Framework

Research Governance Framework

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Standard 1: Clinical Governance

HUMAN RIGHTS

This governance document has been human rights compatibility assessed. No limitations were identified indicating reasonable confidence that, when adhered to, there are no implications arising under the *Human Rights Act 2019.*

PURPOSE, OBJECTIVE AND SCOPE

The purpose of this Research Governance Framework is to ensure a consistent, clear, detailed, accessible framework, including policies, procedures and supporting documentation, are in place to inform and guide CHQ Researchers in the pursuit of research excellence in alignment with the CHQ-FW-17996 Clinical Governance Framework.

This Research Governance Framework applies to all Researchers who are or propose to be involved in research at CHQ.

It is the responsibility of all Researchers undertaking or assisting with research to be aware of and apply the principles and processes outlined within this Research Governance Framework, and all related policies and procedures, as well as all relevant guidelines, standards, general and specific legal obligations (statutory or otherwise) as in place from time to time.

Failure to comply with this Research Governance Framework, or related policies and procedures, may amount to research misconduct on the part of the responsible individual.

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FRAMEWORK

Introduction

Background

Children's Health Queensland's (CHQ) research priorities are driven by our vision for better care and a Healthier tomorrow for all children and young people.

Our efforts are guided by the Children's Health Queensland Research Strategy, and informed by the clinical needs of Queensland children and their families.

We acknowledge research has the potential to create life-changing advances in treatments, prevention, and outcomes for all. That's why our mission is to deliver state-wide translational research to drive evidence-based care, service improvement and innovation.

It is through research that we can prioritise care that matters most. We use data insights including population and clinical statistics to track emerging trends and areas of need and consumer driven feedback. We share our clinical insights and translate research into practice.

We seek to share our child health research and health service expertise. This involves embedding and translating research into service delivery through clinical trials and ongoing efficacy testing of evidence-based interventions.

We seek to translate our research rapidly through health economics, biostatistics, and evaluation techniques. We are growing our funding, investment and collaboration and are working to deliver frameworks for research-based evaluations.

We aim to have research embedded into service delivery across the organisation and have a number of existing and emerging areas of research strength. We are dedicated to ensuring our research is clinically-informed, clinically-relevant and clinically-impactful. In addition to these clinical areas, our Researchers investigate and create partnerships around the development of a dynamic research culture, capacity building for research within service delivery, a focus on emerging health needs and supporting the needs of our future Researchers.

Review

The Director of Research will facilitate ongoing evaluation of the value and effectiveness of this Research Governance Framework in meeting its objectives. The Monitoring and Compliance Officer will monitor the efficacy of the Research Governance Framework in conjunction with usual monitoring activities.

Statutory and Regulatory Provisions

All CHQ Research must comply with all applicable laws, regulations, standards, codes, guidelines especially the National Statement on Ethical Conduct in Human Research (2023) (National Statement), the Australian Code for the Responsible Conduct of Research (2018) (Code) and Good Clinical Practice (GCP).

Overarching Principles

Research Governance

(1) CHQ's research vision is to lead life-changing care for children and young people – for a healthier tomorrow as outlined in the Children's Health Queensland Research Strategy.

(2) CHQ is committed to undertaking world-class paediatric research and securing the health of Australian children through research and innovation, to deliver effective services, educate future generations and improve health care outcomes for our patients/participants.

(3) CHQ is committed to fostering research that enhances patient care, challenges clinical practice, and promotes innovative health service delivery.

(4) CHQ's promotion of innovative health service delivery through research is aligned with the Queensland Government's HEALTHQ32 vision and the Research Strategy 2032.

(5) All CHQ Research must comply with all applicable laws, regulations, standards, codes, guidelines including the National Statement, the Code and Good Clinical Practice (GCP). Research ethics and governance compliance includes the ethical and scientific review of research, contractual and financial management of research and research authorisation by the relevant authority.

- (a) The Office of Research and Innovation provides a summary of Queensland Health policies, procedures and Standard Operating Procedures relating to the overarching governance of research being undertaken within Queensland Health, which support the local governance and processes at CHQ.
- (b) All CHQ Research involving humans, including their data or biospecimens, must be submitted to a Human Research Ethics Committee (HREC) certified by the NHMRC (National Health and Medical Research Council) for Ethics Approval and comply with the National Clinical Trials Governance Framework.
- (c) All CHQ Research must be submitted to the CHQ Research Governance Office for Site-Specific Assessment (SSA) and Research Governance Authorisation.

(6) CHQ has a role in providing a platform to support and facilitate a broad range of research in an ethical and collaborative manner, which meets the needs of clinicians and researchers whilst ensuring that all CHQ Research is conducted in a safe, responsible and ethical manner with the appropriate use of resources.

(7) CHQ is committed to achieving consistent research ethics and governance procedures and processes that facilitate research that allows for valid and accurate research activity reporting.

(8) CHQ will utilise fair and transparent research management procedures and processes to investigate reported research misconduct and complaints.

(9) Conflicts of Interest must be disclosed and managed for all CHQ Research to ensure the integrity of the research process prior to ethical consideration and study commencement.

(10) Where appropriate, CHQ Research should have a plan to translate the research findings into outcomes to benefit the community.

(11) All efforts must be made to minimise duplication of HREC review of CHQ Research and legal review of Research Contracts for multi-site research across Queensland.

(12) CHQ aims to increase its ability to retain high performing CHQ Researchers and to attract high quality health and medical Researchers.

(13) The Research Governance Framework ensures the availability of documents which help guide good research compliance, conduct and management in CHQ.

(14) All CHQ Research must comply with the financial governance principles in all phases of conducting research programs. All financial transactions must be recorded in the relevant financial system and

managed within the overarching financial governance requirements of the Financial Management Practice Manual.

(15) The Research Directorate is responsible for providing advice, training, and education to enable CHQ to be compliant with the Research Governance Framework.

(16) The Research Governance Framework supports compliance with all applicable laws, regulations, standards, codes, guidelines related to the conduct of research in Australia. Common law obligations also arise from the relationships between institutions, researchers and participants, while contractual arrangements may impose further obligations.

Responsible and Ethical Research

This Research Governance Framework is underpinned by the principles of responsible and ethical research outlined in the Code and the National Statement:

- Honesty in the development, undertaking and reporting of research
- Rigour in the development, undertaking and reporting of research
- Transparency in declaring interests and reporting research methodology, data, and findings
- Fairness in the treatment of others
- Respect for research participants, the wider community, animals, and the environment
- Recognition of the right of Aboriginal and Torres Strait Islander peoples to be engaged in research that affects or is of particular significance to them
- Accountability for the development, undertaking and reporting of research
- Promotion of responsible research practices
- Appropriate consumer engagement prior to recruitment

The National Statement outlines the values of respect for human beings, research merit and integrity, justice, and beneficence to inform and guide the ethical design, review, conduct and communication of research. The National Statement must be used to inform research that is funded by, or takes place under the auspices of, any bodies that developed the National Statement, including the NHMRC, the Australian Research Council, and Universities Australia (formerly the Australian Vice-Chancellors' Committee).

It is expected that all who are responsible for research will adhere to the Code and the National Statement in the design, ethical conduct, and review of research at CHQ. The Code and the National Statement do not incorporate all of the laws, regulations, standards, codes, guidelines that apply to the conduct of research.

It is the responsibility of all parties who propose to undertake, administrate, review and/or govern CHQ Research to be aware of, understand, and comply with the applicable laws, regulations, standards, codes, guidelines, standard operating procedures as well as the relevant CHQ policies and procedures.

Key Research Roles at CHQ

Contacts

The table below identifies the key roles in relation to the conduct of Research at CHQ and their contact details:

Role	Contact
Board Research Committee	CHQ_Board@health.qld.gov.au
Research Council	CHQ-Research@health.qld.gov.au
Research Integrity Office	CHQ_RIO@health.qld.gov.au
Human Research Ethics Committee	CHQEthics@health.qld.gov.au
Executive Director of Medical Services	CHQ_EDMS-QCH@health.qld.gov.au
Director of Research	CHQ-Research@health.qld.gov.au
Senior Manager, Research Services and Partnerships	CHQ-Research@health.qld.gov.au
Research Directorate Support Officer	CHQ-Research@health.qld.gov.au
Research Governance Office	CHQ_RGO@health.qld.gov.au
Research and Clinical Trials Monitoring and Compliance Officer	CHQ_ResearchMonitoring@health.qld.gov.au *(Monitoring and Compliance)* CHQ_ClinicalTrials@health.qld.gov.au *(Clinical Trials)*
Research Support and Grants Officer	CHQ_Grants@health.qld.gov.au
Research Education and Training	CHQ_ResearchEducation@health.qld.gov.au
Librarian and Research Metrics Manager	CHQ_Library@health.qld.gov.au
Laboratory and Research Operations Manager	CCHRLabManager@health.qld.gov.au
Clinical Research Facility	crf.cchr@health.qld.gov.au
Research Management Accountant	CHQ_MA_Research @health.qld.gov.au

SECTION 1: Research Grants and Funding

Principles

This Section of the Research Governance Framework is intended to ensure the good stewardship of public resources used to conduct research and that research funds are managed in accordance with relevant funding arrangements, legislation and CHQ and any relevant external bodies policies and procedures.

The following key principles should guide researchers in relation to the application for and management of research funding at CHQ:

- Research expenditure represents a critical measure of CHQ's ability to remain internationally recognised as a leader in biomedical and clinical research. Furthermore, research represents one of the most important avenues to increase its knowledge base.
- Research grant funding is awarded to researchers working on individual research projects for the purpose of advancing research in their field of expertise.
- CHQ must be involved in the research grants application process if it is proposed for CHQ to be identified as the grant administering institution, or a partner in a collaborative application.

