Procedure

TCHHS-OCE-1-PRO-0080

Research approval

1. Purpose

The purpose of this procedure is to provide Torres and Cape Hospital and Health Service (TCHHS) employees and visitors with consistent processes and accountabilities for the approval of research activities. Staff should be supported in obtaining the necessary approvals required for undertaking research activities.

The intended outcome of this procedure is to minimise the risks to patients, staff and the TCHHS by ensuring that:

- Research activities are not conducted without appropriate approval
- Managers of service lines are aware of research activities being conducted in their departments
- The TCHHS has the appropriate resources to support and facilitate the research
- Research undertaken in the TCHHS complies with Queensland Health policies and standards and other relevant guidelines
- The TCHHS has a record of all research activities being undertaken
- The TCHHS has access to all research to maximise the benefits of research outcomes and facilitate quality improvement in health services and care
- All research is authorised by the TCHHS Chief Executive prior to commencement

2. Scope

TCHHS cannot currently authorise clinical trials.

This procedure relates to:

- To all TCHHS permanent, temporary, and casual employees. It also extends to Visiting QH employees, Medical Officers, other partners, contractors, consultants, and students
- All staff who wish to undertake research activities within the TCHHS
- All service line managers/heads of departments who are responsible for a department in which research is being conducted, and
- All Business Managers/Financial Officers who may be responsible for financial budget information supplied for research applications being conducted in their service line, as delegated by the relevant Service Director / Chief Finance Officer

3. Process

All information relating to the research approval process can be found on the TCHHS Research Ethics and Governance Unit website and TCHHS Research Governance internet page. These sites contain links to resources and supplementary documentation. (It is recommended that all researchers review the contents of this website as it will provide additional guidance).

Approval to conduct research can only be provided by the Chief Executive following the completion of the following two mandatory (2) steps

- **Step1. Ethical approval**. An ethics committee assesses if the project is ethically sound; if the benefits outweigh the risks. Research must meet the requirements outlined in the National Statement on Ethical Conduct in Human Research. For research activities involving Hospital and Health Service patients, staff, data, facilities or resources, approval from a registered and certified Human Research Ethics Committee (HREC) – or in the case of research **specifically** targeting Aboriginal and Torres Strait Islander peoples – the Far North Queensland Human Research Ethics Committee (HREC) must be obtained
- **Step 2. Governance approval.** A Research Governance submission review ensures that the TCHHS has the resources (including financial resources) to support the research; and that legal issues are addressed. Additional approvals may be required prior to Governance approval being provided. These are required if access to patient information is being sought without consent (PHA Approval required), research is to be conducted with participants who are unable to give consent (QCAT Approval required), access to pathology information and specimens or assistance with pathology testing is required (Queensland Pathology Approval required) or the research project is a collaboration with a University and or external party i.e. contracted consultant

3.1 Ethical review and approval

Ethical review is a process by which an independent committee assesses the ethics, quality, methods and researcher capabilities of a project against the guidelines provided by the National Health and Medical Research Council (NHMRC). All research must have

- Scientific merit
- Be able to demonstrate that any benefits outweigh any associated risks
- Be conducted by personnel qualified to undertake the research
- Show respect for the participants (with guidelines for vulnerable groups)
- Consider ethical issues associated with the methodology being employed.
- Ethical review is undertaken by an NHMRC registered Human Research Ethics Committee (HREC).

3.2 Steps in applying for ethics approval

3.2.1. Prepare a research protocol

Ethics committees will require a research protocol or study design. It is beneficial to write this before beginning the Human Research Ethics Application (HREA)

The protocol assists with answering many of the questions contained in the HREA application form.

At a minimum, a research protocol must include:

- Investigators and affiliations
- Institutions and addresses where the research will take place
- Background literature
- Aims and hypotheses
- Methods
  - participants and eligibility criteria
  - recruitment processes
  - data collection methods
  - types of data to be collected
  - description of intervention or treatment
  - data analysis and endpoints of the study
- Conditions of participation (e.g. withdrawal)
- Risks to Participants
- Benefits / significance / outcomes
- Security and confidentiality
- Dissemination of findings
- References

3.3 Complete a Human Research Ethics Application (HREA)

Ethical application forms (HREA's) can be found on the Ethical Review Manager (ERM) website.

