Procedure

TCHHS-CLIN-1-PRO-0080

Research approval

1. Purpose

The purpose of this procedure is to provide Torres and Cape Hospital and Health Service (TCHHS) employees, researchers, 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 conducted with 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
- Conflicts of interests in research review processes are identified and managed openly and transparently
- Research undertaken in the TCHHS complies with Queensland Health policies and National Health and Medical Research Council (NHMRC) standards and other relevant guidelines, including but not limited to:
  - *National Statement on the Ethical Conduct in Human Research* (2018),
  - *Ethical Conduct in research with Aboriginal and Torres Strait Island people and communities: Guidelines for researchers and stakeholders* (NHMRC, 2018),
  - *Australian Code for the Responsible Conduct of Research* (NHMRC, 2018),
  - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
  - Queensland Health Research Management Standard (QH-IMP-013-1:2022)
- 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

This procedure relates to:

- All TCHHS permanent, temporary, and casual employees. It also extends to Visiting QH employees, Medical Officers, other partners, contractors, consultants, collaborating researchers, and students.
- All service line managers/heads of departments who are responsible for a department in which research is being conducted.
- All Business Analysts/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 Executive.

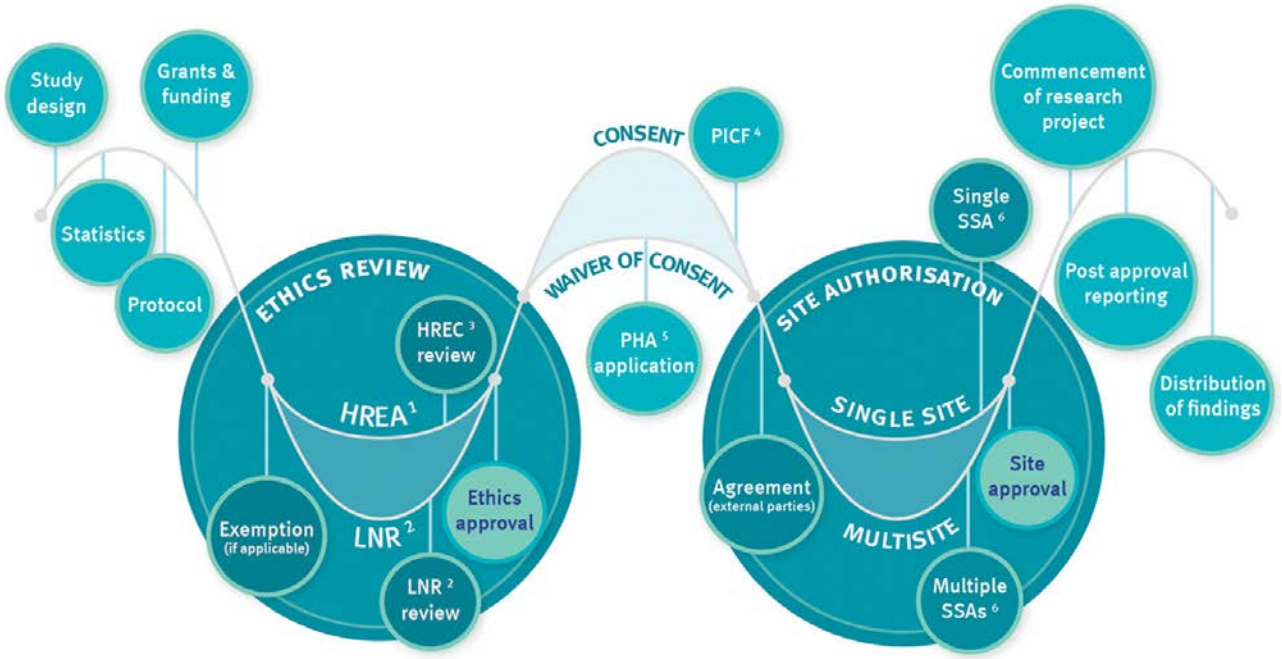
3. Process

All information relating to the research approval process can be found on the TCHHS Research Governance QHEPS page (Intranet) and TCHHS Research Governance website (Internet), including resources and additional guidance to assist researchers.

For research activities involving Queensland Health patients, staff, data or facilities; approval from an appropriate certified Human Research Ethics Committee (HREC) and the TCHHS Chief Executive (CE) or Delegate must be obtained before starting the project.

