Government of **Western Australia**
Child and Adolescent Health Service

CAHS Research Governance Framework

Version 1.0 - August 2025

Perth Children's Hospital and Neonatology | Community Health | Mental Health

Compassion | Excellence | Collaboration | Accountability | Equity | Respect

Version	Version Date	Author	Description
V1.0	19 August 2025	CAHS Research: Senior Leadership Team & CAHS Research Advisory Committee members	Original version

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this disclaimer

Contents

Vision Statement

The vision of the Child and Adolescent Health Service (CAHS) is to improve the health and well-being of children, adolescents, and families through innovative, high-quality research that translates into effective healthcare solutions. We strive to foster an environment where research and clinical practice inform one another to promote better health outcomes across communities.

Purpose, Objective and Scope

The purpose of this Research Framework is to provide a roadmap to developing excellence in paediatric and child health research, that can be translated to support paediatric health policy and service delivery priorities, while ensuring lived experience remains at the forefront of research design and implementation.

This Research Framework applies to all Researchers conducting research at CAHS and aligns with the National Clinical Trials Governance Framework.

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

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

This policy framework recognises research as a core function of CAHS. It promotes a culture of continuous improvement and excellence through research and innovation to help deliver high quality and sustainable clinical care.

Principles

CAHS research is grounded in the following principles:

- **Child and Family-Centred Care:** Research should be designed with the needs and perspectives of children, adolescents, and their families at the core. This includes ensuring that research processes and outcomes are aligned with patient-centred values.

- **Equity and Inclusion:** All research must contribute to reducing health inequities, particularly for vulnerable populations, including those from culturally diverse backgrounds, children with disabilities, and children in low-income or marginalised groups.

- **Collaboration and Partnerships:** Research should be conducted in partnership with other healthcare providers, educational institutions, government bodies, and community organisations. Collaborative research maximizes the potential to innovate and improve outcomes for children and adolescents.

- **Evidence-Based Practice:** Research should aim to improve clinical care by providing high-quality evidence that can be integrated into daily practice. This evidence should be rigorously tested, ethically conducted, and able to inform healthcare delivery.

- **Translational Research:** We commit to advancing research that bridges the gap between discovery and implementation. Research findings should lead to practical, scalable solutions that are implemented into clinical practice or public health initiatives to improve the lives of children, adolescents and their families.

- **Sustainability:** Research initiatives must be sustainable and capable of generating long-term benefits for health services and the community.

Responsible and Ethical Research

This Research Framework is underpinned by the principles of responsible and ethical research outlined in the Australian Code for the Responsible Conduct of Research (2018) and the National Statement on Ethical Conduct in Human Research (2023):

- Honesty in the development, conduct and reporting of research
- Scientific rigour in the development, conduct 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, 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, conduct 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.

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 CAHS. The Code and the National Statement do not incorporate all 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 CAHS Research to be aware of, understand, and comply with the applicable laws, regulations, standards, codes, guidelines, standard operating procedures as well as the relevant CAHS policies and procedures.

Research Engagement and Stakeholder Involvement

Engaging Children, Adolescents, and Families: Meaningful engagement with children, adolescents, and their families is essential to ensure research reflects their needs and preferences.

Community Engagement: Community-based participatory research will be encouraged to ensure that research efforts are grounded in real-world contexts and the voices of those most affected by the issues being studied are heard.

Collaboration with external institutions: Building partnerships with universities, research institutions, and public health bodies to increase access to resources, expertise, and knowledge.

Knowledge Translation: Research outcomes will be disseminated through various channels, including academic publications, presentations, public awareness campaigns through targeted strategies for participants and communities, and through policy briefs for government and healthcare administrators.

Capacity Building and Training

Building Research Capacity: CAHS is committed to developing robust research capacity by providing research training and mentorship opportunities to all clinicians at all levels and career stages, including early-career researchers to senior clinical researchers. This includes workshops, internships, fellowships, early career research funding, collaborative research project opportunities and partnerships.

Professional Development: Ensuring that CAHS staff have ongoing access to training in research methodologies, ethical considerations, consumer involvement in research, how to seek funding and emerging trends in child and adolescent healthcare.

Patient and Family Education: Promoting an understanding of the value of research among children, adolescents, and families, encouraging their participation in research studies and helping them make informed decisions through Consumer and Community Involvement (CCI) programs.