Roles and Responsibilities

See the CHQ-PROC-90035 Research Grants and Funding: Application, Administration and Financial Management Procedure.

Procedure

See the CHQ-PROC-90035 Research Grants and Funding: Application, Administration and Financial Management Procedure.

SECTION 2: Collaborations and Partnerships

Principles

This Section of the Research Governance Framework outlines CHQ's procedures for establishing Collaborations and Partnerships for the conduct of CHQ Research.

CHQ supports and encourages research Collaborations and Partnerships with external entities which can enhance the Research and/or provide benefit to CHQ and public health if managed appropriately.

A research Collaboration or Partnership may be entered into by CHQ Researchers through co-application for project specific funding, co-supervision of Researchers or Research Students, and/or collaboration for specific Research projects.

The following principles should be applied to all Collaborations and Partnerships involving CHQ:

- **Balanced Contributions**: All Collaborations and Partnerships should be built on mutually beneficial and equitable contributions by CHQ Researchers and its Collaborators and Partners.

- **Enhancing Capability**: Where possible, Collaborations and Partnerships should facilitate cooperative knowledge sharing and potential co-creation of new knowledge, for the benefit of patients.
- **Shared Objectives**: All Collaborations and Partnerships should be based on one or more shared interests between the parties and a common desire to meet the strategic objectives.
- **Clarity**: All Collaborations and Partnerships should address, from early in the research planning process, the level and type of engagement which is expected of CHQ Researchers and other Contributors.
- **Agreements**: All Collaborations and Partnerships should be documented in a Research Collaboration Agreement that outlines the responsibilities and expectations of the parties including in relation to the proposed research, confidentiality and any proposed transfer of data or materials.

Roles and Responsibilities

CHQ Researchers

- Ensure all Collaborations and Partnerships comply with this procedure
- Primary responsibility for the establishment and ongoing management of Collaborations and Partnerships.

Service Directors and Heads of Department

- Ensure that research conducted in collaboration or partnership with their CHQ Service / Department is clinically relevant and aligned with CHQ's strategic priorities for research and service delivery.
- Oversight and support to CHQ Researchers for the establishment and ongoing management of Collaborations and Partnerships
- Initial management of any disputes with Collaborators or Partners

CHQ Research Directorate

- Case by case support to CHQ Researchers for the establishment and ongoing management of collaborations and partnerships in accordance with this procedure

Procedure

Entering Collaborations or Partnerships

Prior to commencement and/or early in the development stage of new Research ('Project') the CHQ Researchers should discuss, clarify, and define the:

(1) The management and structure for the Project, including the role, time commitments and expectations for each contributor.

(2) Project scope, time frames, objectives, activities, and milestones.

(3) Plans for procurement of financial and other resources required to successfully complete the Project.

(4) Research Governance processes required for the Project and the process for seeking any necessary HREC approvals (refer to Section 4 of this Framework in relation to Research Approvals).

(5) Expectations of the parties with respect to managing and disseminating information related to the Project and research outputs including some consideration of whether a Confidentiality Agreement is required.

(6) Ownership and use of existing or newly created intellectual property (refer to CHQ-PROC-21005 Intellectual Property Procedure) including any responsibilities, rights, and benefits of commercialisation of research outputs.

(7) Management of Conflicts of Interest (refer to Conflicts of Interest Procedure).

(8) The overall scope of the project including, depending on the complexity of the Collaboration or Partnership, some consideration of whether a Project steering committee may be useful.

(9) Where applicable, the terms and conditions of any pre-existing research or funding agreements that may be relevant to the proposed Partnership or Collaboration.

All Collaborations and Partnerships should be governed by and subject to a formal agreement between all parties (refer to Section 3 of this Research Governance Framework in relation to Research Contracts).

Ongoing Management of Collaborations and Partnerships

To assist in the effective management of Collaborations and Partnerships involving CHQ, CHQ Researchers are expected to:

(1) Maintain regular communication and engagement amongst all Collaborators.

(2) Regularly review the progress of the Collaboration or Partnership and the specific Project, including the ongoing feasibility of the factors identified above; and

(3) Immediately address any changes, including for example reporting and management of any new conflicts of interest that may arise during the life of the Project.

Any dispute arising from a Collaboration or Partnership should be resolved in accordance with any governing agreements between the parties, or in the absence of such agreed terms, subject to the complaints handling policies and procedures of one or more of the other Collaborators/Partners.
Disputes should be escalated immediately through internal reporting lines.

SECTION 3: Research Contracts

Principles

This Section of the Research Governance Framework outlines CHQ's procedures for creating and maintaining Research Contracts.
All Research Contracts must be managed in accordance with this Research Governance Framework and the CHQ-FW-26500 Contract Management Framework.

CHQ Research Contracts include any agreement which involves:

(1) Collaboration with other parties for CHQ Research (such as Collaborative Research Agreements or Health Translation Queensland (HTQ) agreements)
(2) Students enrolled in a Research Honours degree, Research Master's degree or Doctor of Philosophy
(3) Providing or procuring a service for CHQ Research, or sharing of CHQ resources or facilities for Research (such as Research Agreements or Service Agreements)
(4) Any use or supply of data or materials for CHQ Research (such as Data or Material Transfer Agreements)
(5) Confidential discussions in relation to CHQ Research proposals or feasibility (such as Confidentiality Deed of Non-Disclosure Agreements)
(6) Publication of CHQ Research findings (such as Authorship or Publication Agreements)
(7) Funding for CHQ Research (such as Funding Agreements or Grants)
(8) Appointment of or funding for CHQ Researchers (for example, Research Fellowship Agreements)
(9) CHQ Research which comprises or involves a clinical trial (such as the Medicines Australia Clinical Trial Research Agreements)
(10) Secondments, Conjoint Appointments or Honorary Appointment into Research roles

Roles and Responsibilities

CHQ Researchers

- Responsible for ensuring compliance with Research Contracts
- Ensuring all Research Contracts are referred to the CHQ Research Governance Office for review and approval before signing.
- Provide copy of all signed Research Contracts to the Research Governance Office
- **Research Governance Office**
- Refer contracts to Legal Services for review as determined necessary on a case-by-case basis
- Maintain a record and register of all signed CHQ Research Contracts

Procedure

All Research Contracts must be referred to the Research Governance Office for review and approval before signing in accordance with CHQ Financial Delegation Framework. The Research Governance Office will

determine whether the Research Contract requires legal review and will co-ordinate with Legal Services, if required.

CHQ Researchers are responsible for ensuring that CHQ obligations regarding any Research Contracts are met by:

- Determining when and if a Research Contract is required.
- Ensuring Research Contracts are reviewed and approved by the Research Governance Office prior to signing.
- Ensuring Research Contracts are signed in accordance with appropriate CHQ Delegations.
- Ensuring Research Contracts are signed before any research or other activities covered by the contract commence.
- Ensuring that all Researchers are informed of and abide by the terms and conditions of all Research Contracts in relation to Research which they involved in or affected by.
- Ensuring any breaches of a Research Contract are promptly reported to the Research Governance Office.

General Requirements

To the extent possible and appropriate:

(1) The parties to a Research Contract should be organisations and not individuals

(2) CHQ contract templates should be used (contact the Research Governance Office for assistance in identifying appropriate templates)

All Research Contracts must comply with all applicable laws, regulations, and guidelines, and should cover all pertinent aspects of the management and conduct of the proposed Research including:

- Each party's role, responsibilities, and contributions to the Research
- Standards of performance as required
- Funding and management
- Confidentiality and Privacy
- Insurance and Indemnity
- Ownership of Project Intellectual Property and Background Intellectual Property
- Reporting
- Publication
- Dispute Resolution

Research Contract register

The Research Governance Office will maintain a record and register of all CHQ Research Contracts.

SECTION 4: Approval of Research

Principles

The purpose of Section 4 of the Research Governance Framework is to minimise the risks to patients/participants, employees and CHQ through its conduct of CHQ Research by ensuring that:

- Research activities are not conducted without appropriate approval including HREC and local governance approvals.
- Heads of departments and services within CHQ have oversight over research activities being conducted within their departments and services.
- CHQ has the appropriate resources to support and facilitate CHQ Research.
- CHQ Research complies with CHQ policies and procedures and Queensland Health policies and standards, as well as all other applicable laws, regulations, standards, codes, and guidelines.
- CHQ has a record of all CHQ Research activities being undertaken.

Roles and Responsibilities

Researchers

- Must not commence any CHQ Research until all required approvals have been obtained
- Responsible for obtaining and maintaining relevant approvals
- Ensure compliance with any conditions or requirements for approvals

HREC

- Support Researchers in obtaining and maintaining Ethics Approval for CHQ Research involving humans
- Assess and provide Ethics Approval for Research involving humans with a paediatric focus
- Review and oversee annual and final reporting requirements
- Manage and appropriately report on any non-compliances with approval conditions

Research Governance Office

- Support Researchers in obtaining and maintaining Research Governance (SSA) Authorisation for CHQ Research
- Process and manage applications for Research Governance (SSA) Authorisation
- Review and oversee annual and final reporting requirements
- Manage and appropriately report on any non-compliances with approval conditions

Director of Research

- As the Health Services Chief Executive's delegate for research, the Director of Research authorises Research at CHQ sites through the Research Governance (SSA) process.

Senior Manager Research Services and Partnerships

- Authorise CHQ Research at CHQ sites through the Research Governance (SSA) Authorisation process in the event of the Director of Research being unavailable or having a conflict of interest relating to the proposed research.

Procedure

To conduct CHQ Research involving humans, it is a requirement that the research is:

- Approved by an appropriately certified HREC; and
- Authorised by the CHQ Research Governance Office via completion of the Site-Specific Assessment (SSA) Authorisation process.

