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

Standard Operational Procedures for the Approval of Research

Compassion
Accountability
Excellence
Equity
Collaboration
Respect

December 2024

Contents

INTRODUCTION

This document provides employees of the Child & Adolescent Health Service (CAHS) and other external research colleagues, including students, the requirements for ethics review and approval of research involving human participants within CAHS. This document outlines the responsibilities and functions of the various stakeholders involved in research. It is designed to promote good practice, ensuring that CAHS complies with the Australian Code for the Responsible Conduct of Research, 2018 ('the Code') and the National Statement on Ethical Conduct in Human Research 2023 (National Statement).

CAHS HUMAN RESEARCH ETHICS COMMITTEE

To assess the scientific and ethical integrity of proposed research, and monitor its ongoing conduct, CAHS has an established Human Research Ethics Committee (HREC), which is registered with the National Health and Medical Research Council (NHMRC). The primary purpose of the HREC is to protect the welfare and rights of participants in research.

The composition of the HREC is in accordance with the National Statement Section 5.1.30.

The operation of the HREC is governed by *CAHS HREC Terms of Reference (2023)* and the terms set out by the NHMRC in the National Statement.

The CAHS HREC is an NHMRC-registered HREC (EC00268).

CAHS HREC is registered as an Institutional Review Board (IRB) with the Office of Human Research Protections (OHRP) and CAHS possesses a Federal Wide Assurance (FWA). Both the IRB registration and FWA are renewed on a regular basis as required by the US authorities. Details of the FWA number and IRB registration number are available from the CAHS REG office on request.

NATIONAL MUTUAL ACCEPTANCE

The National Mutual Acceptance (NMA) scheme involves all public health organisations across all Australian states, including Western Australia. Multi-centre research projects being conducted at public health organisations can be reviewed only once by a NHMRC Certified Lead HREC participating in the NMA Scheme.

The CAHS HREC is a certified 'Lead HREC' under the National Mutual Acceptance Scheme.

WA HEALTH RESEARCH GOVERNANCE FRAMEWORK

The WA Health Research Governance Framework (Policy and procedures) outlines how single and multi-centre research at WA Health sites is to be conducted. All human research conducted in WA Health must undergo ethics and scientific review by a HREC registered with the NHMRC and operating in accordance with the National Statement. In addition, all research projects must undergo site authorisation at each WA Health site at which it is to be conducted. Both ethics and site approval are required before a project can commence.

Research governance is a framework through which the institution is accountable for the scientific quality, ethical acceptability and safety of the research they sponsor or permit. It is a risk management activity that facilitates standards of research practice and allows for a more detailed and institutionally relevant review of research applications.

The Research Governance Office (RGO) provides an independent systematic evaluation of research applications, which ensures the safety, and minimises the risk, for the patient, the researcher and the institution.

OTHER REQUIRED APPROVALS

Research involving certain groups or types of data may require approval from other entities prior to it being able to commence. In WA these include the following:

Aboriginal or Torres Strait Islander Peoples

Research that involves Aboriginal or Torres Strait Islander participants must also be submitted to the WA Aboriginal Health and Ethics Committee (WAAHEC). Research should be submitted to WAAHEC if one or more of the following apply:

- Indigenous status is a key determinant
- Data collection is explicitly directed at Indigenous peoples
- Indigenous people, as a group, will be examined in the results
- The information or outcomes may have an impact on one or more Indigenous communities
- Indigenous health funds are a source of funding.

Information about this committee and necessary forms can be obtained from https://www.ahcwa.org.au/ethics

WA Health Data Collections

Research that requires access to WA Health data collections and/or involves data linkage should also be submitted to the DoH HREC. Information about the committee and necessary forms can be obtained from the following sites:

Application Forms - Data Linkage WA (health.wa.gov.au)

Department of Health Human Research Ethics Committee

REGISTRATION OF CLINICAL TRIALS

The Clinical Trials Sub-Committee (CTS) at CAHS reviews projects involving a clinical trial or intervention prior to HREC meetings. The CTS will assess the scientific merit and integrity of clinical trials/intervention studies as per the National Statement and provide expert advice to the CAHS HREC for consideration.

The composition of the CTS will include members from varied and experienced scientific and clinical backgrounds. The *CAHS CTS Terms of Reference 2023* govern the operation of the CTS.

The International Committee of Medical Journal Editors (ICMJE) member journals require registration in a public trials' registry as a condition of consideration for publication.

To be eligible for publication, trials must register at or before the onset of patient enrolment.

