Procedure

Ethical and Scientific Review of Human Research

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Executive sponsor	Executive Director Medical Services			**Effective date**	25/10/2021
Author/custodian	Co-ordinator, Human Research Ethics Committee			**Review date**	25/10/2024
Supersedes	Nil				
Applicable to	All staff employed by CHQ (permanent, temporary, casual) within all facilities and services who conduct human research.				
Authorisation	Executive Director Clinical Services				

Purpose

The Children's Health Queensland Hospital and Health Service (CHQ) is committed to the highest standards and practices in the ethical and scientific review of human research. This procedure identifies a consistent and enforceable process for ethical and scientific review of human research being conducted at or in collaboration with CHQ.

Adherence to this procedure will ensure all research conducted within CHQ or in collaboration with external entities, is of the highest ethical and scientific standard and is compliant with relevant legislation, standards and guidelines.

Scope

This procedure applies to CHQ or Queensland Health employees whose usual reporting line is through a CHQ facility or service, who conduct human research within or in association with CHQ, or through access to CHQ participants, health records or data.

Failure to comply with this procedure may amount to misconduct, or research misconduct on the part of the responsible individual. This procedure must be read in conjunction with other CHQ policies and procedures.

Key Principles

The following key principles guide CHQ in establishing appropriate ethical and scientific review of human research processes.

- CHQ is committed to the highest standard of integrity in research practices across all research activities.
- Researchers must protect human participants in research in accordance with the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) and follow the CHQ process for Human Research Ethics Committee approval.
- Research involving human participants, their data or biospecimen/s must undergo ethical and scientific review, approval and monitoring by a National Health and Medical Research Council (NHMRC) certified

Human Research Ethics Committee (HREC). For research involving children and/or their data and/or samples at CHQ, the approving HREC must be paediatric certified.

- Researchers must comply with ethical principles of integrity, respect for persons, justice and beneficence.
- Ethical review is a mandatory requirement for all human research undertaken within CHQ. Its purpose is to ensure that health and medical research proposals conform with ethical standards.
- Any interventional research on patients must be conducted in accordance with the Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) (GCP Guideline)
- It is recommended that ethical review be undertaken in parallel with CHQ research Site Specific Assessment (SSA) review using the Ethical Review Manager (ERM) Applications website.
- Written approval from appropriate ethics committees, safety and other regulatory bodies must be obtained (when required).

Key Responsibilities

Executive Leadership Team

- Ensure collaborative, harmonised, clear and detailed publicly available policies and procedures are in place for the ethical and scientific review of all CHQ research.

CHQ Human Research Ethics Committee (CHQ HREC)

- Provide oversight of the ethical and scientific review of CHQ human research by keeping abreast of international, national and state-wide legislation, regulations and guidelines.
- Promote CHQ strategic requirements and ethical and responsible decision-making which respects the rights of CHQ participants.

CHQ Research Directorate

- Update CHQ ethical and scientific review documents in accordance with CHQ HREC requirements.
- Provision of secretariat/administrative support to maintain and uphold principles outlined in the Research Governance Framework (in development) and related procedures.

Coordinating principal investigator/principal investigator—responsible officer

- Ultimately responsible for all elements of the research project—from initial application to final report.

Employees, researchers, research student supervisors and students

- Adhere to, be aware of and comply with all relevant policies, procedures, guidelines, research protocols and Standing Operating Procedures (SOPs) when conducting research.

Procedure

Prior to the HREC Review Process

Step 1: Establish the research question

Establishing a research question requires rigorous review of literature to ensure there is an unmet need within healthcare delivery. New Researchers are encouraged to discuss with a mentor and liaise with the Head of the Department/Service. It is also recommended to consider partnering with consumers as part of the establishment process.

When developing a research question, it is important to ascertain if specific human or animal ethical and scientific review will be required in addition to HREC approval. This includes research pertaining to:

- paediatric research;
- gene technologies and related therapies;
- ionising radiation;
- use of approved and unapproved medicines and medical devices; access to coronial material for research purposes;
- research involving persons in custody and/or employees of Department of Justice and Attorney-General;
- research that may affect the health and wellbeing of Aboriginal and Torres Strait Islander people and communities;
- research requiring access to state-wide data collections;
- clinical trials with persons unable to provide consent; and/or
- use of animals.

