Standard 1 Governance for Safety and Quality in Health Service Organisations

Procedure

TCHHS-CLIN-1-PRO-0080

Research application and 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, and
- The TCHHS has access to all research to maximise the benefits of research outcomes and facilitate quality improvement in health services and care

2. Scope

This procedure relates to:

- To all TCHHS permanent, temporary, and casual employees. It also extends to Visiting Medical Officers, other partners, contractors, consultants, students, trainees and volunteers
- 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 Financial Officer

3. Procedure

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

For research activities involving Hospital and Health Service patients, staff, data, facilities or resources, approval from a 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) ***and*** the TCHHS Chief Executive (HSCE) or Delegate must be obtained before starting the project.

The following sections outline this process.

Section 3.1. Initial Steps for All Potential Research Activities

Section 3.2. Approval from a Human Research Ethics Committee

Section 3.3. Additional Approvals Required by Legislation or Policy

Section 3.4. Research Governance Authorisation

Section 3.5. Ongoing Maintenance of Approved Research

3.1. Initial Steps for All Potential Research Activities

Confirm the Project Proposal is Research

- Assess whether the proposal is research or clinical audit.

References to assist with determining if the proposal meets the criteria for a research project, Page 7 of the National Statement on Ethical Conduct in Human Research;

- Further Clarification (if needed)

Contact Torres-Cape-Research-Governance @health.qld.gov.au.
Research Governance Officer (RGO) if you are unsure whether the proposed activity is research.

Research projects that are incorrectly identified as clinical audits may place patients, staff and the TCHHS at risk of adverse outcomes. Where concerns remain, it is best to proceed on the basis that the proposal is a research activity. These may be considered as "Low or Negligible Risk" activities, refer 3.2 page 4.

Engage Relevant Stakeholders and Departments

Proposals must be discussed with the line manager and following initial discussions with TCHHS staff (if applicable) discussions must occur with the manager / director of each TCHHS department that may be required to assist with the research. This will facilitate the process of approval.

Ensure all aspects of the proposal are discussed including:

- The level of support required and potential impact (if any) on the department
- Any costs associated with the project and how these will be covered, particularly for sponsored or funded research

3.2. Approval from a Human Research Ethics Committee

Ethical review is an independent review process to ensure projects are ethically sound; the benefits of the research outweigh the risks; and that methods adhere to the National Statement on Ethical Conduct in Human Research. Human Research Ethics Committee (HREC) approval is obtained as follows:

Prepare a Research Protocol

Ethics committees will require a research protocol or study design. It is beneficial to write this before beginning to prepare the ethics application as the protocol assists with answering many of the questions contained in the application form.

At a minimum, a research protocol must include the following details:

- 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 end-points of the study
- Conditions of participation (e.g. withdrawal)
- Risks to Participants
- Benefits / significance / outcomes
- Security and confidentiality
- Dissemination of findings
- References

Complete a Human Research Ethics Committee Application Form

Ethics application forms can be found in the **On-line Forms** system.
Refer to the **Australian On-line forms for Research – User Manual** https://www.ethicsform.org/au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.3.pdf for information on how to complete an on-line ethics application:

- Projects that are considered to be low or negligible risk should use the Low or Negligible Risk (LNR) application form in the on-line system. If you are unsure whether your project would be considered low or negligible risk, use the checklist at the start of the application form to assist you. Alternatively, discuss the project with an ethics committee or the Research Governance Officer,

  Torres-Cape-Research-Governance @health.qld.gov.au.

- For all other research projects complete the National Ethics Application Form (NEAF)
- Ensure the application lists all the sites / facilities involved in the research. Signatures will be required from investigators and the relevant Head of Department(s) on the application form before submission for ethics approval
- Keep a photocopy of the signed, completed ethics application as a record and for submission as the hard copy when applying for TCHHS Research Governance Authorisation **(Section 3.4 below)**

Prepare Supporting Documentation

Depending on the type of study, supporting documents may include:

- Media advertisements such as flyers or posters
- Any information given to participants such as information sheets and site specific 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

Submit the Human Research Ethics Committee Application

All research to be undertaken in a TCHHS facility, with TCHHS staff or patients or accessing TCHHS resources – including 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).

Other research not specific to Aboriginal and Torres Strait Islander health uses the following process:

- Multi-site research can include research being conducted at more than one Queensland Hospital and Health Service i.e. research involving sites outside of the TCHHS, at other Hospital and Health Services with one or more sites at either public or private institutions (e.g. University or interstate health facility). Multi-site research must be submitted through the **Central Coordinating Service** who will allocate your project to a HREC

- A memorandum of understanding has been established between Queensland, New South Wales and Victoria to allow **multi-centre clinical trials that will be conducted across these states to be reviewed under a single HREC review process**. If your project is a multi-state clinical trial, contact the **Central Coordinating Service** for more details and to discuss an appropriate 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 have different submission requirements for Low and Negligible Risk Research Form (LNR Form).