Registries recognised by ICMJE include:

- Australian New Zealand Clinical Trials Registry
- Clinicaltrials.gov
- International Standard Randomised Controlled Trial Number [ISRCTN] Register
- Netherlands Trial Register
- UMIN [Japanese] Clinical Trials Registry

QUALITY IMPROVEMENT PROJECTS

There are three potential approval pathways to consider when conducting a cross-sectional study in the health sector in Western Australia. The choice of pathway depends on several criteria, including consideration of ethical issues. These pathways are explained in the Clinical Audit Handbook, and are the:

- Governance Evidence Knowledge Outcomes pathway (used in public health settings) for quality assurance projects using low risk, routinely collected data. The data collected and reported are generally for internal use only. Most audits use this pathway.

- Low Risk review pathway, for low risk activities where specific study criteria apply. Participants generally provide consent.
- Human Research Ethics Committee pathway, for projects where participants usually provide consent, data may be more sensitive or the activity higher risk, and are generally intended for external use, such as scientific publication.

For information on the difference between quality improvement (QI) and research, and the requirements for QI ethics review refer to Ethical considerations in quality assurance and evaluation activities

Quality improvement (QI) projects sought to be conducted by CAHS staff, which meet the criteria set out in the National Statement S5.1.17 are not required to be submitted for review to the CAHS HREC unless the project has ethical implications.

These projects seek to answer the question "Are we following best practice?" If a project meets the criteria for submission as "Quality Improvement" then it must be reviewed by the Governance Evidence Knowledge Outcomes (GEKO) Triage Committee. To publish the outcomes of Quality Improvement (QI) or Audit activities, approval is required from the GEKO Triage Committee.

For specific advice on your project and the approval level required please contact the Safety and Quality team at CAHS or the CAHS Ethics office.

CONTACTS

Research Ethics & Governance (REG) Office

Department of Research
Office 5E, Perth Children's Hospital
15 Hospital Ave, Nedlands WA 6009

Web: Child and Adolescent Health Service | CAHS - Ethics and governance

Research Ethics

Telephone: (08) 6456 8178 or 6456 8539

Email: CAHS.Ethics@health.wa.gov.au

Research Governance

Telephone: (08) 6456 0517 or 6456 5539

Email: CAHS.RGO@health.wa.gov.au

REFERENCE DOCUMENTS

Researchers should be familiar with the following key documents before preparing a submission.

The documents below are essential for any medical researcher working in Australia, WA and within the WA public health sector. It is also a requirement for researchers at CAHS to complete Good Clinical Practice Training prior to conducting any research activity.

Understand your broad responsibilities as a researcher in Australia:

- National Health and Medical Research Council, Australian Research Council and Universities Australia Australian Code for the Responsible Conduct of Research (2018)

Understand how to design and conduct ethically acceptable research:

- NHMRC National Statement on Ethical Conduct in Human Research (2023)
- World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (2018)

Understand the fundamentals of conducting clinical trials and all human research:

- Therapeutics Goods Administration Australian Clinical Trial Handbook
- Therapeutics Goods Administration Note for Guidance on Good Clinical Practice
- ICH Guidelines for Good Clinical Practice
- WA Health Translation Network GCP in Australia online training

Understand the National Clinical Trials Governance Framework (NCTGF) requirements when conducting Clinical Trials research at CAHS:

Any clinical trials research conducted at CAHS must be compliant with the NCTGF which outlines the requirements in terms of clinical governance and consumer partnerships.

CAHS is committed to partnering with its consumers to help shape research by the people who will benefit from it the most. Researchers should seek input from the patients/clients, participants, parents, and carers who will be most affected by research advancements. It is suggested community involvement be included at the proposal, protocol design, and participation stages of a research project. All consumer engagement at CAHS, regardless of affiliation, must comply with the CAHS Consumer Representative – Recruitment and Management policy.

All questions regarding NCTGF standards at CAHS can be emailed to CAHS.clinicaltrials@health.gov.au .