Research Prioritisation and Resource Allocation

Strategic Research Priorities: Research projects and funding decisions will be prioritised based on alignment with CAHS's strategic objectives, the potential to address health challenges within the child and adolescent population, and the capacity to translate findings into meaningful clinical or community-based interventions.

Resource Allocation: Resources (funding, infrastructure, personnel) will be allocated based on the significance of the research questions, feasibility, and potential impact on child and adolescent health outcomes.

Measuring Success and Impact

Outcomes Measurement: Success will be measured through both short-term and long-term indicators, including improvements in child and adolescent health outcomes, adoption of research findings into clinical practice, publications, and translation into policies, guidelines and standard operating procedures.

Continuous Improvement: A system for continuous feedback and improvement will be implemented to assess the effectiveness of research programs, guide future initiatives, and ensure ongoing relevance to the evolving needs of children and adolescents.

The Child and Adolescent Health Service Research Framework sets out a structured approach to conducting impactful research that improves the health and well-being of children and adolescents. By prioritizing collaboration, ethical practices, and meaningful community engagement, CAHS aims to lead the way in evidence-based care and innovation in child health research.

Key Research Roles at CAHS

Role	Responsibilities
CAHS Board	CAHS Strategic Direction
Executive Director of Medical Services	Governance & oversight Tier 2 Authorisation
Area Director Research Director Research Operations	Research Strategic Direction aligned to CAHS Research Governance & Oversight Tier 3 Authorisation
Research Advisory Committee	Provide clinical research advice Review and endorse research processes and procedures
Integrity Research Advisor	Promote the responsible conduct of research Provide advice to those with concerns or complaints about potential breaches of the Code
Human Research Ethics Committee (HREC)	Review Research submissions Approve Research projects
Clinical Trials Sub-Committee	Review Research submissions Provide feedback to HREC
Manager, Clinic D Research	Manage infrastructure for conducting HREC approved research projects
Research Ethics and Governance (REG) Team	Support HREC Support Site Specific Assessment (SSA) Monitor submitted post approval reports
Research Support and Development Unit (RSDU) Team	Support the planning, development and implementation of research

Section 1: Research Grants and Funding

CAHS strives to support our staff and collaborators to attract research funding for work that is aligned with CAHS vision for healthy kids, healthy communities. Additionally, CAHS Research Department staff strive to provide researcher training and development funding opportunities for example, fellowships and scholarships.

The following key principles guide researchers in relation to the application for and management of research funding at CAHS.

- Process applies to CAHS staff and any external collaborators (including The Kids Research Institute Australia employees) who intend to conduct research activity on-site at CAHS, or research work that involves in-kind support from CAHS staff or resources.
- CAHS Research Department staff must be involved in the research grants application process if it is proposed for CAHS to be identified as the grant administering institution, or a partner in a collaborative application.
- Any grant application that involves CAHS staff time or resources (including data) must obtain CAHS sign off. This includes applications that will be submitted by an external collaborator or that are not CAHS-led.
- All grants require a **CAHS Grant Cover Sheet** to be completed.
- Grant support is provided by the CAHS research grants officer and online resources.

Refer to the grant funding procedure and recommended timelines at CAHS Research Support & Development Standard Operation Procedures.

Section 2: Collaborations and Partnerships

CAHS recognises that effective collaborations and partnerships are essential for advancing research to improve child and adolescent health outcomes. Strategic partnerships with universities, research institutes, other healthcare providers, industry stakeholders, and community groups contribute to the sharing of expertise, resources, and knowledge. The governance and management of these collaborations are critical to ensure they align with CAHS research priorities, ethical standards, and values.

Research projects in partnership with CAHS must be aligned with this Framework. For example, CAHS and The Kids Research Institute Australia (The Kids) research projects must adhere to Site Authorisation section below.

Section 3: Research Agreements and Contracts

Research involving CAHS staff, patients, data or biospecimens and involves a collaboration with an external entity must have a research agreement in place. The type of research activity and entities party to the project will determine the type of research agreement required. WA Health standard research agreement templates are preferred, which are based on the Medicines Australia templates.

Research agreements must be submitted to the CAHS RGO for initial review with the site governance submission. The agreement is considered fully executed after all parties provide their signatures and the CAHS CE or delegate signs.

