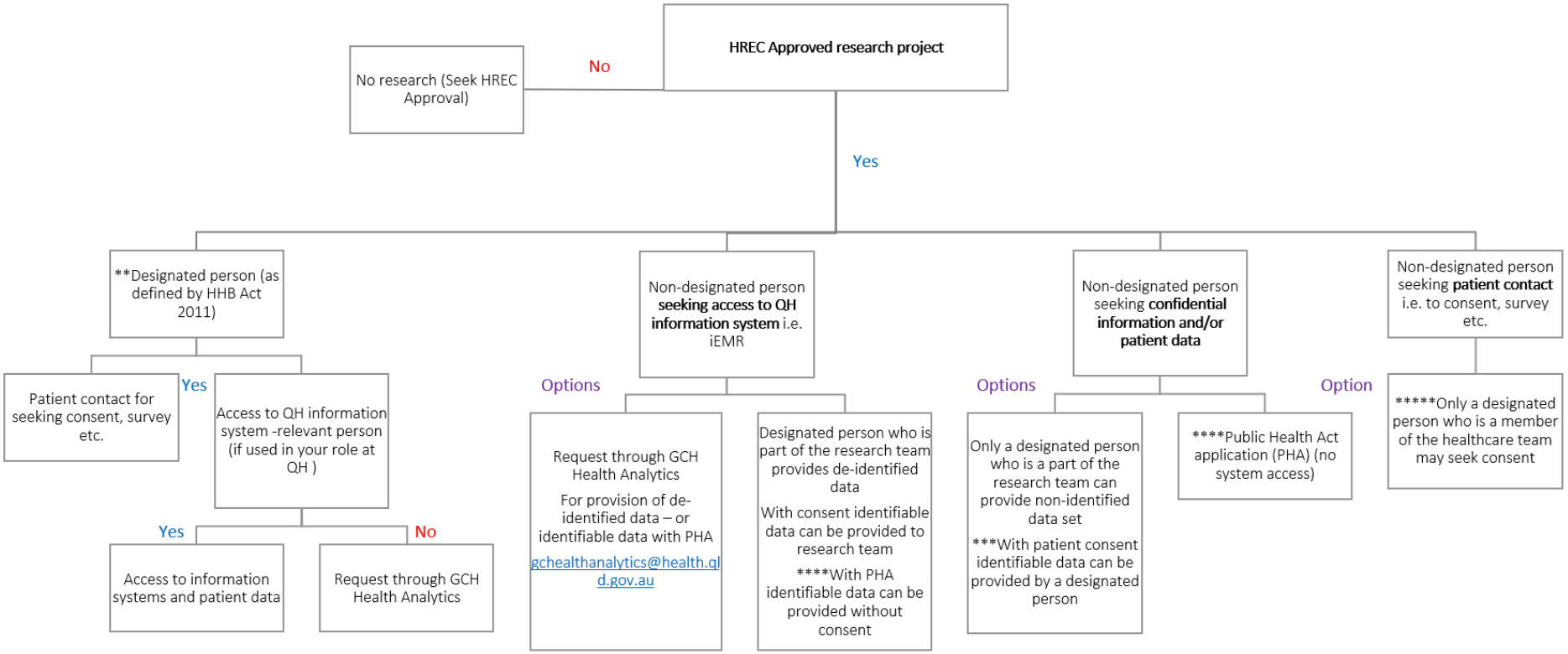
This includes

- Clinical and non-clinical data such as patient, corporate, financial and workforce data
- All on-premise off-premises and cloud applications, systems and services
- Biomedical, Building Management System and specialty devices supported and connected to the Queensland Health network or a network maintained and supported by the Department of Health divisions, agencies and business units, HHS or other entities.

Summary and aggregated data

To protect confidential information, QH can provide anonymous data, such as aggregated and summary statistics. Application and Data Custodians are responsible for managing information security matters to ensure compliance with this policy and the requirements set out in the supporting information security standards.
It is recommended that early contact should be made with *data or application custodians*. It will enable more efficient processes and hopefully save time.

Decision Support Pathway



**A designated person is an employee of the Health Service (HHB Act 2011 pt7 s139A) whereas a relevant person (PH Act 2005 Chpt. 2 s23) is an employee who uses GCH information systems in performing their role).

***If there is patient consent for disclosure of their identifiable data for research purposes, a data set with identifiable information may be provided by a designated person to a non-designated person, access to information systems is prohibited for non-designated persons even with patient consent.

****Public Health Act (PHA) grant allows for disclosure of identifiable data without consent.

*****The treating clinician or healthcare team may advise a patient during a clinical appointment, of a research study that may be relevant to their care, and gain consent for the researchers to contact the patient to discuss the study further.

Research Approval

In order to conduct research in GCH, it is a requirement that all research first obtains the following:

- Ethics approval from a Human Research Ethics Committee (HREC)
- Site authorisation at each facility you are intending to do the research.

Ethics approval is required before Site Authorisation can be granted.