The processes for obtaining Ethics (HREC) Approval and Research Governance (SSA) Authorisation at CHQ are transparent, accountable and will be undertaken in accordance with all relevant laws, regulations, and CHQ policies and procedures.

CHQ Research involving humans must not commence until both processes are formally completed.

Certain types of Research, including that which does not involve humans, may require alternative or additional approvals in order to be conducted at CHQ. It is the responsibility of the Principal Investigator to ensure all research obtains requisite approvals prior to commencing the CHQ Research.

Standard Approvals

Initial Approval

Before seeking any formal approvals for CHQ Research, it is expected that all Researchers will first consult with and obtain an initial approval from relevant Head(s) of the Department and/or Service whose operations and clinical service may be impacted by the proposed CHQ research, for the conduct of the research. Where the relevant Head(s) of the Department and/or Service are an investigator on the project, approval should be sought from a position above with reference to the Financial Delegations Framework.

HREC Approval

HREC review and approval is required to ensure that all CHQ Research involving humans is ethically acceptable and complies with the National Statement, as well as the other applicable laws, regulations, standards, codes, and guidelines.

CHQ Human Research must not commence - and Research Governance (SSA) Authorisation will not be given - until the HREC review process has been completed and letter of approval from the reviewing HREC is received.

The CHQ HREC is registered with the NHMRC, is constituted and functions in accordance with the National Statement and Queensland Health Research Management Policy and operates under published and accessible Terms of Reference (CHQ CHQ-TOR-90025 CHQ Human Research Ethics Committee) and HREC Decision Making Principles. The HREC Office is governed by the Standard Operating Procedures for Queensland Health HREC Administrators in respect of all applications for ethical review submitted to the HREC.

The HREC acts in a consultative and advisory capacity with Researchers to ensure that all clinical, research and management practices are conducted in an ethical and scientifically robust manner. The purpose of the HREC, in accordance with the National Statement, is to ensure that all CHQ Research is conducted in an ethical manner and to promote and foster ethical and good clinical/health research practice that is of benefit to the community.

Key objectives of the HREC are to:

- Protect the mental and physical welfare, rights, dignity, and safety of research participants.
- Facilitate and promote high calibre ethical research through efficient and effective review processes.
- Ensure that all clinical and ethical research is conducted responsibly.

Applications to the HREC are to be made directly via Ethics Review Manager (ERM), which is also available through the CHQ Research page, see the CHQ-PROC-90009 Ethical and Scientific Review of Human Research Procedure.

CHQ is committed to minimising the duplication of ethical and legal review for multi-centre research and is a participant of the National Mutual Acceptance scheme; the national mechanism to allow specific types of multi-centre research to be reviewed by an NHMRC Certified HREC, and for that review to be accepted across all health institutions within participating jurisdictions.

CHQ requires that site feasibility and resource implications be considered as applications for ethical review are submitted to the HREC. Where possible, prior to completion of HREC review, Principal Investigators will discuss site-specific arrangements (such as local resource implications and budget) with the relevant Head of Department(s), Business Manager(s) and the Research Governance Office, to assist in the timely and efficient completion of Site-Specific Applications for governance approval.

Informed Consent

Process

- Principal Investigators must ensure all contact with research participants, consent procedures and handling of participant information complies with:
- All applicable laws, regulations, standards, codes, guidelines and CHQ policies and procedures.
- The relevant research protocol, approvals, and Research Contracts.
- In this regard, Principal Investigators should:
- Always seek to obtain consent through a signed Participant Information and Consent Form (PICF) either in written or electronic format unless otherwise approved by the relevant HREC.
- Ensure informed consent is obtained from the legally and ethically appropriate person with legal responsibility, where the participant is not able to lawfully provide consent.
- Ensure appropriate mechanisms are in place for the PICF or other consenting process to be properly understood by the person providing consent (including providing an interpreter, offering alternative communication methods such as graphics and video to promote health literacy).
- Update and renew informed consent if important new information becomes available which may be relevant to an individual's consent.
- Only use current PICF which has been approved by the relevant HREC.
- Provide a copy of the PICF to the participant and/or their appropriate legal decision maker for them to keep.

Content

At a minimum, a PICF should include the following information in an appropriate, practical, and understandable manner:

- That the participant's participation in the research is voluntary and that the participant may refuse to participate without compromise to their care or professional relationship with health service staff, penalty or loss of benefits to which the participant is otherwise entitled or withdraw at any time, specifying any implications of withdrawal and whether it is possible to withdraw data already collected.
- Our HREC recommends a reading age of year 8-9, and when the nature of the information is thought to be required in the Consent Information Package is unavoidably complex, it is strongly recommended that a simplified, easy to read summary is provided.
- That the research may involve treatments or procedures which are experimental in nature and/or in addition to routine care.
- The purpose of the research and the implications of participation in it.
- The research treatments or procedures (groups) and the manner of assignment to each.
- The participant's responsibilities and any expenses to the participants as a result of participating in the research (if any).
- The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, foetus, or nursing infant.
- The reasonably expected benefits, including to the wider community. When there is no intended clinical benefit to the participant, the participant should be made aware of this.
- The alternatives to participation in the research.
- How the research will be monitored.
- The provision of services and/or availability of compensation for participants adversely affected by the research.
- Contact details of the Researchers and a person to receive complaints.
- Any financial or other declarations of interests of Researchers, sponsor, and institutions. Any options for reimbursement to the participant for participating in the research (See the CHQ-PROC-90009 Ethical and Scientific Review of Human Research Procedure for more detailed information).
- How privacy and confidentiality will be protected and the likely manner and form of dissemination of research results, including publication.

Research Governance (SSA) Authorisation

All research being undertaken at CHQ facilities must be authorised by the CHQ Director of Research or relevant delegate by submitting a Site-Specific-Assessment (SSA) form to the CHQ Research Governance Office in ERM.

An SSA is the local institutional due diligence process by which the suitability of a research study to take place in the context of the specific facility is assessed.

SSA applications must list all CHQ facilities and/or sites where the research is proposed to be conducted, and include a site-specific research budget and relevant contracts, and approval from the heads of the departments. The SSA application must be submitted electronically to the CHQ Research Governance Office

via ERM: https://au.forms.ethicalreviewmanager.com/ (See the CHQ-PROC-90008 Site Specific Assessment and Authorisation for more information).

The CHQ Research Governance Office is governed by the Standard Operating Procedures for Queensland Health Research Governance Officers in respect of all SSA applications submitted.

The SSA application process may be commenced simultaneously with the HREC application process, but Research Governance (SSA) Authorisation will not be given until Ethics (HREC) Approval has been confirmed.

Should CHQ Research commence without Research Governance (SSA) Authorisation, the CHQ Researcher(s) will be instructed to cease the research immediately and all records/ data/ information collected as a result of unauthorised research will be returned to the CHQ Research Governance Office within seven (7) days of a request being issued. This includes documentation collected as hard copy materials and all electronic data/ files. Notification will also be forwarded to the Chair of the relevant NHMRC HREC which approved the Research, and the CHQ Research Integrity Office by the CHQ Research Governance Office.

Other Approvals

Depending on the type of CHQ Research being undertaken, additional levels of approval may be required according to current law, policy, or procedure. These approvals may be required instead of or in addition to Ethics (HREC) Approval and Research Governance (SSA) Authorisation. The list is not exhaustive and the CHQ Research Governance Office should be consulted with any queries or uncertainty about required approvals for CHQ Research.

Public Health Act 2005 (PHA) approval

If access to confidential patient health information is required and patient consent to access the information is not intended or unable to be obtained, approval for data release under the Public Health Act 2005 (Qld) may be required if another disclosure pathway is not available. This is relevant for health information that is identifiable or potentially re-identifiable. For more information see Section 5 of this Research Governance Framework in relation to Research Data and Materials.

Clinical Trial Registration

Every clinical trial involving human subjects must be registered in a publicly accessible database before recruitment of the first subject to provide reliable information to members of the public, health care providers, researchers and sponsors, guaranteeing that the design and conduct of clinical trials are transparent and making the registered clinical trials publicly available for free query and evaluation.

The Australian New Zealand Clinical Trials Registry (ANZCTR) is an online public registry of clinical trials, held at the NHMRC Clinical Trials Centre. It is a Primary Registry in the World Health Organization (WHO)

Registry Network, which means that it fulfils certain criteria for content, quality and validity, accessibility, unique identification, technical capacity, and administration.

The ANZCTR accepts both interventional and observational studies for registration from all countries and from the full spectrum of therapeutic areas including trials of pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies.

Other Australian and New Zealand groups maintain independent registers on specific disease areas.

In addition, the Therapeutic Goods Administration (TGA) maintains an independent register of ongoing trials on therapeutic goods in Australia (as described below).

Therapeutic Goods Administration (TGA)

The TGA regulate the use of therapeutic goods supplied in clinical trials in Australia under the therapeutic goods legislation. The following avenues provide for the importation into and/or supply in Australia of 'unapproved' therapeutic goods for use in a clinical trial (including medical device trials):

- Clinical Trial Approval (CTA) scheme and
- Clinical Trial Notification (CTN) scheme.

The therapeutic goods legislation requires that the use of therapeutic goods in a clinical trial conducted under the CTN/CTA schemes must be in accordance with:

- ICH Guidelines for Good Clinical Practice (GCP)
- National Statement on Ethical Conduct in Human Research (National Statement)
- The procedural protocol as approved by the Human Research Ethics Committee (HREC) responsible for monitoring the conduct of the trial.

