Procedure

TCHHS-CLIN-1,14-PRO-0192

Access to clinical health records for research and clinical audit

1. Purpose

The purpose of this document is to inform staff and researchers of the correct course of action when requesting clinical health records (electronic, paper based or hybrid) for research and clinical audit purposes to ensure that patient confidentiality is protected, consistent with evidenced based practice. Patient confidentiality must be considered in the conduct of all research and clinical audits.

This document is underpinned by relevant legislation, policy and standards as identified below.

2. Scope

This procedure applies to all Torres and Cape Hospital and Health Service (TCHHS) temporary, permanent or casual staff, (including visiting medical officers, visiting health professionals) and contractors, consultants, students and volunteers who seek access to health records for clinical audit and/or research purposes.

3. Procedure

Provision of access to health records for the purposes of research and clinical audits is managed through the TCHHS Strategy Planning & Performance Unit. Referral to the appropriate Data Custodian, including TCHHS Health Information Management Services (HIMS) will be provided to the researcher by this unit. Health Care Professionals are generally permitted to access patient information for research purposes provided they have been given approval to conduct clinical audit and research projects from the appropriate TCHHS authority and have Ethics approval (if required). Access is dependent upon the nature of the information requested, the volume of information requested and the function to be performed by the researcher as the requestor of the information.
Refer to Approval and pricing structure for access to patient information (Appendix 1) for information relating to approvals required for access to health records and a pricing structure for health record access (if charges are applied). HIMS may pass on charges for administrative services associated with the retrieval and provision of health records. Charges associated with data analysis and data provision are provided on request by the Data Custodian.

All projects defined as *research* must provide
i) written approval from an NHMRC certified Human Research Ethics Committee (HREC) before permission will be granted to access clinical records. (Excluding clinical trials all HREC s providing approval must be Queensland Government Hospital and Health Service HRECs, the National Mutual Acceptance scheme is in place for recognition of ethics approval for some clinical trials. An ethics approval granted by an academic institution HREC is not recognised by the Torres and Cape Hospital and Health Service).

ii) written research governance authorisation from the Torres and Cape Hospital and Health Service Chief Executive (HSCE) prior to commencement of research or request for health records.

Please refer to TCHHS Procedure Research application and approval for information on how to obtain research governance authorisation
http://www.health.qld.gov.au/torres-cape/html/research-governance.asp

Access to health information for the purposes of research is governed by legislation, with the applicable legislation dependant on whether the patient has given specific consent for their records to be accessed. Where patient consent is not obtained, researchers may access identifiable (or re-identifiable) patient information for the purpose of research with approval under the *Public Health Act 2005*.

The most common circumstances where access may be granted under this Act are:

- Consent is unable to be obtained – patient contact to obtain consent may be difficult or inappropriate;
- Patient consent has expired; or
- Patient consent does not cover the collection of information from medical records or does not cover the full range of data that will be collected.

Researchers should refer to TCHHS Procedure: Research application and approval for details of obtaining consent, access and use of confidential health information/data under the *Public Health Act 2005*.

Clinical audit

Health records are frequently required for clinical audit and include:

- Clinical review
- VLADs
- QUALITY and Safety reporting
- Morbidity and Mortality meetings
- TCHHS data registries, (e.g. peri-natal registry)
- Other clinical governance and clinical Quality improvement purposes

As a general rule, there is no restriction to access of health records for these purposes provided the requesting officer is a member of staff at TCHHS or a Department of Health employee, and has a legitimate reason to request the health record(s) (*Hospital and Health Boards Act 2011*).

Any other requests will be reviewed on a case by case basis. Externally published clinical audits are regarded as research. (Please refer to TCHHS Procedure Research application and approval for information on how to obtain research governance authorisation http://www.health.qld.gov.au/torres-cape/html/research-governance.asp)

Students who are on placement within the TCHHS may also access health records following provision of a letter of approval from the area of enquiry Head of Department, for the purposes of completing assignments which are part of their education; or for assisting TCHHS staff in clinical audit activities as part of their placement. Students who access records as part of placement are bound by agreements (e.g.Clin Ed Q) between the TCHHS and the education provider.