It is recommended that all researchers contact the HREC before submitting their application to discuss submission requirements. Most Queensland Health HRECs provide a checklist for researchers to ensure submission requirements have been met. Inadequate submissions will delay any HREC approval and therefore delay commencement of the project. For many research projects undertaken in the TCHHS the ethics review is provided by the Far North Queensland Human Research Ethics Committee. Email Cairns_Ethics@health.qld.gov.au for more information. Alternatively, discuss the project with the TCHHS Research Governance Officer (RGO), Email: Torres-Cape-Research-Governance@health.qld.gov.au.

3.4 Prepare supporting documentation

Depending on the type of study, supporting documents included in addition to the HREA application form may be:

- Media advertisements such as flyers or posters
- Any information given to participants such as information sheets and consent forms
- Diary cards
- Appointment cards
- Participant data collection forms or questionnaires
- Funding information
- Investigator CV's
- Investigator brochure
- Clinical Trial Notification Form
- Indemnity Form
- Insurance Certificates
- Letters of Support

3.5 Submit the Human Research Ethics Committee Application

All research in a TCHHS facility, with TCHHS staff or patients or accessing TCHHS resources, including health system information/data and/or which focusses on Aboriginal and Torres Strait Islander clients must be submitted in the first instance through the Far North Queensland Human Research Ethics Committee (FNQ-HREC). Contact the HREC Administrator on Cairns_Ethics@health.qld.gov.au

Other research if not specifically targeting Aboriginal and Torres Strait Islander health information and/or participants may be submitted for an ethics review to another NHMRC certified and registered HREC.

Once a HREC is selected (or been allocated) contact must be made with the committee to confirm their submission requirements. If the project is low risk, ensure the HREC is aware of this as some committees may have different submission requirements for Low and Negligible Risk Research Form (LNR Form).

3.6 Address HREC questions

Projects are reviewed by the HREC and if approved, written notification is sent confirming this as an Ethics approval letter. Additional information may be required by the HREC before approving research.

3.7 Governance review and approval

Research Governance authorisation is the process by which proposed research projects are reviewed to ensure that the TCHHS has the resources to support the research, (e.g. funding, personnel, equipment and infrastructure) and that the research is in alignment with TCHHS's strategic research plan.

Not all research projects that have received ethics approval are able to be authorised in the TCHHS. It is important that applicants engage early in discussions with the appropriate Executive General Managers at proposed research sites. This early engagement will minimise the possibility of research not being supported by these Executive Heads of Departments when approval signatures are requested on the Site-Specific Assessment applications. The SSA applications provide evidence of site support and are part of the materials required a for a governance review to be completed. Contact the TCHHs RGO for advice if unsure of appropriate EGM to contact. Once HREC approval and any additional approvals have been granted all researchers must submit the required documentation for a research governance review both online by uploading documents to the ERM database and supplying a hard copy of all documentation to the TCHHS RGO before the before the governance review can be completed and the research considered for authorisation by the TCHHS Chief Executive.

Researchers are able to seek an ethics approval and a research governance review in parallel. To undertake the processes at the same time please contact the Research Governance Officer Torres-Cape-Research-Governance@health.qld.gov.au.

3.8 Prepare supporting documentation

Prepare any site-specific documentation (e.g. **site specific** Patient information and consent forms. These are to be developed using the ethics committee approved master copy versions of these materials with changes only permitted in these documents to the Header and the Footer annotations

Complete the Site-Specific Assessment form (SSA) by creating a “sub form” against the HREC application in ERM. Most applications will require the full SSA form to be completed. Researchers should not select the minimal data SSA forms without first consulting with Research Governance. In order to obtain the required Head of Department signatures that are mandatory requirements on the SSA forms The completed Site-Specific Assessment form accompanied by a Site-Specific Research budget are to be emailed to TCHHS-Medical-Services@health.qld.gov.au

Site specific Assessment forms with their budgets will be forwarded internally (on behalf of the researcher) to the relevant Head of Department at the proposed research site. Site Specific Assessment applications and budgets will be returned to researchers from this email address after their review by Executives.

A Site-Specific Assessment application identified as TCHHS-North is to be used for all proposed research sites located in the Torres Straits and Northern Peninsula Areas (NPA) with individual research locations identified.

Sites being nominated for research located across Cape York should have individual sites identified and named as TCHHS-South on a separate Site-Specific Assessment form

Research may require one (1) or two (2) Site Specific Assessments to be reviewed and signed off by the appropriate Executive General Managers before uploading and submission to the RGO.