Read about how research is governed within WA Health:

- WA Department of Health Research Governance Policy and Procedures

Understand the principles to ensure research is safe, respectful, responsible, high quality and of benefit to Aboriginal and Torres Strait Islander people and communities:

- NHMRC Ethical Guidelines for Research with Aboriginal and Torres Strait Islander Peoples
- AIATSIS Code of Ethics 2020

Follow available guidance on NHMRC requirements on safety reporting and monitoring requirements:

- Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods 2016
    - Risk-based Management and Monitoring of Clinical Trials involving Therapeutic Goods 2018
    - Reporting of Serious Breaches of GCP or Protocol for Trials involving Therapeutic Goods
    - Data Safety Monitoring Boards

Follow information on the difference between quality improvement (QI) and research, and the requirements for QI ethical review refer to:

- NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities 2014

ABBREVIATIONS

AE	Adverse Event
CAHS	Child and Adolescent Health Service
CPI	Coordinating Principal Investigator
CoI	Conflict of Interest
CRG	Collaborative or Cooperative Research Group
CRO	Clinical Research Organisation / Contract Research Organisation
CTA	Clinical Trial Application
CTN	Clinical Trials Notification
CTRA	Clinical Trial Research Agreement
CTS	CAHS Clinical Trials Sub-Committee
DoH	WA Department of Health
DSMB	Data Safety Monitoring Board
DSUR	Development Safety Update Report
GEKO	Governance Evidence Knowledge Outcomes
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee
IB	Investigator Brochure
National Statement	National Statement on Ethical Conduct in Human Research, 2023
NHMRC	National Health and Medical Research Council
NMHS	North Metropolitan Area Health Service
PCH	Perth Children's Hospital
PI	Principal Investigator
PMH	Princess Margaret Hospital
PRN	Project Reference Number
QA	Quality Assurance
QI	Quality Improvement
REG	Research Ethics and Governance
Researcher	a person who carries out academic or scientific research
RG	Research Governance
RGO	Research Governance Office
SAE	Serious Adverse Events

SOPs	Standard Operating Procedures
SSI	Significant Safety Issue
SUSAR	Suspected Unexpected Serious Adverse Reactions
TGA	Therapeutic Goods Administration
USADE	Unanticipated Serious Adverse Device Effect
USM	Urgent Safety Measures
WAHEAF	WA Health Ethics Application Form
WASM	WA-Specific Module

001- Overview of research approval by CAHS

PROCEDURE - 001	
Overview of research approval by CAHS To provide an outline of the process of obtaining research approval at the Child and Adolescent Health Service (CAHS).	
Scope (Staff):	All researchers wishing to undertake research within CAHS requiring CAHS HREC approval and/or CAHS Site approval
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information and/or CAHS facilities.

Aim

To ensure all applicable research is captured, reviewed, and approved by CAHS prior to project commencement.

Background

All research involving humans to be carried out within the Child and Adolescent Health Service (CAHS) requires Institutional approval and must undergo ethics (including scientific) and governance review. Such research may involve patients, staff, biospecimens or data.

See Diagram 001.1 for schematic representation of approval process.

Key Points

- Institutional (CAHS) approval for research will be granted only after the outcome of the ethics and governance reviews is received by an authorised member of the CAHS Executive.
- Research to be conducted on site at CAHS requires institutional approval and should be submitted to the CAHS HREC (unless already approved by another WA Health or lead HREC) and Research Governance Office.
- All research applications will undergo governance review prior to Institutional approval being granted. This review may occur concurrently with the ethics and scientific review.
- To ensure the research is ethically and scientifically sound, only authorised personnel with appropriate professional qualifications, credentials and institutional approvals will be accepted as Principal Investigator (PI).
- The CAHS HREC will review research applications according to the CAHS HREC Terms of Reference.
- Once a review has been conducted by the HREC and Research Governance and approval is recommended, the application will be presented to the authorised member of the CAHS Executive or Delegate for institutional approval.
- A CAHS institutional approval is valid for a period of three years and is provided with written conditions of approval. Continued HREC endorsement is conditional on adherence to the terms of HREC approval. The HREC can suspend its approval or recommend termination of the project to the institution where necessary. The institution can also suspend or terminate a project.
- An extension to the approval period can be granted for a maximum of three years without HREC review. Beyond this, approvals for extensions can be provided by HREC if justified. Please refer to SOP301 for further information.
- Upon submission of a Research Governance Service (RGS) application, a RGS number is generated and will be used to identify the corresponding project. This number must be included in all correspondence to the REG Office regarding the research and will be quoted on all correspondence from the HREC, REG Office and CAHS.