Research Governance is the framework TCHHS uses to ensure that research is conducted responsibly and safely. The review and approval process considers site suitability, legal compliance, financial and resource management, accountability, and risk management. This framework ensures research conforms to relevant institutional, jurisdictional and national standards, and applicable laws.

Key steps in the research approval process are shown in the diagram below:



Note the above diagram does not represent the proportional time spent in each stage. 1 – Human Research Ethics Application (HREA), 2 – Low or Negligible Risk (LNR), 3 – Human Research Ethics Committee (HREC), 4 – Participant Information and Consent Form (PICF), 5 – Public Health Act (PHA), 6 – Site Specific Assessment (SSA)

The following sections outline the process for obtaining the necessary approvals.

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 Review and Authorisation

Section 3.5 – Ongoing Maintenance of Approved Research

3.1 Initial Steps for All Potential Research Activities

It is recommended that researchers consider the following steps before undertaking any action on a research ‘idea’ to ensure that the project will have the appropriate support and endorsement. Completing a research project can be resource intensive and therefore the value of the research and projected impact (the contribution that research makes to the world and the lives of people living in it) must be considered before any resources are allocated to develop the ‘idea’ into a project.

3.1.1. Confirm support for the project

TCHHS Researchers - Proposed research should be discussed with the line manager and (if applicable) the manager / director of all departments that may be required to assist with the research. Alternatively, departments may have a forum where research projects are discussed and endorsed. Line managers will be able to confirm the appropriate forum in relevant departments.

External Researchers – Proposed research should be discussed with the Executive General Managers (EGM) at proposed research sites. Contact the TCHHS Research Governance Officer (RGO) for advice if unsure of appropriate EGM to contact. Proposals may also be referred to the Research Governance Committee for consideration.

3.1.2. Confirm the project is research

Staff should refer to Quality improvement activity: development, registration and reporting procedure to assist with identifying whether a project is research or a quality improvement / audit. Additional advice may be sought from the RGO or the Clinical Governance Unit.

3.1.3. Prepare a research protocol

A study protocol / project plan is a document which describes in detail the plan for conducting a study. Ethics committees require a research protocol or project plan to be included in all ethics submissions. It is beneficial to write this before you begin preparing the ethics application, as a complete and well thought through protocol will assist in answering many of the questions contained in the human research ethics application (HREA) form.

For further information, refer to the research study protocol template on the TCHHS website.

3.1.4. Support for grant funding applications

Applications for funding opportunities by TCHHS staff and researchers must be submitted for consideration and TCHHS support to the Research Governance Committee. Contact the secretariat for more information and meeting submission deadlines - tchhs-edms@health.qld.gov.au.

3.2 Approval from a Human Research Ethics Committee

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), including the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2018). 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).

3.2.1. Identify an Appropriate HREC

It is recommended that research being undertaken in TCHHS is submitted through the Far North Queensland HREC using the Ethics Review Manager (ERM) system. Other HRECs may be accepted by the TCHHS under the National Mutual Acceptance Scheme, unless the research is specifically targeting Aboriginal and or Torres Strait Islander peoples. Where questions exist regarding the most appropriate ethics committee, researchers can discuss their project with the RGO.

3.2.2. Prepare Supporting Documentation and Submit a Human Research Ethics Application (HREA)

Once a HREC is selected, researchers should contact the committee to confirm the specific submission requirements of that committee. Most Queensland Health HRECs provide a checklist for researchers to ensure submission requirements have been met. The HREC will require copies of any study materials (e.g. Participant Information and Consent Forms, surveys, flyers, interview tools) in order to complete their review. Depending on the type of study, other documents may be required.

The Queensland Health ethics application form can be found in the Ethics Review Manager (ERM) system. Resources are available on the Office of Research and Innovation (ORI) website to support researchers in using ERM. When using an interstate ethics committee, researchers should use the research management system of that committee. 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

3.2.3. 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:

3.3.1. Release of confidential patient health information without consent

***Public Health Act 2005 (PHA)*, Chapter 6, Part 4**

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 may 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.

The Director-General, Department of Health or delegate may authorise the release of identifiable or potentially re-identifiable health information. Approval can be granted only if the Director-General is satisfied that the disclosure of confidential health information is in the public interest. Details on obtaining *Public Health Act 2005* approval can be found from the Office of Research and Innovation (ORI) website. Refer to Appendix C for the PHA application approval process.