All other requests for access to health records (electronic, paper based or hybrid) are reviewed on a case by case basis

NOTE: Receipt of requests for records for research and clinical audit purposes are processed as a Non-Urgent request

Procedure for access to health records

1. Obtain Research Governance authorisation (*Appendix 1 - Approval and pricing structure for access to patient information.)*

2. Complete the request form *(Appendix 2 - Request for access to health records for research or clinical audit*). Scan the request and forward the request to TCHHS-HIM@health.qld.gov.au with an MS Excel spreadsheet list of health records required.
   NOTE: In the case of Clinical Trials approval is only required at the commencement of the trial. This approval will cover access to individual health records required for patient appointments and health records required for data abstraction.

3. As a general rule, Medical Record Departments at TCHHS Hospitals, Multi – Purpose Health Services and Primary Health Care Centres do not have staff resources to locate records and do not have separate storage areas for health records required for research or clinical audit to be reviewed (without prior agreement and arrangement).

4. Only health records that are available at the requested site can be retrieved. A site-specific list will be supplied to a researcher indicating the current HBCIS location codes of unavailable health records.
   It is the responsibility of the requestor to follow-up these health records by either recording a “Request” on HBCIS or by contacting the department holding the health record and arranging a suitable time for access. Alternatively, subsequent lists may be submitted.

5. A limit of 20 health records, as paper version, will be retrieved and supplied at one time. The requestor must make arrangements for the collection of health information.

6. Health records (as a paper version) are not available to be taken off site and may only be reviewed at their site of storage. Electronic record data may be supplied where ethics approval has indicated there is sufficient security access for their storage provided by the research protocol. Health record loans between facilities will not occur without specific authorisation included within the research governance authorisation.

7. It is the responsibility of the requestor to review health record paper based information as provided and request further records (20 health records at a time) if required.

Funded research

8. Where external researchers (not TCHHS staff) have projects which involve access to health records the application should include the budget allocation – including invoice details which provide the details of the contribution to the TCHHS costs associated with accessing health records as per *Appendix 1 - Approval and pricing structure for access to patient Information.* This information will be found in the budget section of the SSA application. (Budget to be included as a per project budget for single invoicing rather than a per site cost).

9. When a Request for Access to Health Records for Research or Clinical Audit is received and the ‘funded research’ box has been checked, the quotation for the cost of the retrieval of the health records which has been prepared by the Health Information Manager and accepted by the requestor will then allow for an Invoice to be raised and the retrieval of the health records will proceed (*Refer Appendix 2 - Request for access to health records for research or clinical audit).*

4. Responsibilities

Position	Responsibility
Executive Director	Review and support/ not support data or health record requests through endorsement/non-endorsement of SSA forms.
Heads of Supporting Departments	Heads of Supporting Departments of service areas are aware of access to data /and or health records in their departments. Local work practices to ensure all researchers are authorised before research health records or data provided.
Line Managers	Line Managers are to be aware of research activities being conducted in their teams. Local work practices to ensure all researchers are authorised before data or health records provided to researchers
HHS staff	Research activities are not conducted without appropriate approval; Participation in research activities only occurs where research has been authorised
Research Governance Officer	Recommendation of research authorisation – including access to data and/or health records undertaken in compliance with *Standard Operating Procedures for Queensland Health Research Governance Officers. Version 5, Nov 2013*

5. Supporting documents

Legalisation and Standard/s:

- *Information Privacy Act 2009*
- *Hospital and Health Boards Act 2011*
- *Public Health Act 2005*
- *Public Health Act 2005* - Application and Information for Researchers

Templates, forms and other related or supporting documents

- National Statement on Ethical Conduct in Human Research (Developed jointly by National Health and Medical Research Council Australian Research Council Australian Vice-Chancellors' Committee) Chapter 2.3 Qualifying or Waiving Conditions for Consent.
- EQuIP National Standards (ACSQHC)
- Standard 14, Criteria 1 – Health records management systems support the collection of information and meet the consumer / patient and organisation's needs.
- Standard 14, Criteria 3 – Data and information are collected, stored and used for strategic, operational and service improvement purposes.