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.

3.3. 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* 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.

- 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, consult the Health Support Queensland (HSQ) website.

- 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.

- 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.

3.4 Research Governance Authorisation

All researchers are to review the TCHHS web pages and use instructions provided to assist in the preparation and submission of Single Site Applications. **See – Research Governance SSAs (below)**

http://www.health.qld.gov.au/torres-cape/html/research-governance.asp

Research Governance authorisation is the process by which 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 projects that are deemed ethically sound can be supported by the TCHHS. It is important that applicants engage in discussions with all departments involved in the research before applying for approval, (**refer to Section 3.1 above**) to minimise the possibility of projects not receiving approval at this stage.

Once HREC and any additional approvals have been granted all researchers must obtain research governance authorisation from the TCHHS before commencing research in the TCHHS. Researchers are able to undertake ethics and research governance authorisation in parallel. To undertake these processes in parallel please contact the Research Governance Officer Torres-Cape-Research-Governance @health.qld.gov.au.

Prepare a Research Governance Application

Applications for Research Governance are to be made using the Site Specific Assessment (SSA) form which may be found under the SSA tab of the Ethics Application in the On-line Forms system. Completion of this form may be commenced whilst awaiting HREC approval, and can be submitted whilst awaiting HREC approval. However if changes to documentation/ or further information on an Ethics application is sought by a HREC committee prior to Ethics approval all changes and new documentation(s) is to be notified and provided to the Research Governance Officer Torres-Cape-Research-Governance @health.qld.gov.au. prior to a research governance review being finalised.

Important factors when completing the Site Specific Assessment form:

- Head of Department Sign off:

All research projects requiring input, services or assistance from a TCHHS department, must submit a completed Single Site Assessment (SSA) for each site to the TCHHS Head of Medical Services in the first instance.

The Executive Director of Medical Services will in the first instance review and if appropriate forward the SSAs to the appropriate stream (i.e. TCHHS Head of Department – Nursing and Midwifery, Allied Health) for their review. Only Head of Department signatures are required - with supporting department signatures not required on each SSA form for research being undertaken in the TCHHS. Advice can be sought from the RGO should a researcher be unclear on the appropriate course of action. Torres-Cape-Research-Governance @health.qld.gov.au

Heads of Departments are responsible for ensuring each researcher has appropriate TCHHS accreditation in place with a scope of practice supporting the intended research. Accreditation is to be in place prior to signing off or support any a Head of Department for any Single Site Application(s) (SSA's)

- Budgets and Financial authorisation:

All projects (whether externally funded or not) must include a budget to confirm the costs associated with the project and whether any costs are requested to be covered through the provision of in-kind support from the TCHHS. In kind support is **not assured** for all projects.

It is recognised that while some projects will have an associated cost for the TCHHS, there may be additional benefits resulting from the research that need to be considered as part of the Research Governance review process.

Where Staff are submitting research governance authorisation forms they are encouraged to provide a justification of the benefits in the budget section of the SSA form, where indicated.

For other submissions including complex studies, (e.g. clinical trials) a separate more detailed budget to that provided in the SSA must be provided. Researchers who need to complete a more detailed budget should contact the **Torres-Cape-Research-Governance Officer** for advice and seek the support of a Business Services Manager.

The key financial components for SSA applications are:

- actual costs have been provided
- justification for covering costs in-kind (including benefits to TCHHS patients) have been outlined, and
- finance authorisation has been obtained

The Head of Medical Services will review all submitted research budgets and may amend budgets prior to forwarding them to the TCHHS Chief Financial Officer for review and sign off. Researchers will be contacted should a submitted budget be amended

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.

Medicines Australia has provided some standard agreements for use in clinical research. If these agreements are not relevant to the type of research you are undertaking, a non- standard agreement can be developed.

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 Research Governance Officer, **Torres Cape Research Governance Officer** should be the first point of contact for any questions about the process for preparing a research agreement.

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. Single site is a single site. Weipa Integrated Health Service and Thursday Island Primary Health Care Centre are 2 sites. (Multiple Torres and Cape Hospital and Health Care Service sites are not a single site)

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

Alternatively Research Governance hard copy submissions may be delivered to:

Torres and Cape Hospital and Health Service

Level 6, William McCormack Place II

5B Sheridan Street

Cairns. QLD4807

Attn: Research Governance Officer

Address Research Governance Questions

Research project applications will be reviewed by the **Torres Cape Research Governance Officer** and if complete, the RGO will undertake a review and make a recommendation to the TCHHS Chief Executive for research authorisation. The RGO or TCHHS Chief Executive may require applicants to address additional questions prior to approval being given.