Step 2: Develop the research protocol and PICF

Preparation of a research protocol is mandatory.

New Researchers are encouraged to consult with a research mentor in determining the most appropriate template to use when preparing a research protocol. Researchers must also develop an appropriate Participant Information and Consent Form (PICF) and other associated supporting documents relevant to the research project.

Below are examples of some supporting documents which may be included as part of your research project:

Ref	Document type
a.	HREA via ERM Applications
b.	Research protocol and PICF (including version control)
c.	Questionnaires/surveys (eg REDCap, other platforms)
d.	Participant diary
e.	Advertising material (eg brochure or leaflet)
f.	Data collection form
g.	Curriculum Vitae (CV) of Coordinating or Principal Investigator, as relevant
h.	Other supporting documentation. Note: Dear Investigator Letters (DIL), Independent Data Monitoring Committee (IDMC) outcome letters where study can continue as planned and protocol deviations are not required by the CHQ HREC unless they have a bearing on the ongoing ethical and scientific validity of a study.
i.	For research using radiological procedures that are performed specifically for research - independent assessment report or verification by a medical physicist (or radiation safety officer) of the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol.

Step 3: Submit to a Human Research Ethics Committee (HREC) (and Animal Ethics Committee if applicable).

The HREC must be certified by the National Health and Medical Research Council (NHMRC) and be part of the National Mutual Acceptance Scheme. CHQ operates a HREC which reviews the ethical and scientific validity of proposed human research, and is certified by the NHMRC for single and multi-centre research. Research projects which involve CHQ participants, data and/or resources as well as specific human and animal research (as outlined in Step 1) must be reviewed by both the CHQ HREC and an appropriate animal ethics reviewing body.

Step 4: Commencing the HREC review process

Human Research Ethics Applications (HREAs) are made online via ERM. All supporting documentation (including research protocol and PICFs) must be uploaded and submitted with the HREA through ERM. It is strongly recommended to commence completion of the Site Specific Assessment (SSA) application at the same time as the HREC review process. Please see CHQ-PROC-90008 Site Specific Assessment and Authorisation of Research Procedure for more information.

Step 5: Single site and multi-centre research

As the CHQ HREC is a NHMRC Certified Committee, it can provide review for single ethical or multi-centre research projects that participate in the National Mutual Acceptance Scheme (NMA) model.

Single Site - If the research project constitutes single site research (or multiple facilities within CHQ) please proceed to Step 6: CHQ HREC Co-ordinator.

Multi-centre Research - In order to understand what kind of ethical and scientific clearance is required it is important for researchers to identify if the research project is considered either single site or multi- centre research, and if there will be any specific human ethical and scientific review requirements. The below table identifies the processes which are required:

Type	Single site research	Multi-centre research	Specific human ethical and scientific review requirements
Description	The research will only be conducted within a single site.	Research will be undertaken in multiple sites/areas.	Additional review is required by an appropriate reviewing body.
Example	Queensland Children's Hospital (QCH) or all CHQ facilities.	PAH, Royal Brisbane and Women's Hospital, Queensland Children's Hospital and/or interstate under the NMA scheme.	Research project includes Aboriginal and Torres Strait Islander research – the reviewing HREC will require a letter of support regarding cultural implications.
Process	Liaise with coordinating HREC office.	All submissions to be coordinated via lead site.	Liaise with relevant reviewing body and coordinating HRECs.

Step 6: CHQ HREC Co-ordinator

During the Initiating and planning a research project phase researchers are encouraged contact the CHQ HREC Co-ordinator via telephone (07) 3069 7002 or email CHQEthics@health.qld.gov.au to discuss the proposed research project and identify which submission pathway is appropriate based on the level of risk and the activity undertaken.

The CHQ HREC has the discretion to request a full review of a research project based on the level of risk to participants. The CHQ HREC Co-ordinator may choose to grant exemption from full HREC review or categorise the research project as a low or negligible risk and offer an alternative review process.

Once determined, with the CHQ HREC Co-ordinator, the level of ethical review required—whether it is Low and Negligible Risk or Risk Greater than Low Risk (Standard Risk), please follow one of the following processes.