Other Procedures, Process Flows and Guidelines:

- Procedure TCHHS Research application and approval TCHHS-CLIN-1-RPO-0080

Forms and Templates:

- TCHHS _ Approval and pricing for access to health records
- TCHHS_ Request for Access to Health Records for Research or Clinical Audit

6. Related documents

- Queensland Health- Department of Health Research Management Policy
- Queensland Health Standard: Research Management Policy – Implementation Standard for Consent, Access and Use of Confidential Health Information
- Department of Health - Clinical Records Management Policy
- Department of Health - Data Management Policy

7. Definitions of terms used in the policy and supporting documents

Term	Definition / Explanation / Details	Source
Research	Refers to investigations designed to increase knowledge or understanding of processes, techniques or outcomes (refer to National Health and Medical Research guidelines); and is often reported to the broader community through publication or presentation.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/
Clinical audit	Refers to investigations designed to assess quality of existing services, processes or techniques. Access to health records may be required for peer review, morbidity or mortality review or other specified audits for the primary purpose of clinical governance or quality management	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents
Clinical Record	A collection of data and information gathered or generated to record the clinical care and health status of an individual or group. Also referred to as a Health Record, Medical Record, Healthcare Record	Australian Standard AS2828.1 Health Records

Electronic clinical record	A health record with data structured and represented in a manner suited to computer calculation and presentation. NOTE: The intended meaning of electronic health record is emerging. When this term is used today it implies the ability to compute the content of the record. Electronic health records are often described as records able to represent a lifetime record of health and care. Electronic health records may include records created in electronic format (born-digital records), database entries and other entities as well as digitized health records	Australian Standard AS2828.2 Health Records
Electronic Document Records Management Systems (eDRMS)	An automated system designed to manage semi-structured or unstructured content including test, images, and video content. A subset of documents managed in an eDRMS can be declared to be records. The eDRMS manages these records using a rigorous set of business rules which are intended to preserve the context, authenticity and integrity of the records	Queensland State Archives Glossary of Archival and Recordkeeping Terms
Record keeping	The act of making, keeping and preserving evidence of government business in the form of recorded information.	Queensland State Archives Glossary of Archival and Recordkeeping Terms

Records	Recorded information created or received by an entity in the transaction of business or the conduct of affairs that provides evidence of the business or affairs and includes: (a) anything on which there is writing (b) anything on which there are marks, figures, symbols or perforations having a meaning for persons, including persons qualified to interpret them (c) anything from which sounds, images or writings can be reproduced with or without the aid of anything else, or (d) a map, plan drawing or photograph.	Public Records Act 2002 Schedule 2 Dictionary

8. Consultation

Key stakeholders who contributed to and/or reviewed this version include:

- Executive Director Medical Services
- Chief Financial Officer
- Director Strategy Planning & Coordination
- Manager Healthcare Purchasing & Performance
- Health Information Manager
- Manager, Primary Health Care Information Systems and Support
- Acknowledgment to Sunshine Coast Hospital and Health Service – Procedure: Health record access to research

9. Approval Governance Pathway

Policy Officer
Research Governance Officer – Department of Medical Services

Policy Custodian
Executive Director of Medical Services

Endorsing Committee or Position
Clinical Governance Committee

Approving Officer
Health Service Chief Executive

The following Officer has **approved** this document

Name : Dr John Gallichio

Position: Executive Director of Medical Services

Signature: _____ *Date:*_____

10. Effective Dates

Approval date	20.5.15
Effective from	20.5.15
Next Date of Review	20.5.17
Supersedes	New

11. Version Control

Version	Date	Prepared by	Comments
1.0	12/05/2015	RGO	

12. Audit Strategy

Audit strategy	Audit of requests for access to health records for research or clinical audit to ensure approval completed prior to processing
Audit tool attached	N/A
Audit frequency	Annual (February)
Audit responsibility	Health Information Manager
Indicators / Outcomes	100% compliance with approval requirements

13. Appendices

Appendix 1 Approval and pricing for access to health records

Appendix 2 Health Information Management Services (HIMS)
Request for Access to Health Records for Research or Clinical Audit