The "**Research Commencement Form – SF11**" is sent with the research authorisation correspondence and must be signed by the researcher and returned to the RGO prior to research commencement at a site.

Begin the Research

- **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 procedures outlined in the research application / protocol, as approved by the HREC and Research Governance.

3.5 Ongoing Maintenance of Approved Research

All approved research must be conducted in accordance with the National Statement on Ethical Conduct in Human Research and where appropriate, the Therapeutic Goods Administration Note for Guidance on Good Clinical Practice.

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

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

Reporting

Annual progress and final reports must be provided to the HREC **and Torres Cape Research Governance Officer**, in accordance with the HREC and Research Governance approval letters. Researchers will also be required to submit details of any serious adverse events (SAEs) to the HREC and Research Governance as they occur. SAE definitions may be found in the Therapeutic Goods Administration Clinical Trials Handbook.

Queensland Health provides standard reporting templates for annual, final and SAE reporting.

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.

Approval Period

Queensland Health HRECs usually provide approval for up to a maximum of 3 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 Research Governance office

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. Responsibilities

Position	Responsibility
Executive Directors	Review and support/ not support research applications through endorsement/non-endorsement of SSA forms.
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 ***TCHHS Contracts Register***

5. Supporting documents

Legislation and Standard/s

- *National Health and Medical Research Council Act 1992*
- Queensland Government *Public Health Act* 2005 Application and Information for Researchers http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp
- Research Management Policy
- Research Management Policy Implementation Standard - Ethical and Scientific Review of Human Research
- Research Management Policy - Implementation Standard for Research Governance

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

6. Related documents

- National Health and Medical Research Council and Universities Australia "Australian Code for the Responsible Conduct of Research" 2007
- National Health and Medical Research Council - National Statement on Ethical Conduct in Human Research 2007 National Health and Medical Research Council "Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research" 2012
- 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 Queensland Health National Ethics Application Form (NEAF)
- Queensland Health – Human Research Ethics Committees
- Queensland Health - Research User Guide, Office of Health and Medical Research, July 2010
- Therapeutic Goods Administration Australian Clinical Trials Handbook, 2006
- Therapeutic Goods Administration Notes for Guidance on Good Clinical Practice, July 2000

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

Term	Definition / Explanation/ Details	Source
Adverse event (AE)	Any untoward medical occurrence in a research participant using an investigational product which does not necessarily have a causal relationship with the product. Therefore, an adverse event (AE) can be any unfavourable and / or unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
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	For 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

Term	Definition / Explanation/ Details	Source
AU RED	Australian Research Ethics Database. A secure web-based research ethics database used by HREC Administrators, Research Governance Officers (RGOs) and other ethics office administrative staff to store ethics and governance documents, applications and correspondence in relation to studies submitted to a Queensland Health Human Research Ethics Committee or Research Governance Officer (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
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 researchers if they witness research misconduct	
Central Coordinat-ing Service (CCS)	The Central Coordinating Service (CCS) allocates multi-centre studies to an appropriately Certified HREC for review. This will be displayed on *AU RED* as *Applications Booked in through CAS*. Researchers must complete a booking form to enable the study to be allocated for HREC review. The booking form can be found by following this link: http://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp All studies being conducted in more than one site must be referred to the CCS. (NOTE: Requirements for research targeting Aboriginal and Torres Strait Islander participants)	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
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: http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/A_streamlined_national_approach_to%20scientific_and_ethics_reviewvof%20multi-centre_health_and_medical_research_in_Australia.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
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
Clinical Research Coordinator (CRC)	The person designated by the Principal Investigator (PI) to be responsible for coordinating the conduct of the research project, including scheduling of participant visits, liaison with Sponsor personnel and the HREC / Research Governance Office(r) (RGO). May also be known as the Site Coordinator or Contact Person.	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
Clinical Research Associate (CRA)	A Sponsor or Contract Research Organisation (CRO) representative employed to monitor clinical trials. The CRA ensures compliance with the clinical trial protocol, checks site activities, reviews Case Report Forms (CRFs) and acts as a communication conduit between sites and the sponsor organisation	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*	
Contract Research Organisation (CRO)	An organisation (commercial, academic or other) contracted by the sponsor to perform one or more or a sponsor's trial-related duties or functions.	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Coordinat-ing 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.	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

Term	Definition / Explanation/ Details	Source
	Guidance documents for undertaking the role of a CPI are on the HMR 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	
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
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)
Health and Medical Research (HMR)	Health and Medical Research formally known as the Research Ethics & Governance Unit (REGU) or the Office of Health and Medical Research (OHMR).	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
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	

Term	Definition / Explanation/ Details	Source
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 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 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
HREC Administrat-or	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 Form (LNR Form)	An application form used for research which is defined as low or negligible risk. The form is available on the *Online Forms* website.	
Low Risk Research	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.	