Upload all supporting documents (including HREC “ethics approved” documents) and upload using the “submit” function in ERM. A checklist is available to support researchers to ensure all required materials are uploaded to ERM for a research governance review.

All projects submitted for governance review must provide a budget.

Key items to consider when preparing a budget are time of TCHHS staff in completing or providing assistance in research tasks e.g. surveys/focus groups/training/consenting of participants, time undertaking research activities within work hours. Include in the budget quotes from the following areas if they are required within the scope of the research project: Radiology, Pharmacy, Pathology and Information Technology. A site finance budget is available on request from the TCHHS RGO

All costs are to be captured and submitted in a budget which accompanies each SSA application. The costs incurred are either indicated as “in kind” support (being requested by the researcher and provided by the TCHHS without passing on the costs to the researcher) or costs which the TCHHS will invoice to the research project (in this scenario

the researcher is to provide the invoice details to the TCHHS). Researchers are to ensure a budget accompanies each Site-Specific Assessment application. Where there is no budget supplied, or it is reviewed as inaccurate or incomplete it will be returned to the applicant and will have to be re submitted before the SSA can be reviewed by the Head of Department. No research without an approved budget will be signed off by the TCHHS Chief Finance Officer and can be authorised by the Health Service Chief Executive .

Site-Specific Assessment forms accompanied by budgets are to be submitted to the email address TCHHS-Medical-Services@health.qld.gov.au . The documents will be forwarded to the appropriate TCHHS executives for review and if supported they will be signed and returned to researchers from this generic email address for submission as part of the research governance review

3.9 Prepare a research agreement (if applicable)

Research agreements are determined by the type of research intending to be undertaken in the TCHHS. If research is being undertaken by an **external** organisation a Research Agreement will be required to be submitted with your Research Governance application.

All non-standard agreements are required to undergo review by a Solicitor, this is organised by the Torres Cape Research Governance Officer and is undertaken at the researchers cost.

The Research Governance Officer has a number of research agreements for particular types of research which can be provided to researchers on request. These Research Agreements if unaltered can be used without further legal review. The TCHHS RGO should be the first point of contact for any questions about the process for preparing a research agreement.

3.10 Additional approvals required by legislation or policy

Depending on the type of research being undertaken, additional levels of approval may be required according to current legislation or policy. These approvals in some cases may be obtained following HREC approval but prior to research governance authorisation

The most common examples of additional approval are:

- *Public Health Act 2005 (PHA)* approval

If access to confidential patient health information is required and patient consent to access the information is not intended to be obtained, a *Public Health Act 2005* approval will be required. This is relevant for health information that is identifiable or potentially re-identifiable. Note: data can be potentially re-identifiable even if information such as name, address, date of birth or UR number are not collected.

Details on obtaining *Public Health Act 2005* approval can be found from the Office of Health and Medical Research.

3.10.1. Clinical and State-wide Services (CaSS) approval

If the research requires access to tissue samples or other data sources held by CaSS (including data in AusLab and AusCare), researchers may require approval from CaSS. For information on accessing tissue samples or data, and you are a Queensland Health employee consult the Health Support Queensland https://qheps.health.qld.gov.au/hsq . If not a Queensland Health employee use the following link https://www.health.qld.gov.au/healthsupport/research

3.10.2. Queensland Civil and Administrative Tribunal approval

If research involves patients who are unable to give informed consent, approval may be required through the Queensland Civil and Administrative Tribunal (QCAT Website). Carers are not able to provide consent for research to be undertaken on patients. Carers are only able to consent on behalf of patients to continue or in some cases instigate new medical treatment where patients are unable to give consent.

3.10.3. Approvals from other institutions

Some research will require HREC approval from other institutions, (e.g. universities). If unsure whether approval from another institution is required contact the HREC at that institution for guidance.

3.11 Submit the Research Governance application

Research Governance submissions should include:

- A cover letter briefly describing the purpose of the research (a copy of the covering letter submitted to the HREC may be used);
- A copy of the complete HREC application (including all supporting documentation – reviewed and approved at the HREC meeting);
- HREC approval correspondence;
- Research agreement, CTN, Indemnity Forms (if applicable);
- Any other approvals required for your type of research (see “Section 3” above);
- A completed and signed SSA form (including separate authorised budget for complex studies).