***Hospital and Health Boards Act 2011 (HHB Act)*, Section 150**

Alternatively, internal staff can apply to access confidential health information without consent under Section 150 the *Hospital and Health Boards Act 2011 (HHB Act)*, if the study meets these conditions:

- The study is for the purposes of evaluating, managing, monitoring or planning health services; and
- All members of the research team who will have access to identifiable or potentially re-identifiable confidential health information are 'Designated Persons' as described in Section 139A of the *HHB Act*.

Seek advice and additional information on Section 150 from the RGO.

3.3.2. Requirements for Clinical Trials

Registration

Researchers are encouraged to prospectively register all their projects with the ANZCTR (Australia and New Zealand Clinical Trials Registry). Registration is aimed at protecting the intellectual capital, improve transparency and quality, and officially announce the study thus reducing duplication and redundancy and to encourage collaboration.

Therapeutic Goods Administration Notification or Approval Scheme (CTN / CTA)

Clinical trial sponsors must notify the Therapeutic Goods Administration (TGA) when an "unapproved" therapeutic product is planned for use in a trial.

Visit the TGA website for more information.

Good Clinical Practice (GCP) training

The guideline for Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting of clinical trials that involve human participants. All Principal Investigators of clinical trials being conducted at TCHHS must provide evidence of accredited GCP certification undertaken within the previous 3 years. Online courses are available from these providers:

- National Drug Abuse Treatment – Clinical Trials Network (Free)
- Syneos Health (Free)
- Global Health Training Centre (Free)
- Genesis Research Services ($10)
- RET Program ($40 – TAAHC partner)

Evidence of GCP certification is required with the Site-Specific Assessment (SSA) submission.

3.3.3. Pathology Queensland approval

If access to tissue samples or other data sources held by Pathology Queensland (PQ) (including data in AusLab and AusCare) you may require additional approval. For information on accessing tissue samples or data, consult the Pathology Queensland website or discuss the project with the local Pathology Director.

3.3.4. 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). Refer to the application form for further details on the types of research that require QCAT approval under the *Guardianship and Administration Act 2000.*

3.3.5. 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 Review and Authorisation

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), that the research is in alignment with TCHHS's strategic research plan, and assess, monitor and mitigate risks relating to research projects in accordance with the TCHHS risk management framework.

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 (EGM) at proposed research sites. 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 an SSA form and required documentation for a research governance review via the Ethics Review Manager (ERM) system. 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 RGO.

3.4.1. Prepare Supporting Documentation and Submit a Site-Specific Assessment (SSA) Form

Applications for Research Governance are made using the Site-Specific Assessment (SSA) form. Complete the SSA form by creating a “sub form” against the HREC application in the Ethics Review Manager (ERM) system. Further guidance on using ERM can be found on the Office of Research and Innovation (ORI) website. The Option 2 SSA form is only available for low-risk low-resource projects in negotiation with the RGO.

Key components of a complete research governance application are:

1. Executive General Manager approval/s (Head of Department equivalent)
2. Budget and financial approval (for greater than $10,000)
3. Study protocol and relevant study documents for conduct at the site (including any site-specific documents)
4. Research agreement (if applicable)
5. Additional approvals required as per Section 3.3 above
6. Evidence of HREC approval and HREA form
7. Completed SSA form, signed by Chief/Principal Investigator
8. Other documents may be required depending on the type of study

A checklist is available to support researchers to ensure all required materials are uploaded to ERM for a research governance review. Refer to Appendix A.

Executive General Manager Approvals

TCHHS is divided into two sectors, North and South, each sector is managed by an Executive General Managers (EGM) who are the delegates for granting Head of Department approval. The Northern Sector includes all Torres Strait Islands and Cape York region south to Bamaga and Injinoo. The Southern Sector takes in Mapoon in the north, to Kowanyama, Cooktown and Wujal Wujal in the south. Pre-submission consultation is encouraged and researchers can contact the EGMs directly to discuss the study and the potential impacts and benefits:

North EGM – TCHHS-North-EGM@health.qld.gov.au

South EGM – TCHHS-EGM-South@health.qld.gov.au

Refer to Appendix B for the approval process for Head of Department and or Finance.

Budget Requirements

All projects submitted for governance review must provide a budget with each SSA application, outlining all expenditure (direct and in-direct costs) and revenue. The costs incurred are either indicated as in-kind contributions (being requested by the researcher and provided by the TCHHS without passing on the costs to the researcher) or direct costs which the TCHHS will invoice to the research project (in this scenario please include the invoice details).

