POLICY

Investigator Responsibilities – Research

Scope (Staff):	All employees, visitors, contractors, students, agents, or volunteers who seek to conduct research at CAHS
Scope (Area):	All 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 the
DOHWA Research Policy Framework

Contents

Aim

This policy provides guidance, instruction, 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.
Coordinating Investigator	(Or Principal Investigator for a multi-site project). The individual that takes overall responsibility for the research project including the ongoing communication with the HREC.
GCP	Good clinical practice (GCP) is the international standard for conducting clinical research. It provides a framework for ensuring participant's rights, safety, and well-being are protected and the data generated is credible.
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.

ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.
Medical Researchers	Any researcher that holds a clinical position which requires an accredited medical qualification. (E.g., Nurse, Physiotherapist, Medical Doctor).
National Clinical Trials Governance Framework (NCTGF)	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.
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 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.
Serious Adverse Event (SAE)/ Serious Adverse Reaction (SAR)	Any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect
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.

Sponsor	The sponsor of a clinical trial is defined as 'an individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study'.
Sponsor Investigator	A Coordinating Investigator who has initiated the research study and fulfills some or all of the role of the Sponsor for the study as delegated by the institution.

Principles

- 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.
- Aligning research activity with the CAHS values, research is to be conducted within the eight principles of responsible research conduct as detailed in the Australian Code for the Responsible Conduct of Research ("the code") and the principles of the National Statement on Ethical Conduct in Human Research ("national statement"), and WADOH Code of Conduct policy.
- CAHS requires researchers who are conducting research at CAHS to have the appropriate:
    - Qualifications and training
    - Approvals, including but not limited to research ethics and site-specific approval
    - Level of system access, including the accessing of patient records, pharmaceuticals, and equipment & devices.
    - Engagement with community
    - Research administrative and financial oversight
    - Acknowledgment of CAHS contribution in research publications

1. Roles and Responsibilities

1.1 Researchers

- Researchers must ensure that their research conduct and practice reflects the principles and responsibilities as set out in the Code. It is also the responsibility of researchers to ensure they comply with the CAHS Research Policy Framework and retain the necessary training and systems access. At all times, Researchers must fulfil the roles and functions as defined in the Clinical Trials Governance Framework,

1.2 Coordinating Investigators

- The Coordinating Investigator is responsible for ensuring that their research activity is compliant with the requirements of the CAHS Research Policy and the National Standard Operating Procedures for Clinical Trial. Coordinating Investigators must also ensure the members of their research team are made aware of this policy and subsequent procedures.

1.3 Principal Investigators

- A Principal Investigator holds the same responsibilities as a Coordinating Investigator for the site that they are conducting the multi-site research.
- When a teletrial is being conducted, the principial investigator will hold the Coordinating Investigator responsibilities for the primary AND satellite sites involved in the teletrial.

1.4 Sponsor Investigators

- The Sponsor-Investigator fulfils the responsibilities of both Sponsor and Coordinating Investigator as per the Therapeutic Goods Administration (TGA) ICH Guidelines for Good Clinical Practice (GCP). In addition to the Coordinating Investigator duties, a Sponsor Investigator is responsible for generating clinical trial documentation; ensuring adequate resources are available for the duration of the trial; and creating appropriate written procedures relevant to the trial.

2. Conflicts of Interest

- A conflict of interest exists where there is a real, or perceived view, that a person is able to derive personal benefit from the actions or decisions they make in their official capacity. To manage conflicts of interests, all researchers must act in accordance with the Australian Code for the Responsible Conduct of Research (2018) and disclose any relevant interests in writing to the CAHS Research Department before you are granted full access to applications that are assigned to you.

2.1 Dual Positions

- All researchers who have an outside employment arrangement, either paid or unpaid, with an organisation that is not CAHS, must declare this as a conflict of interest. The researcher is responsible for completing the CAHS COI registry and Additional/Secondary Employment (D18) form to gain the necessary approval before commencing research. Researcher must ensure they manage these dual research interests with a clear and written agreement on ownership of data and samples, intellectual property, commercialisation etc.