In addition to ethics approval, where the research requires a Queensland Health employee to disclose confidential information about a patient to a researcher, the researcher must identify a lawful authority for the use or disclosure of that information. This **Lawful authority** may include:

- disclosure with consent;
- disclosure between Queensland Health employees or other designated persons, if the purpose of the disclosure is to evaluate, manage, monitor or plan health services. This occurs, for example, when a Queensland Health employee is supported to conduct research to evaluate the impact of a new treatment/process on the HHSs discharge times and the HREC has waived the requirement of consent; or
- a *Public Health Act 2005* approval

If you have no Lawful authority to be given the identifiable data then options include:

- If a member of your research team already legitimately holds the patient information, they can provide a non-identified data set. *(NHMRC National Statement on Ethical Conduct in Human Research (2007) - Updated 2015, Chapter 3.2)*
- Request provision of the non-identified data that meet requirements of your project from GCH Health Analytics. Apply to *gchealthanalytics@health.qld.gov.au* and include the details of the data needed and all relevant approval documents i.e. HREC Approval letter.
  Include *gchresearch@health.qld.gov.au* (the Research Office, who work closely with Health Analytics team.)

See further information in the *Queensland Government Health Service Directive # QH-HSD-035:2016 Research Ethics and Governance p.3*

Disclosure with consent

Where patients consent to the use of their confidential information in research a **Public Health Act (PHA)** application is **not** required.

The HHB Act Section 150A. recognises that consent from a person authorised under a law to make decisions for an adult with impaired capacity (such as a statutory health attorney) now includes disclosure of that person's confidential information. A PHA approval for the disclosure of confidential information is no longer required in this instance.
Learn more in the *FAQs regarding Public Health Act (PHA) approvals* and the *Health Service Directive*

Gold Coast Health specific pathway

At GCH the REGO (Research Ethics and Governance Officer) process is used where the administrative and governance review of your project will be conducted by the assigned REGO and you will be provided with as much guidance as possible early in the application process aimed at reducing the review time.

Research Ethics and Research Governance application forms are prepared and submitted through *ERM Applications*. *https://au.forms.ethicalreviewmanager.com*

Seeking ethical and scientific approval of the research protocol by the Human Research Ethics Committee (HREC). The HREC is responsible for the review of the research/scientific methods, ethical standards, safety and welfare of research participants. Research projects may involve Low or Negligible Risk (LNR) or Medium to High Risk to participants or the organisation. To understand the level of risk associated with a particular study and how to navigate the ethics application process, please contact the REGO Team: mailto:GCHEthics@health.qld.gov.au

Completing a Site Specific Assessment (SSA) to determine the level of support for and suitability of a research study undertaken at GCHHS, whether that study is multi-centre or single- site. The SSA process encompasses the assessment of legal, financial, regulatory and contractual issues in relation to the research.

The outcomes of the HREC and SSA reviews together make up the final documentation that is provided to the CEO or delegate for authorisation. Research cannot commence until both the Ethics Approval and Governance Authorisation have been granted.

For further information please contact:
The Research Ethics and Governance team
GCHResearch@health.qld.gov.au
P: 07 5687 3880

Definitions

Term	Definition	Source
Confidential information	Information, acquired by a person in the person's capacity as a designated person, from which a person who is receiving or has received a public sector health service could be identified, as defined in section 139 of the HHB Act.	Hospital and Health Boards Act (2011) Part 7 s 139
Data identifiability	Data may be collected, stored or disclosed in three mutually exclusive forms: • **individually identifiable data**, where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address; • **re-identifiable data**, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets; • **non-identifiable data**, which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown.	NHMRC National Statement on Ethical Conduct in Human Research (2007) - Updated 2015, *Chapter 3.2*
Designated person	139A Meaning of designated person 1. *Designated person* means a person who is— (a) a public service employee employed in the department; or (b) a health service employee; or (c) the chief health officer; or (ca) the deputy chief health officer; or (d) the chief psychiatrist; or (e) a health professional (other than a person mentioned in paragraphs (a) to (d)) engaged in delivering a public sector health service, whether at a public sector health service facility or another place; or (f) a member of a board of a Service; or (g) a person (other than a person mentioned in paragraph (a) or (b)) engaged temporarily to provide administrative support services for a Service or the department; or (h) a person being educated or trained at a public sector health service facility as part of the requirements for— (i) registration, enrolment or other authorisation (however described) to practise as a health professional; or (ii) completion of a course of study qualifying a person for registration, enrolment or authorisation mentioned in subparagraph (i); or	Hospital and Health Boards Act (2011) Part 7 s139A

	(i) a person providing education or training at a public sector health service facility to a person mentioned in paragraph (h); or (j) a contractor who accesses confidential information under a contract to provide information and communication technology or information management services to a Service or the department; or (k) a volunteer carrying out duties at a public sector health service facility on behalf of a Service or the department; or (l)an inspector; or (m) another person prescribed under a regulation for this paragraph to be a designated person. 2. Any person who was a person mentioned in subsection (1) is also a designated person.	
External Researcher	Individuals wishing to engage in research with GCH from: • Other hospitals, academic institutions or organisations; or • Research students enrolled in universities; or • Individuals invited as a visitor	PR02297 Visiting Researcher Appointment
Relevant person	Relevant person means the following—(a) a person who is, or was, the chief executive; (b) a person who is, or was, involved in the administration or enforcement of this part, including, for example, a health service employee or a public service employee.	Public Health Act (2005) Chapter 2 (53)