Appendix 1: Approval and pricing for access to health records#

Requestor	Request Type	Approval	Cost
TCHHS Medical Officers TCHHS Visiting Medical Officers TCHHS Allied Health TCHHS Nursing/Midwifery	Health records required for clinical review such as VLADs, QASM reporting, Morbidity and Mortality Meetings, TCHHS Databases and other clinical governance purposes	Nil	Nil
TCHHS Professional TCHHS Clinical Trial Coordinators	Clinical review conducted on the specific area/service where the clinician **is currently working**	DD	Nil
Queensland Health	Any clinical review conducted on the specific area/service where the clinician **is not currently working**	DD +EDMS	Nil
	Clinical review not specific to any one area/service	EDMS	Nil
	Unfunded research	HREC + CE	Nil
	Funded research and non-pharmaceutical clinical trials **	HREC + CE	0 – 20 health records – nil charge > 20 health records - $4 per record*
	Pharmaceutical clinical trials	HREC + CE	0 – 20 health records – nil charge > 20 health records - $4 per record*
QLD Institute of Medical Research (QIMR) Not for profit organisations Universities Private doctors	All research projects	HREC + CE	0 – 20 health records – nil charge > 20 health records - $4 per record*
Other public hospitals	All research projects	HREC + CE	0 – 20 health records – nil charge > 20 health records - $4 per record*
QLD Audit of Surgical Mortality (QASM)	Clinical audit of surgical deaths *(Approval exists via existing agreement with QASM)*	Nil	Nil
Students on placement: Medical students Allied health students Nursing/ midwifery students	All research projects	HREC + CE	0 – 20 health records – nil charge > 20 health records - $4 per record
Professional students: Masters students PhD students Other students not on placement	All research projects	HREC + CE	0 – 20 health records – nil charge > 20 health records - $4 per record*
Pharmaceutical or medical supply	Clinical/ Pharmaceutical Trials and Research	HREC + CE	0 – 20 health records – nil charge > 20 health records - $8 per record
Other	All research projects	HREC + CE	0 – 20 health records – nil charge > 20 health records - $8 per record*

*Note: Where health records are required to be retrieved from off-site storage, a charge of $8.00 per record will apply (where charges are applicable).

Health Records supplied as electronic data will be costed on a case by case basis

Legend Approval positions

CE	Chief Executive via research authorisation process
DD	Department Director
EDMS	Executive Director Medical Services
HREC	Human Research Ethics Committee

Appendix 2

HEALTH INFORMATION MANAGEMENT SERVICES (HIMS)
Request for Access to Health Records for Research or Clinical Audit

Please print, complete (including relevant signatures) and scan this form and email to TCHHS-HIM@health.qld.gov.au with an Excel list of required health records

Name:	**Position:**
Organisation:	**Date Required:**
Email address (to advise audit completed & delivered):	

Which TCHHS site are you requesting the health records from:

□ Multi- purpose health service – Cooktown or Weipa

□ Primary HealthCare Centre(s) – Specify site

□ Hospital – Thursday Island or Bamaga

At what location/department/hospital will the records be kept / delivered:

Where are the health records to be tracked to on HBCIS:

Are there special access requirements to this location	□Yes (explain)..... □ No

Which volumes are required?	□ Latest only (e.g. vol 5 of 5)	□ All (e.g. vol. 1-5 of 5)
□ Last 2 (e.g. vol 4&5 of 5)	□Other……	

If the latest volume of the health record is not available do you still want all other volumes requested?
□ Yes □ No

Are the health records required for -
□ Clinical Audit (describe the audit being undertaken)
……
……
……
□Research – □ Funded, if so please include ADDRESS Details for invoice
Name

Address

□ Research – Unfunded

INFORMATION FOR BORROWING HEALTH RECORDS

HIMs require up to seven days to retrieve and deliver health records
- Please include the patient URN & Surname on the list of health records you wish to borrow
- A maximum number of 20 health records can be borrowed at one time
- Only health records within the Medical Records Department or Off-Site Storage will be retrieved
- You will be contacted and advised the health records are ready
- When you have finished with the health records contact the Medical Record Department

Departmental Director (DD) Approval			
Name	Date	Signature	Not Required ☐
Executive Director of Medical Services (EDMS) Approval			
Name	Date	Signature	Not Required ☐
Human Research Ethics Committee (HREC) Approval			
Copy of application and approval document		attached ☐	Not Required ☐
Chief Executive (CE) Approval			
Copy of application and approval document		attached ☐	Not Required ☐
HIMS APPROVED		**DATE**	**PRIORITY**