CCHR facilities

Specific training, approval and/or consultation processes may be required if CHQ Researchers require use of the CCHR research facilities. CHQ Researchers will be required to liaise with the CCHR Laboratory and Research Operations Manager regarding access and training for the laboratory as per the CHQ-PROC-90007 Research Laboratory - Application and Use Procedure.

CHQ Researchers will be required to liaise with the CCHR Clinical Research Facility Nurse Manager in order to meet any requirements for use of the Clinical Research Facility as per CHQ-POL-90039 Clinical Research Facility – Centre for Children's Health Research (CCHR

Gene technology licence

A licence may be required from the Office of the Gene Technology Regulator (OGTR) for certain research involving organisms that have been modified by gene technology. Further information regarding licence requirements can be obtained by contacting the CCHR Laboratory and Research Operations Manager.

CHQ Researchers undertaking home visits or off site

If CHQ Researchers are conducting home visits to perform participant enrolment, education, follow up and/or sample collection, they must comply with the CHQ-WI-90032 Personal Safety for Research Home Visits Work Instruction.

Ongoing maintenance of approvals

All CHQ Researchers are responsible for managing the ongoing approval of the CHQ Research they are involved in including:

- Notifications to approving entities of any relevant changes to the research.
- Obtaining approval for any changes to the research, including in relation to protocol amendments.
- Annual and progress reporting in accordance with the conditions of any approval or licence granted, for example:
  - A Progress Report is required to be completed through the REDCap survey and submitted through ERM to the approving HREC and CHQ Research Governance Office on at least an annual basis; and
  - A Final Report must be completed at the end of research and submitted to the approving HREC and CHQ Research Governance Office.
- Obtaining any extension or renewal before any approval period ends (where indicated).

SECTION 5: Research Data and Research Materials

Principles

This Section 5 of the Research Governance Framework provides guidance on the appropriate generation, collection, access, use, analysis, disclosure, storage, retention, disposal and sharing of Research Data and Research Materials at CHQ.

CHQ recognises that Research Data and Research Materials are valuable assets in research that need to be appropriately managed to fully realise their value and allow for appropriate analysis, verification, and where applicable future use.

It is imperative that good management practices be established and followed throughout the entire research lifecycle from conception of a study to archiving and destruction of Research Data and Research Materials.

Roles and Responsibilities

All persons involved in CHQ Research or with CHQ Research Data and or Research Materials are responsible for ensuring that they comply with all applicable laws, regulations, standards, codes and guidelines, as well as the relevant CHQ policies and procedures related to record keeping and data management.

Principal Investigators	Principal Investigators must: • Ensure that all Research Contracts address, Research Data and Material ownership and related responsibilities.

	• Ensure that all research documentation meets the applicable GCP requirements including that the records are attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available when needed. • Maintain adequate, clear and accurate records of study methods, source data or documents (including for clinical trials, all pertinent observations on each of the site's trial participants) and study records including any approvals granted, during and after conduct of the research that: – Manage Research Data and Research Materials according to ethical approvals, legislative, organisational and any other applicable requirements. – Ensure that appropriate Research Data and Research Materials are maintained to ensure accurate reporting and justify research outcomes, and to defend the findings of the research if challenged. – Ensure the accuracy, completeness, legibility, and timeliness of the Research Data contained in all research documents and required reports. – Ensure that Research Data and Research Materials are maintained in a safe and secure environment, and that Research Data is stored in a retrievable manner. – Ensure backup, archival and monitoring activities are in place to prevent loss of Research Data. – Plan for ongoing custodial responsibilities for the Research Data and Research Materials at the conclusion of the project or on departure from CHQ. – Maintain confidentiality of Research Data and Research Materials when given access to confidential information. – Ensure that all members of a CHQ Research team, including students and third parties where applicable, are aware of their responsibilities in relation to the management of Research Data and Research Materials. – Supervise CHQ Researchers or third parties where applicable.

Procedure

Custodian of Research Data

All CHQ Research which will or is likely to generate Research Data or Research Materials must have a designated 'CHQ Custodian' with responsibility for managing the Research Data and Research Materials for the research.

Unless otherwise assigned, the Principal Investigator for a CHQ Research project will be deemed the CHQ Custodian. For any projects with a Principal Investigator external to CHQ, the most senior CHQ Researcher involved in the research will be deemed the CHQ Custodian unless another CHQ Researcher has been assigned and listed on the Data and Materials Management Plan.

Collection of Research Data and Research Material

It is the responsibility of all CHQ Researchers to ensure that Research Data and Research Material is collected in a fair and lawful manner. This includes ensuring compliance with all applicable laws, regulations, standards,

codes, guidelines and CHQ policies and procedures, as well as the relevant research protocol, approvals, and consent processes.

Data management planning from the beginning of a research project helps to outline how data will be collected, formatted, described, stored, and shared throughout, and beyond, the project lifecycle. Some of the key factors to consider when collecting Research Data and Research Materials are summarised below. However, this section is not exhaustive, and Researchers should contact the Research Governance Office if they have any queries.

National Statement and Research Approvals

All collection, use and storage of Research Data and Research Material for CHQ Research must be conducted in accordance with the National Statement, Ethics Approval(s) and Research Governance (SSA) Authorisation(s) required to be obtained and maintained for the duration of the research.

Collection of Personal Information

In most cases where Research Data are to be collected, used, stored, or disclosed for the purposes of research, consent for the collection and use of Personal Information of participants is required.

When collecting Personal Information, or as soon as practicable after collecting, the Information Privacy Act 2009 (Qld) and the Privacy Act 1988 (Cth) require that individuals are made aware of the following information about the collection:

(1) The identity of the health agency and how to contact it; and
(2) The fact that he or she is able to gain access to the information; and
(3) The purposes for which the information is collected; and
(4) The entities, or the types of entities, to which the health agency usually discloses information of that kind; and
(5) Any law that requires the particular information to be collected; and
(6) The main consequences, if any, for the individual if all or part of the information is not provided.

Consent and collection notification will ordinarily be achieved through the approved Research Participant Information & Consent Form (PICF).

There are some situations where consent and collection notification are not required for the collection of Personal Information for research. This is where the information is health information and the use or disclosure is necessary for research, or the compilation or analysis of statistics, relevant to public health or public safety and:

- It is impracticable for CHQ to seek the individual's consent before the use or disclosure; and
- The use or disclosure is conducted in accordance with approved guidelines (see, Guidelines approved under Section 95A of the Privacy Act 1988); and
- For disclosure, CHQ reasonably believes that the entity receiving the health information will not disclose the health information or personal information derived from the health information.

See the CHQ-PROC-22001 Privacy and Confidentiality Procedure.

Collection of Human Tissue and Biospecimens

The Transplantation and Anatomy Act 1979 (Qld) governs and contains a number of restrictions in relation to the removal and collection of human tissue (including blood) from individuals in Queensland. If CHQ Research involves the removal, collection or use of human tissue or blood, the CHQ Researchers should consult with the CHQ Research Governance Office to ensure it complies with CHQ's legal obligations.

Collection of CHQ Clinical Data

If access to CHQ patient health information is required for research purposes and patient consent to access the information is not obtained, approval may additionally be required under the Public Health Act 2005 (Qld) and the Hospital and Health Boards Act (2011) through submission of a Public Health Act (PHA) application. This is particularly relevant for release of patient health information to non-designated persons (e.g., persons not employed by CHQ) and/or the release of health information that is identifiable or potentially re-identifiable. It is important to note that information may be potentially re-identifiable even if a person's name, address, date of birth or unit record number (URN) is not collected.

See the Office of Research and Innovation for further information and access to the PHA application form.

Storage of Research Data and Research Materials

CHQ requires that:

- Researchers are aware of and understand the requirements of all confidentiality agreements and other conditions or restrictions in place in relation to any Research Data and Research Materials;
- the computing systems and other facilities used in the management of Research Data and Research Materials are appropriate and secure; and
- there are adequate physical security and access control arrangements in place to ensure the safety, security and confidentiality of all Research Data and Research Materials.

Subject to ethical, privacy or any legal, contractual, security or other requirements or limitations:

- Research Data must be stored in electronic format in a common location on the CHQ network, so that it is regularly backed up. It is not sufficient to store Research Data on local computers or external hard drives, which are not routinely backed up by CHQ;
- Where practicable, Research Data should be collected, processed, and analysed via software programs that enable tracking, version control, date stamping, author attribution and Metadata such as REDCap. See CHQ-POL-44118 Research Electronic Data Capture (REDCap) Policy and CHQ-PROC-44119 Research Electronic Data Capture (REDCap) Procedure; and
- Research Materials should be stored within CHQ facilities as appropriate and necessary to ensure the integrity and security of the materials.

Any arrangements for storage of Research Data and Research Materials to be held offsite should also be documented and subject to a contractual agreement.

Researchers must ensure that the security and privacy measures that are used for Research Data and Research Materials are proportional to the risks associated with the confidentiality or sensitivities of such Research Data and Research Materials.

Researchers should contact the Research Governance Office for further guidance.

Access and Use by External Persons

In accordance with the Code, CHQ will allow use and disclosure of Research Data and Research Materials by external persons in accordance with an approved research protocol or otherwise if authorised by the Research Governance Office, having regard to the relevant:

- Ethics Approval(s) and Research Governance (SSA) Authorisation(s);
- PICF;
- Research Contracts, including any confidentiality agreements;
- Other legal and regulatory requirements; and
- CHQ policies and procedures.

Access or re-use of data or information used or generated through Aboriginal and Torres Strait Islander Research will be subject to prior consultation with those peoples and communities.

Where access to or use of Research Data or Materials is refused, reasons must be given.

Researchers should contact the Research Governance Office for more guidance.