Completed applications (i.e. with Head of Department signatures indicating support of research project) should be submitted to the **Torres Cape Research Governance Officer.** One electronic form must be completed for each site and uploaded, and a hard copy of each submission must be provided for processing for each site where research is intended to be undertaken. (i.e. TCHHS -South. Weipa Integrated Health Service and Napranum TCHHS North Thursday Island Primary Health Care Centre and Bamaga Hospital each require a SSA)

The address for mailing hard copies is:

Torres Cape Research Governance Officer
Torres and Cape Hospital and Health Service
PO Box 5607
Cairns. QLD 4870

3.12 Research authorisation

Research project applications will be reviewed by the Torres Cape Research Governance Officer (RGO) and if complete with all required documentation is provided, the RGO will undertake a review and make a recommendation for consideration by the TCHHS Chief Executive of research authorisation. The RGO or TCHHS Chief Executive may require applicants to address additional questions prior to approval being given.

A "**Research Commencement Form – SF11**" is provided as an attachment with research authorisation correspondence. This must be signed by the researcher and returned to the Torres- Cape RGO

Research may only commence at a site(s) following receipt by the researcher of research authorisation correspondence from the TCHHS Chief Executive and the "Research Commencement Form – SF11" has been completed by the researcher and returned to the Research Governance Officer.

Should research commence without research authorisation from the TCHHS Chief Executive the Researcher will be instructed to cease the research project immediately and all records/ data/ information collected as a result of unauthorized research will be returned to the Research Governance Officer within seven (7) days of a request being issued. This includes documentation collected as hard copy materials and all electronic data/ files. Notification of the request to cease research will be forwarded to the Chair of the NHMRC Ethics committee which provided the Ethics approval of the research project

Staff engaged in research activities through collaboration / support or participation in research must ensure adherence to the process outlined in the research approval procedure, as approved by the HREC and Research Governance and all TCHHS employees must ensure research is authorised before they participate

3.13 Ongoing maintenance of approved research

All approved research must be conducted in accordance with the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) and where appropriate, the Therapeutic Goods Administration Note for Guidance on Good Clinical Practice. https://www.tga.gov.au/sites/default/files/ich13595an.pdf

All researchers are responsible for managing the ongoing approval of their research. In particular:

3.14 Changes to a research protocol

Changes to a research project must be re-submitted to the authorising HREC for approval prior to introducing the changes. Researchers may also be required to re-submit these changes for Research Governance authorisation. Consult with the authorising HREC or **Torres Cape Research Governance Officer** about how to manage changes to research projects.

Common changes that **will** require submission to the HREC and Research Governance include:

- Eligibility or changes to the participant group
- Process for obtaining patient consent (where appropriate)
- Data being collected
- Process for collecting data
- Facilities/hospitals –additional sites to be involved in research; or investigators

3.15 Reporting

Annual progress and final reports must be provided to the HREC and Torres Cape Research Governance Officer, in accordance with the conditions of authorisation included in the ethics and research authorisation approval letters.

Failure to comply with reporting requirements may lead to research authorisation being withdrawn by the TCHHS Chief Executive**.**

Researchers are responsible for managing the agreed costs and resources associated with the research project as negotiated and agreed with TCHHS through the incorporation of agreed costs within the budget section of the Single Site Assessment(s) (SSA's). Researchers are required to provide financial reports as part of financial outcomes.

3.16 Approval period

Queensland Health HRECs usually provide approval for up to a maximum of 5 years. The validity date will be documented on the HREC approval letter. If a study requires an extension to beyond this date the researcher must apply to the HREC to extend the ethics approval period **before** the approval date expires.

Once an extension has been granted by the originating HREC (Ethics committee), the documentation requesting the extension and the HREC approval correspondence must be submitted to the Torres and Cape Research Governance office

3.17 Monitoring of approved research

HREC Ethics committees and Research Governance may conduct monitoring audits on approved research. Researchers must comply with any requests from the HREC or Research Governance Officer in relation to monitoring.

4. Governance Responsibilities

Position	Responsibility
Health Service Chief Executive	Oversight of compliance with this procedure
Executive Directors	Review of SSA (research applications) with endorsement or inability to support indicated through signing
Heads of Supporting Departments	Heads of Supporting Departments of service areas are aware of research activities being conducted in their departments. Local work practices to ensure all researchers are authorised before research commenced
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 research commenced
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 undertaken in compliance with *Standard Operating Procedures for Queensland Health Research Governance Officers. Version 5, Nov 2013*
Contract Manager	Executed Research Agreements supplied by the RGO are recorded in the Q Contracts