Low and Negligible Risk Research Review

Step 1: Submit via ERM Applications

Low and Negligible Risk applications can be submitted at any time. Complete the HREA form via ERM. Please include a full listing of sites covered by the submission in a cover letter and indicate the low or negligible risk pathway at the end of the form. Ensure the Low Risk Pathway is chosen when completing the application.

Submit HREA and upload supporting documents via ERM. Please note, applications must be submitted via the ERM website. The HREC Office cannot process emailed, faxed or hard copy submissions

Complete the online SSA form (if required) available via ERM (to be considered complete, the following must be included on the SSA:

- Business Manager/Finance Officer and/or Cost Centre Manager sign-off
- research cost centre/internal order number details
- Head of Department sign-off (if any investigator is the Head of Department, please ensure that appropriate Line Manager signs as Head of Department).
- Please see CHQ-PROC-90008 Site Specific Assessment and Authorisation of Research Procedure for more information. See CHQ-FORM-90027 Low/Negligible Risk Research Submission Checklist.

Step 2: Research fee review

Commercially sponsored research will be charged for ethical review. Please review CHQ-FACT-90030 Schedule for Fees for Ethics and Research Governance Review of Commercially Sponsored Research for the HREC to determine if your submission attracts a fee. If it does, then please ensure appropriate invoicing details are included in the initial submission.

Step 3: Low and Negligible Risk research determination

The review of low and negligible risk research projects in CHQ takes approximately two - three weeks. Upon receipt the determination the CHQ HREC Co-ordinator will advise if the research project is:

- Low and negligible risk and able to proceed to SSA authorisation - see CHQ-PROC-90008 Site Specific Assessment and Authorisation of Research Procedure; or
- More than low and negligible risk research: proceed with full HREC review process (see below). The CHQ HREC will, on certain occasions, accept a right of reply in respect to the decision.

Step 4: Ensure SSA authorisation prior to commencement of research

The research project may only proceed upon receipt of authorisation from the Health Service Chief Executive or delegate. See CHQ-PROC-90008 Site Specific Assessment and Authorisation of Research Procedure for more information.

Greater than Low Risk (Standard Risk) – Full HREC Review

Step 1: Review closing dates

Researchers are required to submit their research applications for full HREC review to the CHQ HREC Office by the appropriate closing date. Meeting and closing dates are listed on the CHQ Research internet page. Submission deadline is 3pm.

Step 2: Submit via ERM Applications

Submit HREA and upload supporting documents via ERM. Please note, applications must be submitted via the ERM website. The CHQ HREC Office cannot process emailed, faxed or hard copy submissions.

Please note this is a different HREA than that used by Universities.

See CHQ-FORM-90031 HREC Standard Risk Submission Checklist

Step 3: Research fee review

Commercially sponsored research will be charged for ethical review. Please review CHQ-FACT-90030 Schedule for Fees for Ethics and Research Governance Review of Commercially Sponsored Research for the HREC to determine if your submission attracts a fee. If it does, then please ensure appropriate invoicing details are included in the initial submission.

Step 4: Full HREC review determination

The evaluation of Greater than Low Risk (Standard Risk) application in CHQ takes approximately 2 weeks from closing deadline. The CHQ HREC Co-ordinator will advise an outcome to the submission in a formal letter from the HREC sent via email. If further information is requested, to make a final determination, this must be supplied to the CHQ HREC Co-ordinator by no later than three meetings/four calendar months. Failure to provide this information may result in the application being withdrawn by the CHQ HREC Co-ordinator, with a new application required to reinstate the research project. All response documentation must be sent via ERM.

Step 5: Ensure SSA authorisation prior to commencement of research

The research project may only proceed upon receipt of authorisation from the Health Service Chief Executive or delegate. Please see CHQ-PROC-90008 Site Specific Assessment and Authorisation of Research Procedure for more information.

CHQ HREC Review Process

Step 1: HREC review administration

The HREC Co-ordinator registers the application on an appropriate register for HREC applications (in line with specifications as set in QH-HSD-035:2016 Health Service Directive for Research Ethics and Governance).