3. Approval of research

- Researchers should also refer to the CAHS Research Standard Operation Procedures when conducting clinical trial activity, which outlines the following:

3.1 Ethical approval

- All research involving humans must have human research ethics approval prior to commencement of research. Applications must be submitted via the WA Health Research Governance Service (RGS) system. To be considered for CAHS ethical approval, all projects must comply with the following:
  - The NHMRC's National Statement on Ethical Conduct in Human Research
  - The Australian Code for the Responsible Conduct of Research
  - Therapeutic Goods Administration (TGA) ICH Guideline for Good Clinical Practice
  - WA Health Research Governance Policy and Procedures
  - The NHMRC's Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities and Keeping research on track II
  - CAHS Standard Operational Procedures for the approval of research
- 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.

3.2 Site authorisation

- All research projects that are to be conducted at CAHS must be submitted for site approval via the WA Health Research Governance Service (RGS) system. Research projects cannot commence at a CAHS site until a site authorisation letter is issued to the Coordinating Investigator.
- To be considered for site authorisation, all projects must comply with the following:
  - Intellectual Property Policy
  - Research Governance Policy
  - WA Health Research Governance and Single Ethical Review Standard Operating Procedures
- Any deviation from, or violation of, the study protocol, must be reported to the Research Governance Coordinator so that site authorisation can be reconsidered.

3.3 Other approvals

- 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.

4. Researcher competency

- It is the responsibility of the administering research organisation, to ensure that researchers have the appropriate skills and qualifications needed to conduct and promote safe and responsible research. Training aims to ensure that the rights, safety, and well-being of human subjects are protected and that clinical trials are conducted in accordance with rigor and integrity.

4.1 PCH Clinic D – Research

- The CAHS research clinic at PCH is a dedicated research outpatient clinic used for clinical research. All researchers conducting research in clinic D must be up-to-date with their research competencies and attend a Clinic D orientation before they are granted access to the research clinic and its facilitates.

4.2 Statutory Registration

- All medical researchers must have current registration with the appropriate statutory registration authority as per the Health Practitioner Regulation National Law (WA) Act 2010.

4.3 Health Screening

- Researchers who conduct research in a clinical area, or have direct interaction with research participants and their families, must ensure that all requirements for health screening and immunisation have been met as per the CAHS Healthcare Worker Immunisation and Health policy.

4.4 Working with Children Check

- Researchers who are engaged in child-related research, or who are conducting research in a CAHS clinical area, are required to complete a Working with Children Check as per the Criminal Record Checking Act 2004.

4.5 Good Clinical Practice (GCP) training

- The GCP guideline outlines the researcher responsibilities, participant consent, documentation, protocols and amendments, requirements such as indemnity, reporting lines for adverse events and provision of medical care for trial participants. CAHS expects that all researchers have undertaken and demonstrated competency in Good Clinical Practice (GCP) training before the commencement of research activities.

4.6 Mandatory and essential training

- All researchers are expected to complete the mandatory and essential training outlined in the Mandatory and Core Requirement Training Framework, as it relates to the researcher's job requirements.

- Comparable training provided by external organisations may meet CAHS requirements, provided it is approved by the CAHS Learning and Development team and that the researcher can prove subject competency.

5. Information Management

- Access to research systems and patient/client and participant data is granted to researchers who have currency of research competency; have fulfilled the relevant safety requirements; and have been granted the appropriate authorisation from CAHS, the Chief Investigator, and the researcher's affiliated organisation.

5.1 Access to Patient medical records (transitioning to digital)

- Formal authorisation is required before researchers access medical records. Investigator Coordinators are responsible for ensuring their research staff complete a PCH Medical Records Form Request and forward to the CAHS Health Information Administration Service (HIAS).
- To access client data from Child and Adolescent Community Health a Data Request form will need to be completed and submitted via the Business Intelligent Unit.
- All researchers must abide by the CAHS Health and Medical Record Management and WA health Information, Access, Use and Disclosure policies.

5.2 Recording research participation in medical records

- If a research study or clinical trial forms part of, or may impact, a patient/client's clinical care, then the participation must be recorded in the Digital Medical Record (DMR) as per the DMR – Recording Research Participation work instruction.
- If a research study or clinical trial relates to Child and Adolescent Community Health services, please email CommunityHealthResearch@health.wa.gov.au for requirements of recording participation.