5. Supporting documents

5.1 Legislation / standard/s

- *National Health and Medical Research Council Act 1992*
- Queensland Government *Public Health Act* 2005 Application and Information for Researchers https://www.health.qld.gov.au/hiiro/html/regu/aces_conf_hth_info
- Research Management Policy https://www.health.qld.gov.au/__data/assets/pdf_file/0020/164162/qh-pol-013.pdf
- Research Management Policy - Implementation Standard for Research Governancehttps://www.health.qld.gov.au/__data/assets/pdf_file/0035/397448/qh-imp-013-1.pdf

5.2 Forms and templates

- On-line National Ethics Application Form (NEAF)
- On-line Queensland Health Site Specific Assessment Form (SSA)
- *Public Health Act 2005* - application for access to health information for the purpose of research

5.3 Related documents

- National Health and Medical Research Council and Universities Australia "Australian Code for the Responsible Conduct of Research" 2018 https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018
- National Health and Medical Research Council - National Statement on Ethical Conduct in Human Research 2007 updated 2015 https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research
- Process for Review and Approval of Clinical Audit/Quality Assurance (QA) Projects, CHI Office of Health and Medical Research, April 2011
- Queensland Health Good Clinical Practice (GCP) Standard Operating Procedures https://www.health.qld.gov.au/hiiro/html/regu/for_researcher/gcp,research-ethics-and-governance-standard-operating-procedures-sop

  Queensland Health Human Ethics Research Application (HREA) https://au.forms.ethicalreviewmanager.com/Personalisation/DisplayPage/23
- Queensland Health – Human Research Ethics Committees
- Queensland Health - Research User Guide, https://www.health.qld.gov.au/hiiro/html/regu/regu_home
- Therapeutic Goods Administration Australian Clinical Trials Handbook, updated 2018 https://www.tga.gov.au/publication/australian-clinical-trial-handbook
- Therapeutic Goods Administration Notes for Guidance on Good Clinical Practice https://www.tga.gov.au/sites/default/files/ich13595an.pdf

6. Definition of terms

Term	Definition / explanation / details	Source
Amendment	A change to the Human Research Ethics Committee (HREC) approved application including the protocol or supporting documentation. If the amendment is administrative in nature an HREC amendment review fee may be waived for commercially sponsored research. Examples of Administrative Amendments include: • Correction of typographical errors in any study documentation • Amended contact details for the sponsor or study staff or • Appointment of new support staff	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Applicant	or multi-centre studies the Coordinating Principal Investigator (CPI). For single site studies the Site Principal Investigator (PI).	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Associate Investigator (AI)	Another term used for Sub-investigator	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
The Australian Code for the Responsible conduct of Research (*the Code)*	The *Australian Code of for the Responsible Conduct of Research* (2007) (the *Code*). This guides institutions and researchers in responsible research practices and promotes integrity in research. It shows how to manage breaches of the *Code* and allegations of research misconduct, how to manage research data and materials, how to publish and disseminate research findings, including proper attribution of authorship, how to conduct effective peer review and how to manage conflicts of interest. It also explains the responsibilities and rights of	

Term	Definition / explanation / details	Source
	researchers if they witness research misconduct	
Certified HREC	An HREC which has had its processes assessed and certified under the National Health and Medical Research Council (NHMRC) National Certification Scheme. NHMRC certification lasts for three years. • To access information on the NHMRC Certification Scheme, click on this link: http://hrep.nhmrc.gov.au/ To find a certified HREC, follow this link: https://www.nhmrc.gov.au/about-us/publications/certification-handbook#:~:text=NHMRC%20collects%20personal%20information%20from,review%20of%20multi%2Dcentre%20research.&text=By%20providing%20this%20information%2C%20institutions,will%20be%20stored%20by%20NHMRC.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Clinical Audit	Quality Assurance programmes may use planned clinical audits along with other monitoring tools to ensure that standards are being met. A Clinical Audit is not research. • Clinical audit tells us whether we are doing what we should be doing and how well we are doing it. Clinical audit is about quality and finding out if best practice is being practised. • Research is about obtaining new knowledge and finding out what treatments are the most effective. Research tells us what we should be doing. Health and Medical Research policy is to make a clear distinction between clinical audit and research and the policy is that clinical audit does not need approval from a research ethics committee. Even if an ethical opinion is sought for a clinical audit and even if an application is made under the *Public Health Act 2005* to disclose confidential information without consent, clinical audits do not require research authorisation as they are not research activities. Local approval processes apply for quality assurance activities.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf

Term	Definition / explanation / details	Source
Contact Person	The person designated by the Principal Investigator (PI) to be responsible for liaising with the HREC / Research Governance Office(r) (RGO). May also be known as the Site Coordinator or Clinical Research Coordinator.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Confidential Information	Confidential Information means any information that— (a) is about a person who is receiving or has received a public sector health service; and (b) could identify the person. *Hospital and Health Boards Act (2011)* See also *Personal Information*	
Coordinating Principal Investigator (CPI)	The Investigator responsible for coordinating a multi-centre research study, and the submission and communication of all subsequent requests and notifications to the site PIs and Reviewing HREC. The CPI and their team are responsible for coordinating the HREC applications and correspondence throughout a multi-centre study, on behalf of the Accepting PIs for which the CPI is responsible. For single site studies the terms Coordinating Principal Investigator, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are all synonymous. Guidance documents for undertaking the role of a CPI are on the HIIRO website: Standard Operating Procedures for Queensland Health Research Governance Officers. Ver 5, Nov 2013 Page 10 of 56 http://www.health.qld.gov.au/ohmr/documents/regu/rgo_sop.pdf	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf Standard Operating Procedures for Queensland Health Research Governance Officers. Ver 5, Nov 2013 http://www.health.qld.gov.au/ohmr/documents/regu/rgo_sop.pdf
Department of Health (DoH)	The Department of Health manages the health system in Queensland.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf

Term	Definition / explanation / details	Source
Good Clinical Practice (GCP)	An international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human participants. May also be referred to as the International Conference on Harmonisation Good Clinical Practice (ICH GCP). For further information go to: http://ichgcp.net	Good Clinical Practice (GCP)
Hospital and Health Boards Act 2011	The Act that recognises and gives effect to the principles and objectives of the national health system agreed by Commonwealth, State and Territory governments. The object of the Act is to establish a public sector health system that delivers high quality hospital and other health services in Queensland having regard to the principles and objectives of the national health system. Part 7 of the Act provides the legislation that governs release of Confidential Information. https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/H/HHNA11.pdf	
Hospital and Health Services (HHSs)	Hospital and Health Services (HHSs) operate and manage a network of public hospitals and health services within a defined geographic or functional area within Queensland.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Human Research Ethics Application (HREA)	The national ethics application form. Used to submit for HREC review. Uploading to the ERM database is undertaken when seeking an ethics review with a Queensland Health HRECs. The Site Specific Assessment form (SSA) is able to be created out of the HREA form when uploaded to the ERM database https://au.forms.ethicalreviewmanager.com/	
Human Research Ethics Committee. (HREC)	Human Research Ethics Committees (HRECs) review research proposals that involve humans or their tissue or data. HRECs are established by organisations, which register their HREC with the NHMRC. It may also be referred to as the Reviewing HREC in multi-centre research studies.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013

Term	Definition / explanation / details	Source
		http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
HREC Administrator	An employee of the institution who provides administrative support and advice on the institution's processes for ethical review of research studies. The HREC Administrator reports to the Chair of the HREC in matters related to the activities of the Committee. The terms HREC Coordinator and HREC Administrator are interchangeable.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
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 (*National Statement on Ethical Conduct in Human Research*, 2007).	
Low and Negligible Risk Research and form (LNR Form)	Section 2.1.6 of *The National Statement* (2007) describes research as low risk where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk. Not applicable where vulnerable populations are research participants. An application form used for research which is defined as low or negligible risk. The form is available on the ERM website.	
Multi-centre Research (MCR)	Includes research conducted through the collaboration of at least two unique institutions that may be situated in more than one state or territory or within a single jurisdiction. It does not refer to research being conducted at several sites or locations *Standard Operating Procedures for Queensland Health Research Governance Officers. Ver 5, Nov 2013 Page 11 of 56* of a single institution. (Certification Handbook – National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research, November 2012, p 1) Multi-centre research must be allocated via the CCS for HREC review.	Standard Operating Procedures for Queensland Health Research Governance Officers. Ver 5, Nov 2013 http://www.health.qld.gov.au/ohmr/documents/regu/rgo_sop.pdf