Received HREC applications via ERM (including listing of allocated reviewers) are compiled by the CHQ HREC Co-ordinator, within CHQ Research, and assigned to HREC members prior to the next scheduled CHQ HREC meeting. Several resources are available to assist researchers in using ERM:

- ERM submissions,
- Training & Quick guides,
- Frequently asked questions - FAQs,
- Help.

CHQ HREC members are required to review allocated HREC applications prior to the scheduled meeting.

Step 2: Conflicts of Interest in the CHQ HREC review process

If any person believes they may have a conflict of interest in relation to CHQ HREC review process, the conflict must be declared and detailed prior to the commencement of the CHQ HREC meeting. For more information see CHQ-PROC-90004 Conflicts of Interest in Research.

Step 3: CHQ HREC meeting

The CHQ HREC is convened and all HREC applications are discussed and reviewed.

Step 4: CHQ HREC determination

Following the scheduled CHQ HREC meeting, committee feedback on the submission is provided and in some circumstances a request for further information is sought. The CHQ HREC Co-ordinator facilitates review of the reply to the "further information letter" to the researcher. This letter will be sent in a PDF form via email to the principal investigator and nominated contact person. Responses from the principal investigator to the HREC and any amended documentation must be submitted through ERM.

Once all required information has been obtained, the submission is considered by the CHQ HREC Chair. Please note the CHQ HREC Chair may again request further information or recommend approval of the application. If approved by the CHQ HREC Chair out of session of a CHQ HREC meeting, the approval decision will be tabled at the next meeting.

Step 5: Approval

Researchers will be formally notified of CHQ HREC clearance; by letter from the CHQ HREC Chair. This letter will be sent in a PDF form via email to the principal investigator and nominated contact person as well as the Research Governance Officer.

The time to reach HREC approval will not take more than the sixty (60) day (stop-clock days*) benchmark as set by the NHMRC. Registration of the CHQ HREC approval of the research is documented within ERM.

Researchers are responsible for ensuring research activities do not commence prior to receiving HREC approval and SSA authorisation. Refer to CHQ-PROC-90008 Site Specific Assessment and Authorisation of Research Procedure for further information.

**Sixty (60) calendar days are allowed for the ethical review of an application. Where a valid application is received, the clock starts on the submission closing date for the HREC meeting at which an application will be reviewed. The clock stops when a request for further information or clarification is requested from the applicant. The clock recommences when the requested information or clarification has been received. The clock is stopped when the HREC formally notifies the applicant of the final decision.*

ONGOING MANAGEMENT OF HREC CLEARANCE

Step 1: Notification of Commencement of Project

Researchers are responsible for ensuring that the Notification of Commencement of Project is submitted to the HREC Office via email to CHQEthics@health.qld.gov.au.

Step 2: HREC/RGO Annual Progress Report/Final Report

Researchers are responsible for ensuring that CHQ-FORM-90010 Human Research Ethics Committee/Research Governance Office Progress Report is submitted annually on the date of initial HREC approval, to comply with HREC clearance requirements. Please see CHQ-FW-90038 Research Governance Framework for more information.

Step 3: Amendments to research protocols

Any changes to the research project, in respect of aims, design and anticipated outcomes, which have previously been approved by the CHQ HREC, must be formally submitted as an amendment via ERM, for review and approval by the CHQ HREC.

Upon receipt, the CHQ HREC Co-ordinator will validate the submission and prepare documentation for CHQ HREC Chair/Deputy Chair review. Amendments (if deemed appropriate) are reviewed out of session by the CHQ HREC Chair/Deputy Chair, and the HQ HREC Co-ordinator. Upon CHQ HREC approval, a formal letter in PDF format is sent to the principal investigator and nominated contact person as per initial submission. If approved by the CHQ HREC Chair/Deputy Chair out of session, the approval decision will be tabled at the next CHQ HREC meeting.

Step 4: Serious Adverse Event (SAE)/Suspected Unexpected Serious Adverse Reaction (SUSAR) Report

Safety Reporting for clinical trials must follow NHMRC Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods and the Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods. All Safety Reporting must be submitted via the ERM web portal for researchers, by creating a sub-form under the relevant project and application form.