The requirements for research agreements are outlined in the following policies, procedures and guidelines:

- NHMRC: Collaborative research: A guide supporting the Australian Code for the Responsible Conduct of Research (2020)
- WA Health Procedure: Research Governance

Section 4: Research Agreements and Contracts

Ethics Review

Researchers must comply with all ethical review and approval requirements in conducting research in CAHS. Ethics review assesses the ethical and scientific validity of research projects. All research projects conducted at CAHS must have current ethics approval from a National Health & Medical Research Council (NHMRC) certified Human Research Ethics Committee (HREC). The HREC must be either an approved lead HREC under the WA Single Ethical Review scheme or the National Mutual Acceptance (NMA) scheme.

The requirements for ethical review and approval are outlined in the following policies, procedures and guidelines:

- NHMRC: National Statement on Ethical Conduct in Human Research
- NHMRC: Australian Code for the Responsible Conduct of Research
- ICH: Guideline for Good Clinical Practice
- NHMRC: Ethical conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities and Keeping Research on Track II
- CAHS Policy: Research
- CAHS Policy: Investigator Responsibilities – Research
- CAHS Standard Operating Procedures for Approval of Research
- WA Health Policy: MP 0162/21 - Research Governance
- WA Health Procedure: Research Governance

Site Authorisation

Researchers must comply with all Site Authorisation requirements when conducting research at CAHS. This includes compliance checks which aim to protect the participant, researcher and the organisation from risk and ensure compliance with legal, contractual, financial and regulatory requirements, including insurances, indemnities and HREC approval.

CAHS supports collaborative research with other institutions. Research can involve a wide range of collaborations within institutions and between institutions, both nationally and internationally. Researchers involved in joint research projects across institutions must ensure that a research agreement is established for each collaboration.

The requirements for Site Authorisation are outlined in the following policies, procedures and guidelines:

- CAHS Policy: Research
- CAHS Policy: Investigator Responsibilities – Research
- CAHS Standard Operating Procedures for Approval of Research
- WA Health Policy: MP 0162/21 - Research Governance

- WA Health Procedure: Research Governance
- WA Health Policy: Intellectual Property Policy

Other legislation, regulations, guidelines, codes and policies may be required to conduct research. Researchers are responsible for ensuring all approvals, licences and/or permits are in place prior to the commencement of research.

Research projects can commence at CAHS when a site authorisation letter is issued to the Coordinating Principal Investigator or Principal Investigator.

Section 4: Research Data & Materials

This section provides guidance on the appropriate generation, collection, access, use, analysis, disclosure, storage, retention, disposal and sharing of Research Data and Materials at CAHS.

The requirements for Research Data & Materials are outlined in the following policies, procedures and guidelines:

- CAHS Policy: Investigator Responsibilities – Research
- CAHS Policy: Clinical Documentation
- CAHS Policy: Confidentiality, Disclosure and Transmission of Health Information
- CAHS Policy: Abbreviations for Clinical Documentation
- CAHS Policy: Information Breach Response
- CAHS Policy: Asset Management
- CAHS Policy: Clinical Registries
- CAHS Policy: Hazardous Chemicals and Dangerous Goods Management
- CAHS Policy: Medical Equipment Management
- CAHS Policy: Waste Management
- WA Health Policy: Information Management

Section 6: Monitoring of Research Compliance

Independently monitoring an active research project is an internal mechanism for ensuring the quality of research data and the safety of all participants at CAHS.

For all research projects being monitored, the CAHS monitor should:

- continuously review annual or ad hoc reports submitted by the research investigator.
- periodically check compliance if the expected reports were received.
- if applicable, perform a monitoring visit or audit, after a risk assessment has been performed identifying the high-risk areas to focus on.
- If applicable, any serious breaches regarding research integrity or against research protocol is discussed with the Integrity Research Advisor. Refer to Section Research Integrity and **CAHS Managing Potential Breaches - Research Conduct Procedure**.

The requirements for monitoring of research compliance are also outlined by the policies listed in the Site Authorisation section, as well as the following frameworks, policies and procedure.

- CAHS Monitoring research compliance standard operating procedures.
- The National Clinical Trials Governance Framework (NCTGF) standards

Section 7: Research Personnel

Research personnel are required to comply with all relevant CAHS policies and procedures relating to the conduct of research and proportionate to their role.