Term	Definition / explanation / details	Source
National Mutual Acceptance	The national mechanism to allow specific types of multi-centre research to be reviewed by an NHMRC Certified HREC, and for that HREC review to be accepted across all public health institutions within participating jurisdictions. For further information, go to: http://www.health.qld.gov.au/ohmr/html/regu/mutual_accept.asp *The National Statement* (*NS*) *The National Statement on Ethical Conduct in Human Research* (2007) Updated 2018. A guidance document developed by the NHMRC, the Australian Research Council and the Australian Vice-Chancellors' Committee to provide guidelines for researchers, HRECs and others conducting ethical review of research. It also states institutions' responsibilities for the quality, safety and ethical acceptability of research that they sponsor or permit to be carried out under their auspices https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018	
Negligible Risk Research	Section 2.1.7 of The *National Statement* describes research as *negligible risk* where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.	
Non-Identifiable Data	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. Subsets 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. (*National Statement on Ethical Conduct in Human Research*, 2007up dated 2018) https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018	

Term	Definition / explanation / details	Source
Opt Out Consent process	A consenting process where the default position is that potential participants are in the project, unless they opt out. It is less costly and time consuming and results in greater levels of participation. The risk is that people will participate without understanding or really wanting to participate. It is incumbent upon the researchers and HRECs to ensure that the use of Opt Out consent is ethically defensible and is considered informed consent. There are few instances in medical research involving humans, where this would be an acceptable form of consent. In Queensland, a *Public Health Act 2005* (*PHA*) approval is required to disclose confidential information without the consent of a person https://www.legislation.qld.gov.au/view/pdf/inforce/current/act-2005-048	
Personal information	Personal information is information or an opinion, including information or an opinion forming part of a database, whether true or not and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion. *Information Privacy Act 2009* See also *Confidential Information* https://www.legislation.qld.gov.au/view/pdf/inforce/2017-06-05/act-2009-014	
PHA	*Public Health Act (2005)*	
Principal Investigator (PI)	The investigator responsible for the overall conduct of the research study at a site. • For multi-centre studies the PI may be known as the Accepting PI if they do not have CPI responsibilities. • For single site studies the terms Coordinating Principal Investigator, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are used interchangeably	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf

Term	Definition / explanation / details	Source
Quality Assurance Activity (QA)	A clinical governance activity that is a requirement of the compulsory *National Safety and Quality Health Service Standards* and an associated *Australian Health Service and Quality Accreditation* (AHSSQA) Scheme. https://www.safetyandquality.gov.au/sites/default/files/2019-04/National-Safety-and-Quality-Health-Service-Standards-second-edition.pdf This includes patient satisfaction surveys, surveillance and monitoring and clinical audits. If there are research elements then it will be reviewed as research activities requiring ethics approval and research authorisation	
Queensland Health	The term used to describe reference to the Department of Health and Hospital and Health Services	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Re-identifiable Data	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(*National Statement on Ethical Conduct in Human Research*, 2007up dated 2018) https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018	
Research Governance Office(r) (RGO)	The Office(r) or coordinated function within an institution / HHS whose responsibilities are: • Assessing the site-specific aspects of ethically approved research applications; • Making recommendations to the HHS CE or delegate as to whether a research study should be granted authorisation at that site; and	Standard Operating Procedures for Queensland Health Research Governance Officers. Ver 5, Nov 2013 http://www.health.qld.gov.au/ohmr/documents/regu/rgo_sop.pdf

Term	Definition / explanation / details	Source
	• Monitoring authorised research at the site to ensure it meets appropriate standards	
Research Governance Process	The process by which an RGO assesses the suitability of study to take place within their HHS and recommends authorisation to the HHS CE. Once authorised, the study may commence at that HHS.	Standard Operating Procedures for Queensland Health Research Governance Officers. Ver 5, Nov 2013 http://www.health.qld.gov.au/ohmr/documents/regu/rgo_sop.pdf
Reviewing HREC	The certified HREC that has been allocated to review research studies. 60-day clock The period of 60 review days allowed for the deliberation of an ethical decision on an application. For research not requiring review at a full HREC meeting, the clock starts on receipt of a valid application. For research requiring review at a full HREC meeting, the clock starts on the relevant HREC meeting closing date. The 60-day *Standard Operating Procedures for Queensland Health Research Governance Officers. Ver 5, Nov 2013 Page 13 of 56* time limit excludes stop clock days. May also be called 60 Review Days.	Standard Operating Procedures for Queensland Health Research Governance Officers. Ver 5, Nov 2013 http://www.health.qld.gov.au/ohmr/documents/regu/rgo_sop.pdf
Single Ethical Review Process (SERP)	The mechanism to allow ethical review of multi-centre research by one NHMRC Certified HREC rather than submitting a study to multiple HRECs for review.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Single site research	Research to be conducted at one site only.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf

Term	Definition / explanation / details	Source
Site Coordinator	The person designated by the Principal Investigator (PI) to be responsible for liaising with the HREC / RGO. May also be known as the Clinical Research Coordinator, Contact Person or Study Liaison Officer	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Site-Specific Governance Amendment	An amendment request for an authorised research study that may be submitted by the applicant to the RGO only (thereby by-passing the HREC). Examples would be changes to site contracts and changes to participating site staff other than the PI.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Site Start Date	The site start date refers to either the anticipated first point of recruitment (i.e. the date when the advertising or screening for participants begins) or start of data collection	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Stop Clock facility	For HREC applications, the time when the 60-day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the HREC for further information or clarification. The clock will re-start automatically when a response from the applicant is logged in to *AU RED* .For SSA applications, the time when the 25-day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the RGO for further information or clarification.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf

Term	Definition / explanation / details	Source
Study Site	Means the location(s) under the control of the Institution where the study is actually conducted.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Study Start Date	The study start date refers to either the anticipated first point of recruitment (i.e. the date when the advertising or screening for participants begins) or the start of data collection at any site involved in the study	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Sub Investigator	May also be called Associate Investigator (AI) or Associate Researcher. ICH GCP defines a sub-investigator as *any individual member of the clinical trial team Standard Operating Procedures for Queensland Health Research Governance Officers. Ver 5, Nov 2013 Page 14 of 56* designated and supervised by the investigator at a trial site to perform critical trial related procedures and/or to make important trial related decisions.	Standard Operating Procedures for Queensland Health Research Governance Officers. Ver 5, Nov 2013 http://www.health.qld.gov.au/ohmr/documents/regu/rgo_sop.pdf
25-day clock	The period of 25 days allowed for the SSA authorisation by the HHS CE or delegate of a research application. The clock starts on receipt of a valid governance application	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Therapeutic Goods Administration (TGA)	The Therapeutic Goods Administration is the agency responsible for regulating therapeutic goods. https://www.tga.gov.au/	

Term	Definition / explanation / details	Source
Validation	An administrative check carried out by an HREC Administrator or RGO to verify that all applicable application documentation is submitted prior to review. Decisions on validation should be made within one week of receipt.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Validation date	For research not requiring review at a full HREC meeting, the date on which a valid application is received by an HREC Administrator. For research requiring review at a full HREC meeting, the relevant HREC meeting closing date. For research governance: the date on which a valid application is received by an RGO	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf

7. Consultation

- Executive Director of Medical Services

8. Approval governance pathway

8.1 Document author

The following officer is the author of this procedure

- Rosemary Schmidt, Research Governance Officer

8.2 Document custodian

The following officer will have responsibility for implementation of this procedure

- Health Service Chief Executive

8.3 Endorsing committee/position

The following committee/officer will have responsibility for implementation of this procedure

- Executive Leadership Forum Governance Committee

8.4 Approving officer

The following officer has approved this document

- Dr Anthony Brown, Executive Director Medical Services

Signature: _____ Date: _____

9. Effective dates

Schedule	Dates
Approval date	19/08/2020
Effective from	19/08/2020
Next date of review	19/08/2024
Superseded procedure	V 1.0

10. Version control

Version	Date	Prepared by	Comments
1.0	8/12/2014	RGO	
1.1	19/06/2020		Author provides finished version
1.2	24/06/2020		Reviewed by Policy and clinical document manager
1.2	19/08/2020		To ELF for approval
2.0	27/08/2020		Approved by Executive Director Medical Services

11. Evaluation strategy

Strategy	Evaluation
Risk	Consequence rating – Governance, legal and compliance Major Likelihood rating – High Overall risk rating – High
Evaluation strategy	Governance • Performance review ERM database audit level of monitoring through number of progress reports Compliance • Number of authorised and unauthorised research projects d

Strategy	Evaluation
Frequency	Biannual
Evaluation responsibility	Research Governance Officer

12. Document communication and implementation plan

Action	Responsible position
Identify the target group • All Torres and Cape Hospital and Health Service staff	HSCE Research Governance Officer
Provide a time line for communication and implementation milestones • Update of versions • Annually	Research Governance Officer
Identify method of communication • HSCE Broadcast news • Research Internet and Intranet sites • Face to face training professional development meeting • Continued advice by telephone and email	HSCE Research Governance Officer