Key items to consider when preparing a budget are time or labour costs of TCHHS staff in completing or providing assistance in research tasks, such as surveys/focus groups/training/consenting of participants, time undertaking research activities within work hours. Any expenses for additional tests, scans or services required within the scope of the research project, such as Radiology, Pharmacy, Pathology, Information Technology, Health Information (medical records retrieval). Include in the budget quotes from any relevant areas. Other expenses can also include travel costs, governance review fees, publishing fees, or equipment etc. Revenue or income paid to TCHHS must also be listed in the budget, such as participant payments.

A site finance budget template is available on request from the TCHHS RGO. Where applicable, evidence of funding such as grant approval letter and grant agreement should also be uploaded.

Costs totalling less $10,000 are approved by the EGMs (as per Section 3.4.2 above).

Costs totalling $10,000 or more require finance approval. The budget should be submitted to the North and South Business Analysts for review, who will coordinate Executive Director of Finance, Information and Digital Services approval (on behalf of the researcher).

Business Analyst – North: Dion.Trimmer@health.qld.gov.au

Business Analyst – South: Margaret.Nowak@health.qld.gov.au

Refer to Appendix B for the approval process for Head of Department and or Finance.

Site-Specific Documents

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 relating to site information only and updates to the Header and the Footer annotations.

Upload all supporting documents to the SSA form in ERM.

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 or in collaboration with an external organisation, a Research Agreement will be required with the Research Governance application.

All non-standard agreements are required to undergo review by a Solicitor, this is organised by the (RGO) and is undertaken at the researcher's cost.

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

3.4.2. Research authorisation

The SSA application and supporting documents are reviewed by the RGO, who is responsible for making a recommendation for consideration by the TCHHS Chief Executive of research authorisation. The RGO or Chief Executive may require applicants to address additional questions or provide clarifications, prior to authorisation 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 RGO by email.

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 RGO.

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 returned to the RGO 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 also be forwarded to the HREC which provided ethics approval.

Staff engaged in research activities through collaboration / support or participation in research must ensure adherence to the process outlined in the research approval procedure, and the study is conducted as per the HREC and Research Governance approvals. All TCHHS employees must ensure research is authorised before they participate.

3.4.3. Conflicts of Interest

The *Australian Code for the Responsible Conduct of Research* (NHMRC, 2018) defines conflicts of interest existing where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests. This refers to a financial or non-financial interest which may be a perceived, potential or actual conflict of interest.

The Queensland Health Research Management Standard (QH-IMP-013-1:2022) states:

- Conflicts of interest may exist where a person's or institution's interests or responsibilities have the potential to influence the carrying out of institutional roles or research obligations.
- Conflicts may relate to financial interests, other private, professional or institutional benefits or advantages that depend on the research outcomes.
- The values of clinical care, welfare of society and science should prevail over commercial imperatives and monetary values.
- Conflicts of interest must be appropriately managed so as to not compromise the validity and integrity of the research process and undermine public confidence in the institution.

The Standard also advises institutions have transparent processes to deal with conflicts of interest:

- to identify and manage actual, perceived and potential conflicts of interest that involve HRECs, research reviewers, funding review committees, researchers or research participants must be in place.

TCHHS is committed to declaring interests openly and managing actual, perceived and potential conflicts of interest transparently. In the management and oversight of research activities at TCHHS, conflicts of interest may arise with staff members, Executive Sponsors, Health Service Chief Executive and Board Members.

Disclosure of Interests

In the SSA form, researchers are required to declare any known potential conflicts of interest for consideration. During the site assessment and review process for research applications, requests for letters of support, grant applications, and any other research related requests, the RGO identifies and records all actual, perceived, and potential conflicts of interest in the review file. Any Executive member who is part of the review process is also responsible for identifying potential conflicts and reporting it to the RGO noting and appropriate management.

Management of Interests

Where a staff member in the review process has a conflict of interest with the research, they will be excluded from assessing, supporting, approving, or post authorisation monitoring of a research project. For example, the executive is a principal or associate investigator on the research team; the executive has a personal relationship with a researcher, or a personal interest in a specific project, and or funding supporting the project. In these instances, their role for assessing research applications will be deferred to another member of the executive team:

- Research Governance Officer: to Manager Office of the Chief Executive
- Executive Director of Medical Services: to Executive Director of Nursing
- Health Service Chief Executive: to Board Chair

3.5 Ongoing maintenance of approved research

All approved research must be conducted in accordance with research guidelines, legislation, regulations, and international standards. All researchers are responsible for managing the ongoing approval of their research. In particular:

3.5.1. Changes to the research protocol or supporting documentation

Changes to a research project must approved by the HREC and Research Governance prior to introducing the changes. Consult with the approving HREC or RGO 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 participant consent
- Data being collected / Process for collecting data
- Facilities/hospitals – additional sites, or changes to investigators

3.5.2. Reporting

Annual progress and final reports must be provided to the HREC and Research Governance, in accordance with the conditions of authorisation included in the ethics and research authorisation approval letters. Additional reporting may be required for serious adverse events and safety issues as they occur.