Transfer or Removal of Research Data or Research Materials

Researchers are not permitted to transfer, remove, or duplicate any Research Data or Research Materials from CHQ without necessary approvals and execution of appropriate agreements between CHQ and the recipient. This includes when CHQ Researchers leave CHQ.

If Research Data is required to be transferred or removed from CHQ premises, it should be moved via secure electronic data transfer, in a manner that protects the data security and integrity, using appropriate CHQ and/or Queensland Health secure file transfer platforms.

Where a CHQ Researcher leaves CHQ and requests to take a copy of Research Data

In the event of a CHQ Researcher or CHQ Custodian leaving CHQ, they may request and be permitted to take and maintain a copy of the Research Data or Research Materials for further use.

Requests must be made in writing to the Research Governance Office and will be reviewed and decided on a case-by-case basis by the Director of Research, in their absolute discretion.

Requests will be reviewed in consideration of and subject to:

- Ethical, governance, legal, statutory and privacy requirements;
- Intellectual property considerations, including potential uses of the data and ownership of body of work already existing;
- Any funding body or other existing agreements in relation to the Research and/or the relevant Research Data and Research Materials;
- Any potential conflict(s) which may arise from releasing the Research Data or Research Materials with CHQ requirements, other CHQ Research (including any ongoing CHQ Partnership or Collaboration) or future CHQ Research; and
- Any other issues that the Director of Research considers relevant to their decision.

Original Research Data and Research Material (including any keys to study codes) are the property of CHQ and must not be removed from CHQ.

If the Director of Research agrees to a request to take and maintain a copy of Research Data or Research Materials, a formal contract must be agreed by CHQ and acknowledged by the individual CHQ Research Lead or CHQ Custodian (or their new employer). This contract must be executed before any Research Data or Research Material is transferred. The contract should recognize the prior work, ownership, and any existing agreements for the relevant research.

NOTE: Any future use of Research Data or Research Material will require approval by a HREC and Research Governance Office (possibly in the form of a new Ethics (HREC) Approval/SSA authorisation or as an amendment to the original approval/s).

Archiving and Retention of Research Data

Researchers must:

- Keep clear and accurate records of the research methods and data sources, including any approvals granted, during and after any CHQ Research; and
- Retain Research Data, including electronic data in a durable, indexed, and retrievable form, and manage Research Materials according to the relevant approvals, agreements, and law.

Research Data and sufficient Research Materials (where practicable) must be retained to verify the outcomes of Research, and if necessary, defend them against challenge.

Archiving, retention and disposal requirements for Research Data and Research Materials should be clearly described in a Data and Materials Management Plan and comply with Record Archiving and Disposal Procedures and the Queensland Government General Retention and Disposal Schedule.

Archiving of Research records should only occur after the Research is closed out. See Section 11 of this Research Governance Framework, Closing Out Research.

If Research Data is within the paper medical record the chq_scanning@health.qld.gov.au email should be contacted and request to put a **CLINICAL TRIALS PARTICIPANT** sticker on the paper chart.

The period for which Research Data and Research Materials should be retained will be determined by the specific type of Research, subject to any applicable State, Territory or national legislation. The NHMRC Management of Data and Information in Research Guide to the Code provides further recommended timeframes for retention of Research Data, and any other requirements may be specified in the Ethics (HREC) Approval or Research Governance (SSA) Authorisation, any relevant Research Contracts or other CHQ policies and procedures. Researchers should consult the sources for additional information and guidance specific to the specific type of Research they are undertaking:

- Disposal and retention schedule for clinical records (health.qld.gov.au)
- Management of Data and Information in Research - A guide supporting the Australian Code for the Responsible Conduct of Research
- Record Archiving and Disposal Procedure

SECTION 6: Monitoring

Principles

This Section 6 of the Research Governance Framework provides guidance on the processes and procedures for monitoring CHQ Research.

The purpose of monitoring is to ensure that research is conducted in a manner which:

- Is consistent with the approved research proposal;
- Protects the rights and wellbeing of the research participants;
- Ensures the quality and accuracy of Research Data and Research Materials; and
- Ensures ongoing legal and regulatory compliance by CHQ.

Monitoring of approved CHQ Research is conducted in accordance with principles of compliance, accountability, transparency, quality control, risk management, health and safety, environmental protection, and efficiency.

It may take various forms, including reports from Researchers, review of safety reports, review reports from independent agencies, review of study site files, consent documentation, source documents and Research Data and on-site monitoring.

Researchers must comply with any request from the Research Directorate for information about research for the purpose of research monitoring and cooperate with any review or audits undertaken.

This Research Governance Framework only governs internal monitoring of research by CHQ. Some research may be subject to additional monitoring and audit requirements, especially clinical trials.

Roles and Responsibilities

Executive Leadership Team	• Ensure collaborative, harmonised, clear, and detailed publicly available policies and procedures are in place for the ethical, scientific and Research Governance (SSA) Authorisation of all CHQ Research.
CHQ HREC	• Review Progress Reports / Final Reports for research approved by the HREC and verify that research is being conducted in accordance with the relevant research protocol, approvals, and Research Contracts.
CHQ Research and Clinical Trials Monitoring and Compliance Officer	• Ensure, via CHQ's research governance arrangements, that CHQ Research is monitored in accordance with: – All applicable laws, regulations, standards, codes, guidelines (especially including the National Statement, the Code and GCP) and CHQ policies and procedures; and – The relevant research protocol, approvals, and Research Contracts. • Ensure that CHQ exercises appropriate quality control over CHQ Research including clinical trials, to ensure that CHQ Research and Researchers (and other staff over whom it has authority) comply with: – All applicable laws, regulations, standards, codes, guidelines and CHQ policies and procedures; and

	– The relevant research protocol, approvals, and Research Contracts. – Determine the frequency and type of monitoring undertaken which reflects the degree of risk to research participants and fosters the ongoing education of Researchers in the responsible and ethical conduct of research.
Principal investigators/research team	• Fully co-operate with the on-site monitoring process, respond to all queries, and implement all necessary changes in the required time frame. • Ensure CHQ Research practices reflect current professional (ethical and legal) standards for research, including promptly responding to reporting and monitoring requirements. • Ensure all contact with research participants, consent procedures and handling of participant information complies with: – All applicable laws, regulations, standards, codes, guidelines and CHQ policies and procedures; and – The relevant research protocol, approvals, and Research Contracts. • Ensure that staff members conducting or involved in CHQ Research involving clinical interventions do so within the staff members scope of practice, approved credentialing privileges and clinical experience. • The study coordinator(s) and/or contact person(s) nominated by the Principal Investigator for any CHQ Research should be available during all monitoring visits to provide any documentation or answer questions as required.

Procedure

Reporting

Annual Progress Research Reports are required to be submitted on at least an annual basis to:

- For any CHQ Research subject to Ethics (HREC) Approval, the approving HREC; and
- The Research Governances Office.

A Final Report is required to be submitted at the end of all CHQ Research to the approving HREC and Research Governance Office.

There may be additional reporting requirements for some research as specified in the relevant research protocol, approvals, or Research Contracts.

Refer to Ethics and Governance Post Approval Reporting | Children's Health Queensland.

Monitoring Visits

The procedure for arranging and responding to monitoring visits is described below.

(1) *Scheduling a monitoring visit*

The CHQ Research and Clinical Trials Monitoring and Compliance Office will contact a Principal Investigator via telephone and/or in writing at least two weeks in advance of a proposed monitoring visit if their research

has been identified for monitoring. This notification will generally be by email and relevant templates will be provided to assist in preparation for the monitoring visit.

If a response is not received by the Research Directorate Office within 14 days a reminder will be sent to the Principal Investigator, the nominated contact person, and relevant Service Director / Head(s) of Department. If there has still been no response to the reminder request, then a final notification will be sent to the Principal Investigator, nominated contact person and relevant Service Director / Head(s) of Department and forwarded to the HREC Chair and/or Director of Research for their consideration/necessary action.

It is a requirement of ongoing HREC approval for monitoring to take place.

(2) *Monitoring visit*

The monitoring visit will involve a meeting with the Principal Investigator and other Researchers to discuss matters relating to the Research and its conduct. At the commencement of the meeting the CHQ Research and Clinical Trials Monitoring and Compliance Officer will introduce the purpose of the monitoring visit, ask general questions regarding the Research, note any relevant delegations and answer any questions regarding the on-site monitoring process.

The Research Directorate representative may request to see/review/verify any of the following in relation to CHQ Research:

- Trial Master File (TMF) and/or Investigator Site File (ISF) which contain specific/regulatory essential documents relevant to the research. These are documents which individually and collectively permit evaluation of the conduct of research and the quality of the data produced.
- Source data including but not limited to:
  - PICFs;
  - The process / procedures for obtaining informed consent;
  - Hospital charts and/or electronic records to verify participant eligibility;
  - Treatment/interventions and follow up as per the research protocol;
  - Reported serious adverse events (SAE) and suspected unexpected serious adverse reactions (SUSAR);
  - Data storage and protection arrangements;
  - Investigational product storage and accountability arrangements (if applicable); and/or
  - The process / procedures for participant recruitment.

For smaller studies, the above will be assessed for every research participant. For larger studies, the Research Directorate may nominate a reasonable sample of research participants for assessment. This sample will be randomly selected, but consideration may be given to assessing an equal number of participants from different treatment groups and/or including participants who did not complete the research protocol.

All Researchers are required to cooperate and comply with any requests from the CHQ Research Directorate in relation to monitoring undertaken under this Section 6 of the Research Governance Framework.

(3) *Preliminary monitoring findings*

During a monitoring visit the representative from the CHQ Research Directorate will discuss findings with the Principal Investigator and other Researchers involved in the Research including recommendations and/or gaps in compliance. These may be related to:

- Regulatory requirements;
- Employees and delegated responsibilities;
- Research protocol and amendments;
- Process for taking informed consent;
- Research participant recruitment processes;
- Data and/or case report form recording;
- Investigational product retention or accountability issues (if applicable); and/or
- Data protection.