Safety Reporting Guidelines are available via the HREC Website CHQ-PROC-90024 Safety Reporting for Clinical Trials.

Researchers must report serious adverse events (SAE) and suspected unexpected serious adverse reactions (SUSAR) to the Sponsor.

The Sponsor is defined by the GCP Guideline 1.53 as 'An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial'. Note the term sponsor is relevant to all research – not just commercially sponsored research (eg grant-funded, or unfunded research may be sponsored by the university or hospital that is the administering institution).

The Sponsor is responsible for management and reporting of safety and adverse events.

Where CHQ is the nominated Sponsor of a study, the Sponsor must follow the recommendations in the NHMRC Guidance.

Step 5: Other post clearance submissions

Upon receipt, the CHQ HREC Co-ordinator will validate the submission and prepare documentation for CHQ HREC Chair review. Post clearance submissions are reviewed out of session (if appropriate) by the CHQ HREC Chair and the CHQ HREC Co-ordinator. Appropriate correspondence confirming review is sent to the Principal Investigator and nominated contact person.

Supporting documents

Procedures, Guidelines and Protocols

- Health Service Directive: Research Ethics and Governance HSD-035:2016
- National Health and Medical Research Council, Australian Code for the Responsible Conduct of Research
- National Health and Medical Research Council, Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities
- National Health and Medical Research Council, Safety monitoring and reporting in clinical trials involving therapeutic goods, 2016
- National Health and Medical Research Council, National Statement on Ethical Conduct in Human Research, 2018
- CHQ-POL-90003 Research Integrity Policy
- CHQ-PROC-90006 Research Complaints and Misconduct
- Standard Operating Procedures for Queensland Health HREC Administrators, Version 4 – November 2013
- Therapeutic Goods Administration: Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2)
- CHQ-PROC-90024 Safety Reporting for Clinical Trials
- CHQ-PROC-22001 Privacy and Confidentiality
- National Health and Medical Research Council, Guidelines approved under Section 95A of the Privacy Act 1988
- CHQ HREC Decision Making Principles
- CHQ HREC Advertising for Research
- CHQ-PROC-90008 Site Specific Assessment and Authorisation of Research Procedure

Forms and Templates

- CHQ-PROC-90009-1 Child Adolescent Information Sheet
- CHQ-PROC-90009-2 Parent Guardian Consent Form
- CHQ-PROC-90009-3 Parent Guardian Information Sheet
- CHQ-TOR-90025 CHQ Human Research Ethics Committee (HREC) Terms of Reference
- CHQ-FORM-90011 Notification of Commencement of Research Project
- Research Protocol Template
- CHQ-FORM-90010 Human Research Ethics Committee/Research Governance Office Progress Report
- CHQ-FORM-90012 Research Close Out Checklist
- CHQ-FORM-90013 Data and Materials Management Plan
- CHQ-PROC-90008-1 Site Specific Assessment and Authorisation Checklist

Consultation

Key stakeholders who reviewed this version:

- CHQ HREC Chair
- CHQ HREC Co-ordinator
- Business Manager Research
- Director of Research
- A/Director Legal Services

Audit/evaluation strategy

Level of risk	Medium
Strategy	Observe practice, File/Matter Review
Audit/review tool(s) attached	Nil
Audit/Review date	Annually
Review responsibility	Co-ordinator, Human Research Ethics Committee
Key elements / Indicators / Outcomes	Self-assessment of compliance with obligations

Procedure revision and approval history

Version No.	Modified by	Amendments authorised by	Approved by
1.0 30/06/2021	HREC Coordinator	Business Manager Research	Director of Research

Keywords	Ethics, Human, Research, Committee, NHMRC, 90009
Accreditation references	NSQHS Standards (1-8): NHMRC Act - Institutional Annual Compliance to applicable standards and guidelines: • Australian Code for the Responsible Conduct of Research (2018) • National Statement on Ethical Conduct in Human Research 2007, updated 2018 • Guidelines Approved under Section 95A of the Privacy Act 1988 (2014) • Guidelines under Section 95 of the Privacy Act 1988 (2000) • Principles and accessing and using publicly funded data for health research (2016) • Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018) ISO 9001:2015 Quality Management Systems: (4-10)