6. Medications

6.1 Provision of medications

- Medication must only be prescribed and dispensed by authorised staff in accordance with the PCH Medication Administration policy and Medication Preparation, Checking and Administration policy. Authorised personnel must be compliant with CAHS research competency requirements as outlined in section 4 of this Investigator Responsibilities procedure.

6.2 Medication chart administration

- Any medication that is administered to a participant, either within a CAHS clinical area or the dispensing of medication for home use, must be recorded into the participant's medical records by an authorised staff member. Researchers and authorised staff must ensure they are familiar, and work in compliance, to the Medication Preparation, Checking and Administration policy.

7. Financial Administration

- Research that is being conducted at a CAHS site, or with the collaboration of a CAHS staff member, is expected to be administered under governance frameworks which ensure integrity, accountability, and good conduct. CAHS holds the right to reject a research proposal or any research funding from organisations that do not align with the CAHS values.

7.1 Approval of funding requests

- To attract research funding that is aligned with CAHS' vision for "healthy kids, healthy communities", researchers who intend to conduct research activity on-site at CAHS, or research work that involves in-kind support from CAHS staff or resources, must seek approval from the CAHS Executive through the grant submission approval process.
- The research must align to CAHS strategic objectives, values, and research priorities. The project must also reflect high quality research and demonstrate the intention of improving the health and wellbeing of research participants, CAHS patients/clients, and the WA community.

7.2 Research finances

- Coordinating Investigators are responsible for appropriate expenditure of research monies. For research grants and contracts that are administered in CAHS, the Coordinating Investigator must ensure expenditure is in compliance with the WA DOH Financial Management Model under section 535 of the Standard Model for Managing Clinical Research (a financial model for managing research funds which provides a uniform method to account for clinical research funds that are collected and spent within WA Health), and the conditions of the funding body.
- Where the research funding is administered by a non-WA Health organisation, researchers must ensure appropriate governance of financial activity and operate in accordance with the administering organisation's financial policy and the WA Financial Management Act 2006

7.3 Grant acquittal and reporting

- It is the responsibility of the Coordinating Investigator to ensure that study milestones and reporting requirements are completed in line with the funding agreement. The information provided must be accurate, timely, auditable and adhere to the WA Health Financial Management Policy Framework.

8. Community engagement

- CAHS promotes research that is enriched by the experience, interests, and needs of the community. 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.

8.1 Consumer Engagement

- CAHS is committed to partnering with its consumers to help shape research by the people who will benefit from it the most. Observing the CAHS Consumer Engagement Strategy, researchers should seek input from the patients, participants, parents, and carers who will be most affected by research advancements.
- All consumer engagement should be sought in a structured manner, with CAHS researchers utilising the CAHS consumer engagement department. Researchers with external affiliations are permitted to use their organisation's consumer networks, however all consumer engagement at CAHS, regardless of affiliation, must comply with the CAHS Consumer Representative – Recruitment and Management policy.

8.2 Language and cultural services

- Language and cultural diversity should not be a barrier to 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 CAHS Language Service Policy and WA Health System Language Services Policy.

9. Data and reporting

9.1 Data Management

- Researchers are accountable for the security of information and trial data. Researchers are required to comply with the WA Health's Information Management Governance Policy and the NHMRC's Management of Data and Information in Research which govern the collection, use, storage, retention, disclosure and destruction of research information.

9.2 Safety Monitoring

- The sponsor is responsible for establishing the process by which safety of participants will be monitored during a trial. The monitoring process is based on the risk, size, and complexity of the trial. Where there is a Sponsor-Investigator, the Coordinating Investigator will be responsible for the trial's safety monitoring, as per the NHMRC Safety and Monitoring Guidelines. All Safety Reports required for ethical review are to be submitted online via the RGS..

9.3 Serious and Adverse Event reporting

- Serious and Adverse events that occur as a result of a research study must be reported as per *Procedure 304 - Safety and Adverse Event Reporting*, in the Standard Operational Procedures for the Approval of Research.