(4) *Completion of monitoring*

The Research Directorate will prepare a monitoring report following each monitoring visit considering any information and documents provided at or otherwise in support of the monitoring visit.

The monitoring report will outline the findings of the monitoring activities and include a list of recommendations or actions to be completed. The report will be issued within two weeks of the on-site monitoring visit to:

- The Principal Investigator;
- The other Researchers involved in the research (as agreed with the Principal Investigator);
- Relevant Head(s) of Department (as appropriate); and/or
- HREC Chair and HREC Office for placement on the HREC file and noting at the next scheduled meeting (for studies approved by the HREC).

A copy of the monitoring report and all relevant documentation will be retained by the Research Directorate.

(5) *Follow-up actions*

It is the Principal Investigator's responsibility to ensure any necessary changes are implemented, however if any advice or assistance is required, the Research and Clinical Trials Monitoring and Compliance Officer will be available to help. The Principal Investigator of the research project is obliged to respond to required actions within an agreed and timely manner, generally a period of 3 months or sooner.

If issues are not resolved, the matter will be referred to the HREC for further action.

External Audits of Research and Clinical Trials

When the Principal Investigator/Research Team conducting a research study or clinical trial at CHQ are notified of an external audit to be undertaken, it is the Principal Investigator's responsibility to notify the following positions that that a monitoring visit has been scheduled to be undertaken:

- Executive Director Medical Services (EDMS)
- Relevant Divisional Director
- Director of Research
- Research and Clinical Trials Monitoring Compliance Officer

The outcomes of the audit, including any recommendations, adverse findings and disciplinary action are to be communicated to the above positions. The EDMS is ultimately responsible for ensuring all findings have been resolved to the satisfaction of all parties.

SECTION 7: Gender Equity

Principles

This Section 7 of the Research Governance Framework outlines CHQ's commitment to support diversity and inclusion in its workplace.

CHQ acknowledges that there are challenges to gender equity in health and medical research in terms of career progression and retention as identified by the NHMRC Women in Health Science Committee. CHQ is committed to supporting a gender equal health and medical research workforce through retention and advancement strategies. CHQ requires that Researchers and CHQ Research to comply with the principles of gender equity set out below.

CHQ supports the NHMRC's Gender Equity Strategy and is committed to take steps to support the key aims and the activities identified.

Roles and Responsibilities

It is the responsibility of all CHQ personnel to comply with laws, regulations, standards, codes, guidelines and CHQ policies and procedures for gender equity and diversity in research as well as all other functions of CHQ.

Procedure

CHQ is committed to supporting diversity and inclusion in its workplace, and requires Researchers and CHQ Research to comply with the principles of gender equity and diversity in research by:

(1) Promoting a workplace culture that appreciates and supports gender equity.

(2) Provides funded primary carers leave for parents and transitional support to encourage return to work.

(3) Ensures remuneration equity for equal or comparable responsibilities.

(4) Monitors and report gender diversity in research funding, research activities and outcomes within CHQ across all levels, facilities, and streams.

(5) Enables appropriate representation and gender equity for CHQ Researchers in leadership roles.

(6) Recognises the contribution of all outstanding researchers in a gender equitable manner.

(7) Ensures consistency in assessment of career disruptions in applications submitted for CHQ Researcher support or research awards.

(8) Supports gender equity for CHQ Researchers at critical stages of career development.

(9) Allows for implementation of flexible work arrangements across all research positions (where feasible).

(10) Provides for equal opportunity and progression of all genders across the research career pipeline.

(11) Ensures every research committee and grant review panel achieves appropriate gender equity in its membership.

(12) Provides mentoring and training in research on managing disruptions and career advancement.

(13) Has the following policies, procedures, and training in place to support research environments that are free from bias, discrimination and sexual or other harassment and to address any instances of such behaviour:

- QH-POL-266 Workplace Harassment Policy;
- QH-POL-228 Sexual Harassment Policy;
- QH-POL-101 Anti-discrimination, human rights, and vilification Policy; and
- CHQHHS-HRFMWK-06 Employee Complaints Management Framework.

SECTION 8: Research Personnel

Principles

This Section of the Research Governance Framework outlines CHQ's procedures for ensuring all Researchers (including Research Trainees) are made aware of and comply with all relevant CHQ policies and procedures relating to the conduct of research.

Roles and Responsibilities

Principal Investigators

- Responsible for ensuring that all Researchers have been trained, credentialed, and onboarded appropriately for CHQ Research.

Research Supervisors

- Ensure formal arrangements are in place for the supervision of any Research Trainees
- Oversight and responsibility for the training and work conducted by Research Trainees

Research Directorate

- Facilitating access to necessary training

Procedure

Supervision of Research Trainees

Research Trainees include students and junior researchers.

Research Supervisors are CHQ Researchers (who are not Research Trainees) who are involved in the supervision of one or more Research Trainees at CHQ at any time.

All Research Trainees must be assigned to a specific, appropriately qualified Research Supervisor to supervise their involvement in any CHQ Research.

Research Supervisors must ensure:

- There is a formal arrangement in place for the involvement and supervision of Research Trainees in any CHQ Research.
- Prior to the involvement of any Research Trainee in any CHQ Research, each Research Trainee's name is added to the relevant delegation log, and the ratio of Research Trainees to Research Supervisors is appropriate to ensure effective intellectual interaction and effective oversight of the Research at all times.
- Research Trainees are not put at risk including to chemical hazards, infectious disease, and psychological trauma.
- All Research Trainees undergo appropriate induction and training.
- Research Trainees receive appropriate credit for their work.

Research Supervisors should also guide the professional development of all Research Trainees. This involves providing guidance in all matters relating to research conduct and overseeing all stages of the research process, including identifying the Research objectives and approach, obtaining ethics and other approvals, obtaining funding, conducting the research, and reporting the research outcomes in appropriate forums and media.

SECTION 9: Partnering with Consumers

Principles

The purpose of this Section 9 of the Research Governance Framework is to outline CHQ's procedures for fostering the engagement and involvement of consumers in CHQ Research.

Research informs health care decisions. Research organisations, researchers, consumers, and community members should work collaboratively to support and facilitate research design and conduct. The contribution that consumers and community members make to research, and its development, conduct and communication has many positive outcomes such as improved quality, decreased cost and more effective translation. The active involvement of consumers and community members in health and medical research benefits the quality and direction of research at CHQ. Consumer and community involvement is about research being carried out with consumers and community members rather than to, about or for them.

Patients/participants and family members are to be encouraged and given the opportunity to ask questions, give feedback, clarify information and actively participate in the development and communication of research.

Staff are responsible for providing information in a way that is understandable and that meets their needs and are to check consumer's understanding of discussions.

Researchers should refer to the NHMRC Statement on Consumer and Community involvement in Health and Medical Research for further guidance on research with consumers, and ensure alignment with CHQ's Consumer and Community Engagement Strategy. CHQ HHS acknowledges the importance of consumer and community opportunities to participate and be involved in research, viewing it as an integral part of person-centred care.

Roles and Responsibilities

It is the responsibility of Researchers to comply with all applicable laws, regulations, standards, codes, guidelines and CHQ policies and procedures to ensure necessary engagement and involvement of consumers in CHQ Research. However, Principal Investigators have some specific responsibilities which are described below.

Procedure

Consumer involvement is becoming an important aspect of research design, implementation, and translation into practice. Effective consumer and community involvement benefits many stakeholders including the public and researchers. CHQ recognises the importance of involving consumers in research and is driving a consumer engagement strategy, including education and advocacy, in alignment with the CHQ Research Strategy.

Principle Investigators should refer to the CHQ-PROC-25001 Consumer Engagement, and the CHQ-PROC-25001 Consumer Engagement: Applying Consumer Engagement Processes, which include resources and tools that describe how engagement with consumers and communities is planned, implemented, evaluated and reported across CHQ. The Research Directorate and Consumer Engagement Office can provide assistance and guidance on the process. CHQ resources and guidelines involving consumer engagement include:

- CHQ-WI-30600 Consumer Engagement: Remuneration Process
- CHQ-PROC-25001 Consumer Engagement
- CHQ-GDL-25003 Consumer Engagement – Applying Consumer Engagement Processes

Other resources providing information to support the involvement and engagement of consumers in research include:

- Health Consumers Queensland
- NHMRC Statement on consumer and community involvement in health and medical research
- National Safety and Quality Health Service Standards (NSQHS) – Second Edition
- Australian Clinical Trials Alliance – Toolkit for Researchers and Research Organisations
- ACCESSCR - Clinical Trial Solutions: Demystifying the National Clinical Trials Governance Framework for Health Consumers
- Patient-Centred Outcomes Research Institute
- Australian Health Research Alliance – Consumer and Community Involvement

SECTION 10: Aboriginal and Torres Strait Islander peoples

Principles

This Section 10 of the Research Governance Framework outlines how CHQ recognises and will respect the rights of Aboriginal and Torres Strait Islander people to control and maintain their culture and heritage in the context of Research. CHQ is committed to ensuring that Aboriginal and Torres Strait Islander peoples are empowered to lead, participate in and/or be appropriately consulted about all stages and aspects of research that impacts on or is of particular significance to Aboriginal and Torres Strait Islander peoples.

The NHMRC has published Ethical conduct in research involving Aboriginal and Torres Strait Islander Peoples and Communities, to ensure ethical research with Aboriginal and Torres Strait Islander Peoples and Communities should:

- Improve the way all researchers work with Aboriginal and Torres Strait Islander people and their communities;
- Develop and/or strengthen research capabilities of Aboriginal and Torres Strait Islander people and their communities; and
- Enhance the rights of Aboriginal and Torres Strait Islander Peoples as researchers, research partners, collaborators, and participants in research.