TCHHS RGO uses a risk management framework to assess, monitor and mitigate risks relating to research projects. The RGO may request more information from a project report or more frequent reporting depending on the risk assessment.

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. Researchers are required to provide financial reports as part of financial outcomes. Where a study is funded or subject to additional approvals or contractual arrangements, researchers may also be required to provide further reports (including financial acquittals) to external parties.

3.5.3. HREC Approval Period

The Research Governance Authorisation is valid for the term of the HREC approval. Researchers must ensure that they maintain valid and current HREC approval in accordance with the terms of 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 HREC, the amendment and evidence of HREC approval must be submitted to Research Governance.

3.5.4. Monitoring of Approved Research

HRECs and Research Governance may conduct monitoring audits on approved research. Researchers must comply with any requests in relation to monitoring.

Clinical interventional research or clinical trials may also be audited by the research sponsor (e.g., university, pharmaceutical company). Any audit findings from sponsors must be provided to the RGO for consideration by TCHHS. The RGO may also undertake additional audits for high risk / interventional research at specific study intervals, such as recruitment, intervention, follow up, and close out.

Principal investigators and study coordinators are required to engage with participants and provide opportunities for consumer feedback. Participant feedback from research projects is managed in accordance with the TCHHS Procedure for Consumer Feedback – Compliments, Complaints and Suggestions. The research team should ensure participants are given access to the Consumer Feedback Form or referred to Give Feedback page, during or after any study activity at TCHHS.

Audit findings, including participant feedback, are reported to the Research Governance Committee (via the RGO) to ensure any learnings or required changes are implemented.

4. Governance Responsibilities

Position	Responsibility
Health Service Chief Executive	Oversight of compliance with this procedure Authorisation of research
Executive Directors	Review of 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*
Contract Manager	Oversight and management of Research Agreements
Consumer Liaison Officer North & South	Oversight, assessment, monitoring, escalation, and reporting of consumer feedback

5. Supporting Documents and Reference Material

- *National Health and Medical Research Council Act* 1992
- *Public Health Act* 2005 Application and Information for Researchers
- Research Management Policy
- Research Management Standard - Implementation Standard for Research Governance
- Research Management Guideline: External Funding and Infrastructure Support
- Risk Management Framework (TCHHS, 2022)
- *National Statement on Ethical Conduct in Human Research* (NHMRC, 2018)

- Australian Code for the Responsible Conduct of Human Research (NHMRC, 2018), and supporting guides
  - Authorship
  - Management of data and information in research
  - Peer review
  - Disclosure of interests and management of conflicts of interest
  - Supervision
  - Collaborative research
  - Publication and dissemination of research
  - Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research
- *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and Communities: Guideline for research and stakeholders* (NHMRC, 2018)
  - *Keeping Research on Track II 2018*
  - *AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research 2020*
- Statement on consumer and community involvement in health and medical research (NHMRC, 2016)
- Payment of participants in research: information for researchers, HRECs and other ethics review bodies (NHMRC, 2019)
- Consumer feedback – compliments, complaints, and suggestions (TCHHS Procedure, 2022)
- Therapeutic Goods Administration Australian Clinical Trials Handbook, updated 2018
- Therapeutic Goods Administration Notes for Guidance on Good Clinical Practice
- Clinical investigations of medical devices for human subjects – Good Clinical Practice (ISO 14155:2020)
- Medical Genetic Testing: Information for health professionals (NHMRC, 2010) and Biobanks (NHRMC, 2010)
- Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC, 2016)
- Risk-based Management and Monitoring of Clinical Trials involving Therapeutic Goods (NHMRC, 2018)
- Data Safety Monitoring Boards (DSMBs) (NHMRC, 2018)
- Queensland Health Good Clinical Practice (GCP) Standard Operating Procedures

6. Definition of terms

Term	Definition / explanation / details	Source
Amendment	A change to the Human Research Ethics Committee (HREC) approved research project including the protocol or supporting documentation	Standard Operating Procedures for