10. Publications and Authorship

- CAHS encourages researchers to publish their research findings to help in the advancement of scientific knowledge, research applications, and translation to

clinical practice. Researchers should ensure that the privacy and confidentiality of participants is protected in any publication, as stated in the National Statement.

10.1 Authorship

- Any individual who has made a significant intellectual or scholarly contribution to research and its output and agrees to be listed as an author, must be recognised as an author on the research publication. The description for a significant intellectual or scholarly contribution are defined in the Authorship Guide in the code.

10.2 CAHS Recognition

- All publications resulting from research conducted by CAHS staff, at a CAHS site, or using CAHS resources, must include “The Child and Adolescent Health Service” in the publication by-line and be compliant with the CAHS Publication policy.

11. Clinical trials

11.1 Standards

- Any clinical trials conducted at CAHS must be compliant with the National Clinical Trials Governance Framework.
- Clinical Trials must be conducted in line with the National Clinical Trial Standard Operations Procedures or an equivalent standard.

11.2 Clinical Trial Notification (CTN)

- It is the sponsor’s responsibility to ensure that an authorised Clinical Trial Notification (CTN) has been submitted to the TGA before the clinical trial commences. For CAHS-Sponsored Investigator Initiated clinical trials, this responsibility sits with the Principal Investigator.

11.3 Insurance

- Clinical Trials must have adequate insurance to cover injury of participants should it occur. Investigator Initiated trials, and those sponsored by collaborative or not-for-profit groups, are covered by the Insurance Commission of Western Australia.
- Commercially sponsored trials must have insurance provided for the entire trial and six years after, to cover any late claims or side effects. A valid insurance certificate will be assessed as part of the site-specific application (SSA). The principal investigator must ensure updated versions of the certificate (i.e. in the case of annual policies) are kept in the study file, as necessary.

References and related external legislation, policies, and guidelines *(if required)*
Australian Code for the Responsible Conduct of Research
Authorship Guide
Clinical Trial Notification (CTN)
Criminal Record Checking Act 2004
Research Policy Framework (WA DOH Policy)
Financial Management Act 2006
Health Practitioner Regulation National Law (WA) Act 2010
Healthcare Worker Immunisation Policy (WA DOH Policy)
Information, Access, Use and Disclosure (WA DOH Policy)
Intellectual Property(WA DOH Policy)
Management of Data and Information in Research
NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods 2016
National Statement on Ethical Conduct in Human Research
Research Governance Framework
Research Governance Service
RGS Progress Reporting requirements
TGA: ICH Guideline for Good Clinical Practice (GCP)
WA Financial Management Act 2006
WA Health Research Governance and Single Ethical Review Standard Operating Procedures
WA Health System Language Services Policy

Related CAHS internal policies, procedures and guidelines
CAHS Code of Conduct
CAHS Conflict of Interest
CAHS HREC Terms of Reference
CAHS SOP for the approval of research
Clinic D orientation
Consumer Engagement Strategy 2020-2022
Consumer Representative – Recruitment and Management (CAHS Policy Manual)
DMR – Recording Research Participation work instruction.
Financial Management Model
Grant submission approval process
Health and Medical Record Management (CAHS Policy Manual)
Language Services (CAHS Policy Manual)
Managing Potential Breaches (CAHS Policy Manual)
Mandatory and Core Requirement Training (CAHS Framework)
Medication Administration (PCH Medication Management Manual)
Medication Preparation, Checking and Administration Guideline (PCH Medication Management Manual)
Medication Prescribing and Administration Policy (WACHS Policy)
Medication Administration (PCH Medication Management Manual)
Publications (CAHS Policy Manual)
Research Policy (CAHS Policy Manual)
Research Governance (WA DOH Policy)
Standard Model for Managing Clinical Research

Useful resources (including related forms) *(if required)*
Additional/Secondary Employment (D18) form
CAHS Grant Coversheet
Consumer Representative - Recruitment and Management Guideline
Good Clinical Practice (GCP) training
Grant submission approval process
PCH Medical Records Form Request
Working with Children Check
Working with Consumers and Carers Toolkit

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

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