Term	Definition / Explanation/ Details	Source
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
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) Revised 2009. 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. http://www.nhmrc.gov.au/guidelines/publications/e72	

Term	Definition / Explanation/ Details	Source
NEAF	National Ethics Application Form. There are two formats for this document – the *NHMRC* version, and the *Online Forms* version. Both formats are acceptable for HREC review. The *Online Forms* version is the preferred form for use in Queensland Health HRECs. The *NHMRC* version of the form must be transferred to the *Online Forms* version to enable it to be uploaded to *AU RED*. The Site Specific Assessment form (SSA) is only able to be created out of the *Online Forms* version of the NEAF.	
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*, 2007)	
Online Forms	The *Online Forms* website is an online system that enables users to complete their applications for research ethics and governance review electronically. The website hosts a licensed copy of the NHMRC's NEAF, as well as the site specific assessment forms for the public health systems of New South Wales, Queensland, South Australia and Victoria. www.ethicsform.org/au/SignIn.aspx	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
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	
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*	
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. http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.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*, 2007	
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*, 2007	

Term	Definition / Explanation/ Details	Source
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 • Monitoring authorised research at the site to ensure it meets appropriate standards	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
Research Governance Process	The process by which an RGO assesses the suitability of study to take place within their institution / HHS and recommends authorisation to the HHS CE. Once authorised, the study may commence at that institution / 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

Term	Definition / Explanation/ Details	Source
Serious Adverse Event (SAE)	The definition of a Serious Adverse Event (SAE) will be defined by the Sponsor and included in the Protocol. Generally, an SAE in human drug trials is defined as any untoward medical occurrence that at any dose, results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage	Standard Operating Procedures for Queensland Health HREC Administrators Version 4- November 2013 http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf
Suspected Unexpected Serious Adverse Reactions	SUSARs are considered a subset of SAEs.	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 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
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

Term	Definition / Explanation/ Details	Source
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 Specific Assessment Form (SSA)	A tool to assist RGOs in the research governance process to document the level of support and suitability of a research study to be conducted at a site, irrespective of whether that study is multi-centre or single site	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
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
State Specific Modules	Victoria, Western Australia and the Australian Capital Territory have developed additional modules for HREC review that must be completed and submitted as part of the HREC review of clinical trials, when sites from those States / Territories are participating in multi-centre research. For further information go to: Vic: http://health.vic.gov.au/clinicaltrials/application-instructions.htm WA: http://www.health.wa.gov.au/researchdevelopment/home/hrec.cfm ACT: http://healthresearch.anu.edu.au/human-research-ethics-committee.html	State Specific Modules

Term	Definition / Explanation/ Details	Source
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
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

Term	Definition / Explanation/ Details	Source
Therapeutic Goods Administra-tion (TGA)	The Therapeutic Goods Administration is the agency responsible for regulating therapeutic goods. http://www.tga.gov.au/about/about.html	
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

8. Consultation

- Executive Director, Medical Services, TCHHS
- Manager, Research Governance, Sunshine Coast Academic and Research Centre, SCHHS
- Heath and Medical Research, Department of Health

9. Approval Governance Pathway

Policy Officer
Research Governance Officer

Document Custodian
Executive Director of Medical Services

Endorsing Committee or Position
Clinical Governance Committee

Approving Officer
Dr Jill Newland
Health Service Chief Executive
Torres and Cape York Hospital and Health Service

The following Officer has **approved** this document

Name:	Dr Jill Newland
Position:	Health Service Chief Executive

Signature: _____ *Date:* _____

10. Effective Dates

Approval date 8 December 2014

Effective from 8 December 2014

Next Date of review 8 December 2017

Supersedes

N/A

11. Version Control

Version	Date	Prepared by	Comments
0.1	10.10.14	R Schmidt Research Governance Officer	Reviewed by a/Executive Director Medical Services
0.2	11.10.14	R Schmidt Research Governance Officer	Reviewed by a/Executive Director Medical Services
0.3	17.11.14	R Schmidt Research Governance Officer	Reviewed by a/Executive Director Medical Services

12. Audit Strategy

Level of risk	High if not followed
Audit strategy	Au Red Review
Audit tool attached	Au Red Review Report template
Audit frequency	6 monthly
Audit responsibility	Research Governance Officer
Indicators / Outcomes	Review of AU- Red Review Template Reports, Communication to Clinical Governance Committee

13. Appendices

Nil