POLICY

Research Policy

Scope (Staff):	All employees, visitors, contractors, students, agents, or volunteers
	who seek to conduct research at CAHS.
Scope (Area):	CAHS (CACH, CAMHS, PCH and Neonatology)

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

<u>DOHWA Research Policy Framework</u>

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Equity

Aim

This policy provides guidance and direction to researchers, regarding the Child and Adolescent Health Service's (CAHS) expectations of researchers when conducting research activity at a CAHS facility or where research work involves CAHS resources.

Risk

The risk of not complying with this framework, include:

- Increased risk of patient/client/participant harm.
- Non-compliance with legislation and WA Health Department policy.
- Risk of legal claims including trespass to the person (assault and battery) and/or negligence.
- Damage to CAHS' reputation.

Definitions

Definitions		
CAHS	Child and Adolescent Health Service, which includes the Perth Children's Hospital and all CAHS community and remote sites.	
Good Quality Research	Research that provides evidence that is robust, ethical, and stands up to scrutiny. It adheres to the NHMRC principles of honesty, rigour, transparency, fairness, respect, recognition, accountability, and promotion.	
HREC	Human Research Ethics Committee is a body established in accordance with Chapter 5.1 of the National Statement that conducts the ethical review of a research project.	
NHMRC	National Health and Medical Research Council is a national organisation who provides a framework for research integrity and development.	
Research	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.	

Researcher	A researcher is a staff member, student, contractors, visitor or agent of any organisation that participates in the conduct of research.
RGS	The Research Governance Service is a centralised IT system for investigators, project members, sponsors, site administrators, Human Research Ethics Committees and Research Governance Offices.
Site Authorisation	Site authorisation 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 and indemnities.

General Principles for the conduct of research within CAHS:

 CAHS recognises that good quality research supports and improves services for patients/clients, research participants and the community, with the intention of improving their health and wellbeing.

1. Code of conduct

1.1 Australian Code for the Responsible Conduct of Research

- Aligning research activity with the <u>CAHS values</u>, research is to be conducted within the eight principles of responsible research conduct as detailed in the <u>Australian Code for the Responsible Conduct of Research</u> ("the code") as it relates to:
 - o Authorship
 - Collaborative research
 - Disclosure of interests and management of conflicts of interest
 - Managing and investigating potential breaches of the code
 - Management of data and information in research
 - o Peer review
 - Publication and dissemination of research
 - Supervision
 - Research Integrity Advisors
- These activities should also be performed in conjunction with the CAHS policies:

- o Publications
- Management of Conflicts of Interest
- Confidentiality Disclosure And Transmission Of Health Information
- Investigator Responsibilities

1.2 Breaches to the Australian Code for the Responsible Conduct of Research

- A breach is defined as a failure to meet the principles and responsibilities of <u>the code</u>. These breaches include, but are not limited to:
 - Not meeting required research standards
 - o Fabrication, falsification, misrepresentation of research data
 - Plagiarism
 - Failure to appropriately maintain research data
 - Failure to provide adequate guidance or supervision to research staff or trainees under their supervision
 - Misleading ascription of authorship including failing to offer authorship to those who qualify or awarding authorship to those who do not meet the requirements
 - Failure to disclose and manage conflicts of interest
 - Failure to conduct peer review responsibly
- Any researcher that has is suspected to be in breach of the code will be investigated by the CAHS HREC and CAHS Governance Office in accordance with the <u>Guide to Managing and Investigating Potential Breaches of the</u> <u>Australian Code for the Responsible Conduct of Research</u>. The findings of the investigation will be reported to the CAHS Executive Board for review and response.

2. Investigator Responsibilities

CAHS requires researchers who are conducting research at CAHS to have, the
appropriate qualifications and training; approvals, appropriate system access;
engagement with community; research administrative and financial oversight;
and acknowledgment of CAHS contribution in research publications; as outlined
in the Investigator Responsibilities (Currently being written)

3. Ethical Review of Research

 All research involving humans must have human research ethics approval prior to commencement of research. To be considered for CAHS ethical approval, all projects must align to the NHMRC <u>National Statement on Ethical Conduct in</u> <u>Research Involving Humans</u> and CAHS <u>Human Research Requests for</u> <u>Approval policy.</u> Researchers must abide by the conditions of approval and notify the CAHS
HREC of any deviation from, or violation of, the study protocol, to ensure the
appropriate ethical integrity of the research can be monitored and maintained.

4. Research Governance

- All research projects that are to be conducted at CAHS must be submitted for site approval via the WA Health Research Governance Service (<u>RGS</u>) system. Research projects cannot commence at a CAHS site until a site authorisation letter is issued to the Coordinating Investigator.
- Any deviation from, or violation of, the study protocol, must be reported to the Research Governance Coordinator so that site authorisation can be reconsidered.

5. National Clinical Trials Governance Framework (NCTGF)

Any research conducted at CAHS must be compliant with the <u>NCTGF</u>, a
nationally consistent approach to the accreditation of health services for the
conduct of clinical trials which outlines the requirements for clinical trials
governance in terms of clinical governance and consumer partnerships.

5.1 Clinical Governance

 CAHS promotes the integration of human research activities into routine healthcare delivery. CAHS supports research that enables the public health system to adapt to the changing health needs and requirements of the community which improves health outcomes.

5.2 Partnering with Consumers

 CAHS is committed to partnering with its consumers to help shape research by the people who will benefit from it the most. Researchers are encouraged to seek a wide range of participation from community members for involvement at the proposal, protocol design, and participation stages of a research project.

5.2.1 Community engagement

 Observing the CAHS <u>Consumer Engagement Strategy</u>, researchers should seek input from the patients/clients, participants, parents, and carers who will be most affected by research advancements. All consumer engagement at CAHS, regardless of affiliation, must comply with the CAHS <u>Consumer</u> <u>Representative – Recruitment and Management policy.</u>

5.2.2 Language and cultural services

 Language and cultural barriers should not limit the consumer contribution or participation in CAHS research. Researchers are encouraged to engage with the PCH Language Service for assistance with interpreters, translators, and cultural liaison officers. The use of these services should comply with the <u>CAHS</u> <u>Language Service Policy</u> and <u>WA Health System Language Services Policy</u>. References and related external legislation, policies, and guidelines (if required)

Australian Code for the Responsible Conduct of Research

DOHWA Research Policy Framework

Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research

National Statement on Ethical Conduct in Research Involving Humans

National Clinical Trials Governance Framework

Related CAHS internal policies, procedures and guidelines

CAHS values

<u>Confidentiality Disclosure And Transmission Of Health Information</u> (CAHS Policy Manual)

Consumer Representative – Recruitment and Management (CAHS Policy Manual)

Human Research Requests for Approval (CAHS Policy Manual)

<u>Investigator Responsibilities</u> (CAHS Policy Manual)

Management of Conflicts of Interest (CAHS Policy Manual)

Managing Potential Breaches – Research Conduct (CAHS Policy Manual)

Language Service Policy (CAHS Policy Manual)

Publications (CAHS Policy Manual)

Useful resources (including related forms) (if required)

Consumer Engagement Strategy

Research Governance Service (RGS)

WA Health System Language Services Policy

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

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Healthu kids, healthu communities					

Healthy kids, nealthy communities Excellence Collaboration Accountability

Compassion

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