Section 8: Partnering with Consumers

CAHS Research Department staff are recognised that consumers offer unique and valuable insights across the research life cycle, helping to frame research, conduct research and to translate research outcomes to help ensure research quality and relevance. We recognise that there are various levels and stages of involvement including as part of governing boards, research advisory groups, investigators, and research buddies. (NHMRC 2016 Consumer and Community Involvement)

CAHS commitment to consumer engagement is demonstrated to through the Consumer Engagement Strategy which describes our commitment to partnering with consumers in how we plan, design and deliver our services to ensure they better meet the needs of our children and young people." Consumer involvement in research is guided by the Research Strategy objective to "Engage with partners and consumers in planning and conducting research".

CAHS Research Department staff are committed to building capacity of researchers in their engagement with consumers by providing access to Consumer and Community Involvement (CCI) scholarships for professional development. Additionally, resources such as the CCI bank are available to facilitate meaningful consumer partnerships throughout the research process.

The requirements for research involving Partnering with Consumers are outlined in the following policies, procedures and guidelines:

- CAHS Policy: Consumer Involvement in Healthcare Design and Management
- CAHS Policy: Consumer Representative Recruitment and Management
- The National Clinical Trials Governance Framework (NCTGF) standards

Refer to CAHS Research Support & Development Standard Operation Procedures.

Section 9: Diversity

Research involving Aboriginal and Torres Strait Islander peoples and Culturally and Linguistically Diverse group (CALD) must be underpinned by a strong commitment to ethical practices that respect cultural values, knowledge systems, and the rights of these communities.

CAHS research projects involving Aboriginal and Torres Strait Islander & CALD communities must:

- Be reflective of the needs of the community
- Show respect for cultural protocols of the community
- Directly benefit the community
- Incorporate and promote cultural safety

Aboriginal and Torres Strait Islander peoples

Acknowledging the historical and ongoing impacts of colonisation, research must prioritise collaboration, respect, and cultural safety throughout all stages of the research process. Engaging Aboriginal and Torres Strait Islander people in research is not only a legal and ethical obligation but also a key to fostering mutual trust and promoting beneficial outcomes for these communities.

Approval from the Western Australia Aboriginal Health Ethics Committee (WAAHEC) is required when CAHS research projects involve research in, or in relation to, Western Australia. Refer to Western Australian Aboriginal Health Ethics Committee – AHCWA website for these mandatory requirements.

The following framework, policies, procedures and guidelines, are also available as a reference, if involving Aboriginal and Torres Strait Islander peoples**:**

- WA Aboriginal Health and Wellbeing Framework 2015-2030 identifying key guiding principles.
- NHMRC Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders 2018 and Keeping Research on Track II
- AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research
- The National Clinical Trials Governance Framework (NCTGF) standards

Section 10: Research Impact & Translation

CAHS recognise the importance to drive health and medical health translation into health-related policy and practice to ensure we remain at the forefront of improved clinical care and health service enhancements for children and adolescents. This commitment to research impact and translation is integral to our mission and underpins the strategic objectives of our health service.

CAHS Research commitment is demonstrated through the Research Strategy objective to "d*evelop mechanisms that capture and measure the value, impact and translation of research at CAHS*" to guide future activity which aligns with genuine value to the health service, child health outcomes and consumer experience.

Section 11: Research Integrity

Research that is conducted with integrity is carried out by researchers with a commitment to:

- searching for knowledge and understanding
- following recognised principles of research conduct
- conducting research honestly
- disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding

Research must be designed, conducted and reported in accordance with

- NHMRC: Australian Code for the Responsible Conduct of Research
- CAHS Policy: Research
- CAHS Policy: Investigator Responsibilities – Research
- CAHS Policy: Managing Potential Breaches – Research Conduct

Section 12: Clinical Trials Governance (NCTGF)

CAHS Managers (Clinical or non-clinical) should ensure well-designed and integrated systems are in place to provide a high-quality clinical trial service provision. This may include systems and processes to:

- Advise and inform the governing body on matters related to clinical trial services.
- Integrate quality clinical trial service provision into organisation plans, policies and procedures relevant to clinical trial service provision.
- Support clinicians who embrace clinical trial leadership roles.
- Ensure patient and consumer rights are reflected in all aspects of clinical trial service provision.

The requirements for Clinical Trials Governance are outlined in the National Clinical Trials Governance Framework (NCTGF) standards.

This document can be made available in alternative formats on request.

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Healthy kids, healthy communities

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