Procedure

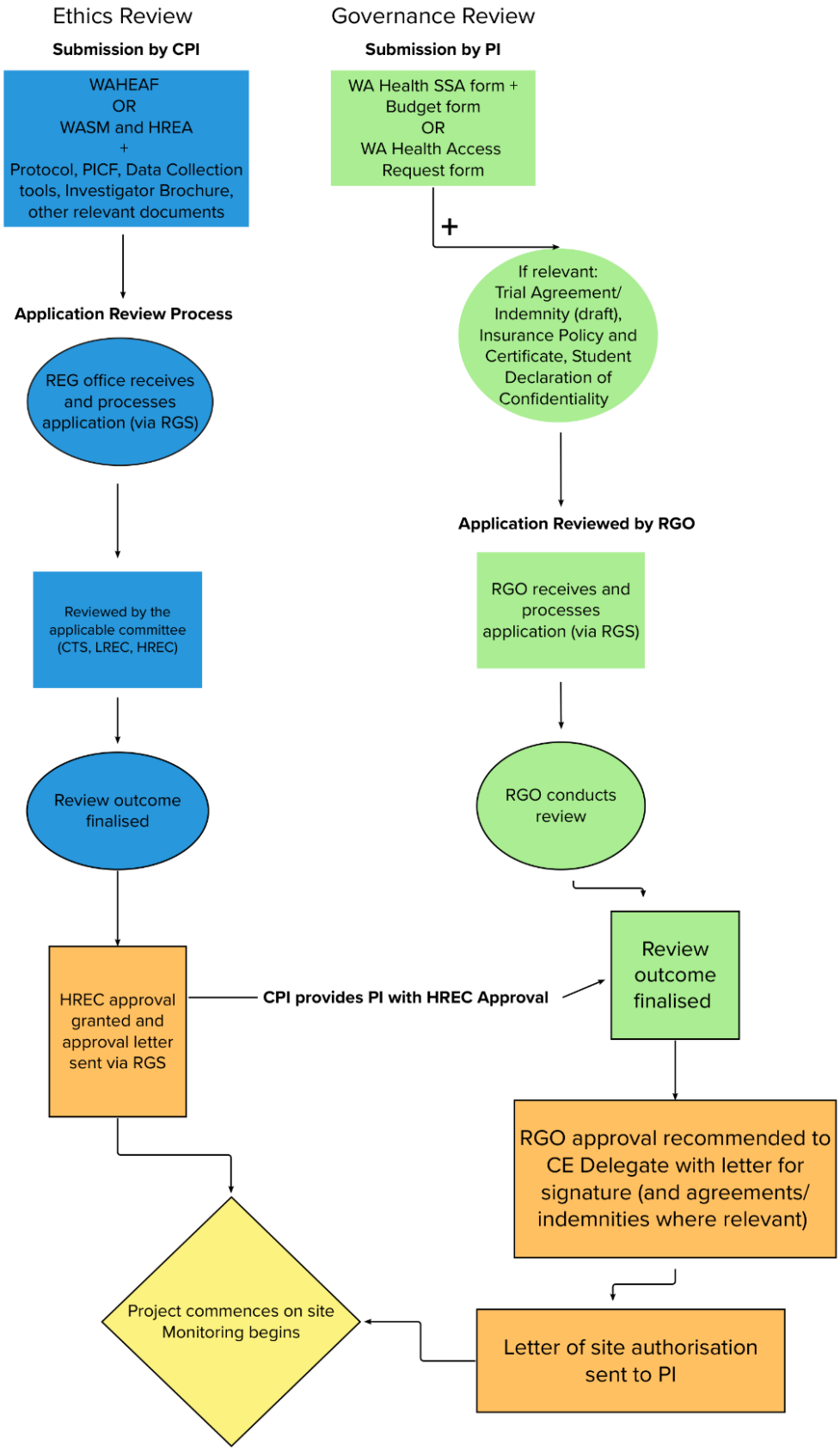
1. Researchers must register for RGS access using the *New User Sign Up* option in RGS.
2. To create a new project workspace in RGS, researchers select *Create Project* in the RGS menu.
3. Once the new RGS project workspace has been approved, researchers must complete the submission of their project via RGS including the provision of all required information for review.
4. The following documents are required for all studies and should be provided when submitting a research application for ethics review:
    - application form – WA Health Ethics Application Form OR the Human Research Ethics Application and WA-Specific Module
    - submission coversheet (available on the CAHS research website).
    - research protocol (available on the CAHS research website)
5. In addition to the above, the following documents should be provided as required:
    - participant information sheet and consent form
    - recruitment documents e.g., letter, email template, poster, flyer, advertisement etc.
    - data collection tools e.g., questionnaire, survey, interview outline, data collection form etc.
    - other participant documents (identification card, diaries)
    - investigator brochure (for Clinical Trial Notification/Clinical Trial Exemption studies)
    - other relevant HREC approvals e.g., WAAHEC
    - radiation safety officer/Radiological Council report
6. Once a completed application has been submitted, a member of the REG Office will assess the application to ensure that all required documentation has been submitted and the application is complete. Incomplete submissions will not be accepted for review.
7. The application will be triaged by a member of the REG office. The type of review each application undergoes is dependent on the nature of the research. CAHS has adopted three review procedures:
    - standard ethical review – HREC
    - clinical trials review – CTS and HREC
    - low risk review - LREC