Roles and Responsibilities

It is the responsibility of all Researchers to ensure that Aboriginal and Torres Strait Islander people's considerations are appropriately addressed and embedded into all CHQ Research.

Procedure

The NHMRC ethical guidelines on research involving Aboriginal and Torres Strait Islander peoples provide a set of principles to ensure research is safe, respectful, responsible, high quality, of benefit to Aboriginal and Torres Strait Islander people and communities and of benefit to research. The Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders defines six core values — spirit and integrity, cultural continuity, equity, reciprocity, respect, and responsibility. Applying these values and other ethical principles will ensure that research conducted with or for Aboriginal and Torres Strait Islander people and communities, or their data or biological samples, is ethically conducted. The following guidelines should be applied when undertaking any research involving Aboriginal and Torres Strait Islander peoples or Indigenous Cultural and Intellectual Property:

- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities; Guidelines for CHQ Researcher's stakeholders 2018; and
- Keeping research on track II 2018.

These documents should be read alongside:

- The Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) Guidelines for Ethical Research in Australian Indigenous Studies 2012
- The Queensland Health Aboriginal and Torres Strait Islander Cultural Capability Framework 2010-2033

- NHMRC Road Map 3: A strategic framework for improving Aboriginal and Torres Strait Islander health through research
- Additional resources published by the Lowitja Institute and the Queensland Aboriginal and Islander Health Council.

There is currently no certified Aboriginal and Torres Strait Islander HREC in Queensland, however the HREC includes at least one member who identifies as Aboriginal or Torres Strait Islander. Researchers who intend to partake in any Collaboration or Partnership involving Aboriginal and Torres Strait Islander Peoples may wish to contact one of the following for more information:

- Australian Institute of Aboriginal and Torres Strait Islander Studies Research Ethics Committee
- Aboriginal Health & Medical Research Council Ethics Committee (NSW)
- Human Research Ethics Committee for the Northern Territory Department of Health and Menzies School of Health Research
- Aboriginal Health Research Ethics Committee (SA)
- Western Australian Aboriginal Health Ethics Committee

See CHQ's Aboriginal and Torres Strait Islander Health Equity Strategy.

SECTION 11: Closing Out Research

Principles

The purpose of this Section of the Research Governance Framework is to describe the procedures for properly closing out CHQ Research.

Closing out should not occur until research is complete and all participants have completed their involvement and/or all research queries have been addressed in accordance with the relevant research protocol, approvals, and Research Contracts.

Proper closing out of research ensures that all research related activities are appropriately completed, reconciled, reported, and recorded in accordance with the applicable legal, regulatory, and procedural requirements. It enables CHQ and Principal Investigators to ensure all necessary documentation is in place should it be necessary in the future to access or audit CHQ Research (generally) or Research Data or Research Materials.

Roles and Responsibilities

It is the responsibility of the Principal Investigator to ensure compliance with all applicable laws, regulations, standards, codes, guidelines and CHQ policies and procedures when closing out CHQ Research. They are responsible for carrying out the procedure below.

The Research Governance Office will maintain a record of completion.

Procedure

At the end of CHQ Research, the Principal Investigator must:

(1) Ensure the research has been completed by:

(a) Reviewing all relevant research material against the research protocol; and

(b) Consulting and confirming with all collaborating parties and sites.

(2) Liaise with the Research Support and Grants Officer to ensure all relevant grants and funding obligations have been reconciled and acquitted, if applicable.

(3) If the research comprised or involved a clinical trial, update any clinical trial registers.

SECTION 12: Communicating Results

Principles

This Section of the Research Governance Framework outlines the procedures for ensuring the responsible communication and dissemination of CHQ Research outcomes and other avenues to share CHQ Research Data, Research Materials, and resources.

Roles and Responsibilities

See CHQ-PROC-90005 Publications and Authorship Procedure.

Procedure

When Researchers are communicating CHQ Research, there are several considerations that must be taken into account to be a carefully planned process. It is the responsibility of all Researchers to obtain approval from the Principal Investigator before proceeding. There are a number of guides to support Researchers, including:

- NHMRC Dissemination and communication guide
- NHMRC Publication and dissemination of research guide
- NHMRC Open Access Policy

Requirements for the publication and dissemination of CHQ Research are included in the CHQ-PROC-90005 Publications and Authorship Procedure but additional practical considerations when planning for the general communication of CHQ Research findings include (but are not limited to):

- Confidentiality and privacy – see CHQ-PROC-22001 Privacy and Confidentiality Procedure
- Considerations relating to potential to generate IP/commercialisation – see CHQ-POL-21004 Intellectual Property Policy.
- Ownership of data and relevant approvals in place from co-contributors of the works – see Section 5 of this Research Governance Framework, Research Data and Research Materials
- Branding – ensuring that branding of Research aligns with the CHQ policies and procedures, and any co-branding or other requirements that may be part of a collaborative research agreement (where other parties are involved)
- CHQ presentation or poster templates are used where applicable
- CHQ Event, Conference and Poster Templates
- CHQ PowerPoint templates

- All conference attendance representing CHQ is undertaken in accordance with any relevant CHQ or Queensland Health policies including (but not limited to):
  - Travel Policies and Directives
  - Domestic travel
  - Overseas travel
  - QH-POL-226 Seminar and Conference Leave – Within and Outside Australia
- And any other applicable policies, procedures, or other conditions relating to employment

SECTION 13: Research Integrity

Principles

This Section of the Research Governance Framework outlines how CHQ will ensure that all CHQ Research upholds the highest standards of research integrity and complies with all applicable laws, regulations, standards, codes and guidelines (especially including the National Statement, the Code and GCP).

Roles and Responsibilities

See the CHQ-POL-90003 Research Integrity Policy, Conflicts of Interest Procedure and the CHQ-PROC-90006 Research Complaints and Misconduct Procedure.

All individuals undertaking research at a CHQ facility or on behalf of CHQ (whether already employed at CHQ or not) including students (Research Personnel) are required to undertake Research Integrity Training. The training may be accessed through any external provider where the training is related to implementing the Australian Code for the Responsible Conduct of Research.

Procedure

See the CHQ-POL-90003 Research Integrity Policy, Conflicts of Interest Procedure and the CHQ-PROC-90006 Research Complaints and Misconduct Procedure.

In order to support Researchers to undertaking responsible conduct of Research, CHQ is committed to providing ongoing training and education.

SECTION 14: Additional NHMRC Policies and Guidelines

Principles

This Section of the Research Governance Framework outlines how CHQ will ensure that all CHQ staff performing research (researchers and research office support staff) follow new and additional requirements (updated policies and guidelines) for CHQ as a NHMRC Administering Institution.

Roles and Responsibilities

CHQ Research Directorate will update all research staff and researchers regarding new NHMRC policies and guidelines as required.

All researchers, research supervisor and research support staff at CHQ are to be compliant (even if CHQ is not your NHMRC Administering Institution for grant funding) with the following:

- Applicable Laws and Obligations
- NHMRC policies and priorities
- Approved Standards and guidelines

Updates:

NHMRC Open Access Policy:

As of 01 January 2024, all publications must be made open access in a repository or other acceptable location within a 12-month period from the date of publication. To find out more please visit https://www.nhmrc.gov.au/about-us/resources/nhmrc-open-access-policy

It is recommended researchers appropriately budget within funding applications for Open Access fees to ensure compliance. Queensland Health has a free data repository, Database of Research Activity (DORA) that can host publications.

Please contact CHQ Grants Office for more information regarding Open Access.

Guidelines to Counter Foreign Interferences in the Australian University Sector:

Administering Institutions, Participating Institutions and researchers should be aware of the Australian Government's Guidelines to Counter Foreign Interference in the Australian University Sector when assessing and managing the risks of foreign interference in Australian research.

Whilst these guidelines are directed towards the University sector, CHQ as an organisation interacts with foreign entities such as universities, hospitals, pharmaceutical companies, societies, and professional groups. Hence, it is necessary for CHQ researchers and research support staff to be cognisant of these guidelines.

To find out more about the guidelines, please visit https://www.education.gov.au/guidelines-counter-foreign-interference-australian-university-sector

SUPPORTING DOCUMENTS

Legislation and other Authority:

- Hospital and Health Boards Act (2011)
- Information Privacy Act 2009 (Qld)
- Privacy Act 1988 (Cth)
- Public Health Act 2005 (Qld)
- National Health Medical Research Council Act 1992 (Cth)
- Therapeutic Goods Act 1989 (Cth)

Standards:

- Children's Health Queensland Research Strategy 2023-2025
- Research Strategy 2032
- National Clinical Trials Governance Framework
- National Statement on Ethical Conduct in Human Research 2023 | NHMRC
- NHMRC Open Access Policy
- Queensland Health Research Management Policy
- Separation of Employment Policy (H1)
- Gender Equity Strategy 2022-2025
- QH-POL-266 Workplace Harassment Policy
- QH-POL-228 Sexual Harassment Policy
- QH-POL-101 Anti-discrimination, human rights, and vilification Policy
- Travel Policy
- QH-POL-226 Seminar and Conference Leave – Within and Outside Australia
- CHQ-POL-20002 Onboarding Policy
- CHQ-POL-24702 Informed Consent
- CHQ-PROC-21004 Intellectual Property Policy
- CHQ-POL-44118 Research Electronic Data Capture (REDCap) Policy
- CHQ-POL-90003 Research Integrity Policy

Supporting documents:

- Standard Operating Procedures for Queensland Health HREC Administrators
- Standard Operating Procedures for Queensland Health Research Governance Officers
- ICH Guidelines for Good Clinical Practice (GCP)
- Guidelines approved under Section 95A of the Privacy Act 1988

- Financial Management Practice Manual.
- Queensland Government General Retention and Disposal Schedule
- The NHMRC Management of Data and Information in Research Guide to the Code
- Separation of Employment Procedure
- NHMRC Statement on Consumer and Community involvement in Health and Medical Research
- Health Consumers Queensland
- Australian Clinical Trials Alliance – Toolkit for Researchers and Research Organisations
- ACCESSCR - Clinical Trial Solutions: Demystifying the National Clinical Trials Governance Framework for Health Consumers
- Patient-Centered Outcomes Research Institute
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders
- Keeping research on track II 2018.
- Guidelines to Counter Foreign Interference in the Australian University Sector
- Guidelines for Ethical Research in Australian Indigenous Studies 2012
- Queensland Health Aboriginal and Torres Strait Islander Cultural Capability Framework 2010-2033
- NHMRC Road Map 3: A strategic framework for improving Aboriginal and Torres Strait Islander health through research
- Aboriginal and Torres Strait Islander Health Equity Strategy 2022-2025.
- Australian Institute of Aboriginal and Torres Strait Islander Studies Research Ethics Committee
- NHMRC Dissemination and communication guide
- NHMRC Publication and dissemination of research guide
- Domestic travel
- Overseas travel
- CHQ Employee Complaints Management Framework.
- CHQ Board Research Committee Terms of Reference
- CHQ Financial Delegations Framework
- CHQ-PROC-90035 Research Grants and Funding: Application, Administration and Financial Management
- CHQ-PROC-21005 Intellectual Property Procedure
- CHQ-FW-26500 Contract Management Framework.
- CHQ-PROC-90009 Ethical and Scientific Review of Human Research Procedure
- CHQ-PROC-90008 Site Specific Assessment and Authorisation of Research
- CHQ-WI-90032 Personal Safety for Research Home Visits Work Instruction
- CHQ-PROC-22001 Privacy and Confidentiality Procedure.

- CHQ-PROC-44119 Research Electronic Data Capture (REDCap) Procedure
- CHQ-PROC-20005 Corporate Mandatory and Required Training Procedure
- CHQ-PROC-25001 Consumer Engagement
- CHQ-PROC-25003 Consumer Engagement: Applying Consumer Engagement Processes
- CHQ-WI-30600 Consumer Engagement: Remuneration Process
- CHQ-PROC-90005 Publications and Authorship Procedure.
- CHQ-PROC-90006 Research Complaints and Misconduct Procedure
- National Standard Operating Procedures for Clinical Trails, including Teletrials, in Australia
- Centre for Children's Health Research - CHQ-POL-90039 Clinical Research Facility - Centre for Childrens Health Research (CCHR) V2.pdf - All Documents (sharepoint.com)
- Clinical Research Facility - Centre for Children's Health Research (CCHR)

CONSULTATION

Key stakeholders who reviewed this version:

• Senior Manager Research Services and Partnerships • Director of Research • CHQ Human Research Ethics Office • HREC Chair	• Research Governance Officer • Research Grants Officer • Research and Clinical Trials Monitoring and Compliance Office

DEFINITIONS

Term	Definition
Aboriginal and Torres Strait Islander Research	As defined in the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research. Includes all research that impacts or is of particular significance to Aboriginal and Torres Strait Islander peoples, including planning, collection, analysis and dissemination of information or knowledge, in any format or medium, which is about and may affect Indigenous peoples both collectively and individually.
CCHR	Centre for Children's Health Research
CHQ	Children's Hospital Queensland Hospital and Health Service
CHQ Research	All Research conducted at CHQ.
CHQ Researcher	Includes all persons employed or engaged by CHQ (permanent, temporary, casual and honorary) and all persons and third parties acting for, or on behalf of, CHQ (including

	contractors, consultants, students, student supervisors, volunteers) to conduct, or assist with the conduct of, Research or related activities.
CHQ Research Strategy	Children's Health Queensland's *Research Strategy 2023-2025* describes how we will collaborate with strategic partners across government, health, social services, education, research, private and non-government organisations to develop, share knowledge and translate knowledge into practice.
Clinical Research Facility	The Clinical Research Facility (CRF) is located within the CCHR Building and provides a dedicated and safe environment to conduct a wide range of research activities. This multipurpose paediatric research facility provides specialist facilities and equipment and supports an extensive range of research projects and low risk clinical studies, supported by CHQ, and partners with the University of Queensland and Queensland University of Technology.
Code	*NHMRC Australian Code for Responsible Conduct of Research* (2018)
Collaboration	A working relationship between persons or parties who engage in Research together. In this Research Governance Framework 'Collaborator' means a person or entity other than CHQ who engages in a Collaboration with CHQ.
Collaborative Research Agreement	A Research Contract between CHQ and a Collaborator.
Conflict of Interest	A Conflict of Interest exists where a CHQ Researcher has private interests that could improperly influence, or be seen to influence, their decisions, or actions in the performance of their duties as a CHQ Researcher.
DMMP	CHQ-FORM-90013 Data and Materials Management Plan
Ethics (HREC) Approval	All Australian research involving human participants is required to be ethically reviewed and approved by a HREC which is registered with the NHMRC before it can commence.
Foreign Interference	Foreign interference occurs when activities are carried out by, or on behalf of, a foreign actor that are coercive, clandestine, deceptive or corrupting and are contrary to Australia's sovereignty, values and national interests.
GCP	*ICH Guideline for Good Clinical Practice* as adopted by the Therapeutic Goods Administration in Australia
HREC	Human Research Ethics Committee
National Statement	National Statement on Ethical Conduct in Human Research 2023 | NHMRC
NSQHS Standards	National Safety and Quality Health Service Standards
NHMRC	National Health and Medical Research Council
Open Access	NHMRC Open Access Policy is underpinned by the principle that publicly-funded research should be shared openly and at the earliest possible opportunity. Open access is about making research outputs freely available to use and share, which is distinct from simply 'free to read'.

Partnership	A working relationship between persons or parties who work collaboratively together to achieve a common purpose, possibly by generating or sharing research knowledge. Partnerships may involve parties from different sectors, health services, academia, industry, or non-government organisations. In this Research Governance Framework, 'Partner' means a person or party other than CHQ who engages in a Partnership with CHQ.
PICF	Participant Information & Consent Form.
Principal Investigator	The nominated delegate with primary responsibility and accountability for a research project.
Research	An investigation undertaken to gain knowledge, understanding and insight. The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions, and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.
Research Data	Data are facts, observations, or experiences on which an argument, theory or test is based. Data may be numerical, descriptive, or visual. Data may be raw or analysed, experimental, or observational. Research Data includes: • Laboratory and field notebooks. • Primary Research Data (including Research Data in hardcopy or in computer readable form). • Information obtained directly from a person in interview, questionnaire, focus groups, personal and medical histories, demographics, biographies, audiotape, audio visual records, photographs, film. • Clinical, social, or observational information from a source other than the person whose information it is, such as from medical history notes, doctors' notes, surgical notes, carer or relative. • Test responses. • Models. • Information derived from human tissue such as blood, bone, muscle, organ, and waste products, including genetic and radiological information.
Research Contract	All contracts and other agreements to which CHQ is a party and which involve or are related to CHQ Research.
Research Governance (SSA) Authorisation	The Research Governance Office must assess the suitability of all research that is proposed to be conducted at a CHQ site or facility. This process is known as the 'Site-Specific Assessment' (SSA) process. Research must not commence at a CHQ site or facility until the Research Governance Office has provided authorisation.
Research Materials	Physical objects acquired through a process of scholarly investigation from which Research Data may be derived. It may include raw physical materials such as samples or biological material, or physical or digital objects such as artefacts, questionnaires, sound recordings or video. Depending on discipline, primary materials may be considered Research Data, and may be required to be retained if they are required to validate the outcomes of research and defend those outcomes against challenge.
Research Supervisor	CHQ Researchers (who are not Research Trainees) who are involved in the supervision of one or more Research Trainees at CHQ at any time.
Research Trainee	include students and junior CHQ Researchers.

FRAMEWORK REVISION AND APPROVAL HISTORY

Version No.	Modified by	Amendments authorised by	Approved by	Comments
1.0 25/10/2021	Business Manager Research	Director of Research	Executive Director Clinical Services	
2.0 08/12/2022	Business Manager Research	Director of Research	Executive Director Clinical Services	
2.1 18/12/2023	Business Manager Research	Director of Research	Executive Director Clinical Services	
3.0 19/03/2024	Senior Manager Research Services and Partnerships	Director of Research	Executive Director Clinical Services	
3.1	Senior Manager Research Services and Partnerships	Director of Research	Executive Director Clinical Services	
4.0 18/12/2024	Research and Clinical Trials Monitoring and Compliance Officer	Director of Research	Executive Director Clinical Services	Unscheduled review

Key words	Research, framework, research governance, ethics, HREC, grant, clinical research facility, authorship, publication, research integrity, misconduct, consumers, gender equity, students, monitoring, clinical trials, Administering Institution, NHMRC, onboarding research personnel, onboarding, 90038
Accreditation references	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 2023 • Guidelines Approved under Section 95A of the Privacy Act 1988 (2014) • Guidelines under Section 95 of the Privacy Act 1988 (2000) • National Principles of Intellectual Property Management for Publicly Funded Research (2013) • 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) • NHMRC Open Access Policy 2022 (updated November 2023) • Guideline to Counter Foreign Interferences in the Australian University Sector (2021) ISO 9001:2015 Quality Management Systems: (4-10)