Term	Definition / explanation / details	Source
Applicant	For multi-centre studies the Coordinating Principal Investigator (CPI). For single site studies the Site Principal Investigator (PI).	Queensland Health HREC Administrators
Associate Investigator (AI)	Another term used for Sub-investigator	
Australian Code for the Responsible conduct of Research *(the Code)*	This guides institutions and researchers in responsible research practices and promotes integrity in research.	
Certified HREC	An HREC which has had its processes assessed and certified under the NHMRC National Certification Scheme. To find a certified HREC and more information on NHMRC Certification Scheme.	Standard Operating Procedures for Queensland Health HREC Administrators
Contact Person	The person designated by the Principal Investigator (PI) to be responsible for liaising with the HREC / RGO. May also be the Site Coordinator or Clinical Research Coordinator.	
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 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 Standard Operating Procedures for Queensland Health Research Governance Officers
Department of Health (DoH)	The Department of Health manages the health system in Queensland.	Standard Operating Procedures for Queensland Health HREC Administrators

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).	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.	*Hospital and Health Boards Act 2011*
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
Human Research Ethics Application (HREA)	The national ethics application form. Used by HRECs to assess scientific and ethical acceptability of a research project.	
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.	
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.	
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* (NHMRC, 2018)
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.	http://www.health.qld.gov.au/ohmr/html/regu/mutual_accept.asp

Term	Definition / explanation / details	Source
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.	*National Statement on Ethical Conduct in Human Research* (NHMRC, 2018)
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.	
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. 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. See also *Confidential Information*	*Information Privacy Act 2009*
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

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. 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	https://www.safetyandquality.gov.au/sites/default/files/2019-04/National-Safety-and-Quality-Health-Service-Standards-second-edition.pdf
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
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* (NHMRC, 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 • Monitoring authorised research at the site to ensure it meets appropriate standards	Standard Operating Procedures for Queensland Health Research Governance Officers
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.	
Reviewing HREC	The certified HREC that has been allocated to review research studies.	Standard Operating Procedures for Queensland Health HREC Administrators
Single site research	Research to be conducted at one site only.	
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	

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 Research Governance Officers
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
Study Site	Means the location(s) under the control of the Institution where the study is actually conducted.	
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	
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 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
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	
Therapeutic Goods Administration (TGA)	The Therapeutic Goods Administration is the agency responsible for regulating therapeutic goods. https://www.tga.gov.au/	
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

7. Consultation

- Executive Director of Medical Services
- Executive General Managers (North and South)
- Manager, Office of the Chief Executive
- Business Analysts, Finance
- Manager Health Information Services
- Manager Healthcare Purchasing and Performance

- Senior Business Intelligence Officer, Digital Health Services

8. Approval governance pathway

8.1 Document author

The following officer is the author of this procedure

- Research Governance Officer

8.2 Document custodian

The following officer will have responsibility for implementation of this procedure

- Executive Director Medical Services

8.3 Endorsing committee

The following committee will have responsibility for implementation of this procedure

- Research Governance Committee

8.4 Approving officer

The following officer has approved this document

- Health Service Chief Executive

Signed: 20/07/2023

9. Effective dates

Schedule	Dates
Approval date	20/07/2023
Effective from	20/07/2023
Next date of review	20/07/2025
Superseded procedure	V 2.0

10. Version control

Version	Date	Prepared by	Comments
2.0	27/08/2020	RGO	Approved by Executive Director Medical Services
2.1	28/04/2023	RGO	Updated to include conflict of interest management, risk management framework, clarify additional approval requirements (including for clinical trials), monitoring and reporting processes, workflows for approvals, and add data system guide.
2.2	03/05/2023		Reviewed by RGC
3.0	20/07/2023		Approved by HSCE

11. Evaluation strategy

Strategy	Evaluation
Risk	Consequence rating – Governance, legal and compliance Major Likelihood rating – Possible 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
Frequency	Biannual
Evaluation responsibility	Research Governance Officer

12. Document communication and implementation plan

Action	Responsible position
Identify the target group • All TCHHS employees	HSCE RGO
Provide a timeline for communication and implementation milestones • Update of versions • Annually	RGO
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 RGO

13. Appendices

Appendix A: Research Governance Submission Checklist

Appendix B: Head of Department / Finance Approval Workflow

Appendix C: Public Health Act Approval Workflow

Appendix D: Health Data Systems

Appendix E: Defining research table

Appendix F: Quick guide for research and quality at TCHHS