Related internal policies, procedures and guidelines
CAHS Low Risk Ethics Committee (LREC) Terms of Reference
CAHS Human Research Ethics Committee (HREC) Terms of Reference
CAHS Clinical Trials Subcommittee (CTS) Terms of Reference
Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
Australian Code for the Responsible Conduct of Research https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2007
WA Health Research Governance Framework Research (health.wa.gov.au)

WA Department of Health – Research Governance Service (RGS) https://rgs.health.wa.gov.au/
WA Aboriginal Health Ethics Committee Western Australian Aboriginal Health Ethics Committee – AHCWA

Diagram 001.1 CAHS Research Application Review Process



HREC PROCEDURES

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101 – Submission of a Research Application to the HREC

PROCEDURE – 101	
Submission of a Research Application to the HREC To describe the requirements when submitting a research application to the Child and Adolescent Health Service (CAHS) Human Research and Ethics Committee (HREC).	
Scope (Staff):	All researchers wishing to undertake research within CAHS requiring CAHS HREC approval.
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information and/or CAHS facilities.

Aim

To ensure all applicable research is captured, reviewed, and approved by CAHS HREC prior to project commencement.

Background

In June 2023, CAHS implemented three review procedures, proportionate to potential risk to participants:

1. Standard ethical review – full HREC review
2. Clinical trials review – CTS and full HREC review
3. Low risk review – LREC review

Key Points

Upon submission of an RGS application a RGS number is generated and will be used to identify the corresponding project. This number must be included in all correspondence to the REG Office regarding the research and will be quoted on all correspondence from the REG office and CAHS.

Procedure

1. Once all documentation has been correctly submitted, the application will be triaged by a member of the REG office.
2. The CPI will be notified by the REG office via email regarding which review process the application will be reviewed.
3. Applications qualifying for a low risk review, will be reviewed by members of the LREC via email circulation according to the LREC Terms of Reference.
4. Applications that involve a clinical trial or intervention will be added to the agenda for the next scheduled CTS meeting for review. CTS recommended applications will then be added to the agenda for the next scheduled HREC meeting for review.
5. Applications that do not qualify for a low risk review and not involving a clinical trial/intervention, will be reviewed by the HREC at the next scheduled HREC meeting.

Related internal policies, procedures and guidelines
CAHS Low Risk Ethics Committee (LREC) Terms of Reference CAHS Human Research Ethics Committee (HREC) Terms of Reference

CAHS Clinical Trials Subcommittee (CTS) Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
WA Department of Health – Research Governance Service (RGS) https://rgs.health.wa.gov.au/

102 - Managing a Conflict of Interest in Research

PROCEDURE - 102	
Managing a Conflict of Interest in Research To describe the process of managing a conflict of interest identified within a project reviewed by Child and Adolescent Health Service (CAHS).	
Scope (Staff):	CAHS HREC, CTS, LREC and Research Department
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information and/or CAHS facilities.

Aim

All researchers conducting research under the auspices of CAHS have an obligation to disclose and manage actual, potential or perceived conflicts of interest.

Background

A conflict of interest in research is defined as "*a situation in which financial or other personal considerations may compromise or have the appearance of compromising a researcher's professional judgment in conducting or reporting research*".

Even the perception that a conflict of interest exists can raise concerns about the integrity of individuals or the management practices of the institution, potentially undermining community trust in research.

This SOP is written in accordance with Chapter 5.6 of the *National Statement*.

Key Points

To manage their responsibilities under the Code, researchers must:

- comply with WA Health processes for managing conflicts of interest to identify, disclose, record, manage and regularly review/update any actual, perceived or potential conflicts of interest
- comply with any additional Conflict of Interest requirements of external bodies relevant to their research or role, e.g., funding bodies, conference organisers, publisher
- in the case of clinical trials, include the nature of the sponsorship and the relationships between the sponsor, trial participants and the researcher in any disclosures.

Researchers who are employees of CAHS, other WA Health Service Providers or WA Health must comply with MP 0138/20 – Managing Conflicts of Interest Policy and ensure that all conflicts are registered online in the Conflict of Interest Register.

Additional guidance for CAHS employees can be found on the intranet.

Procedure

1. All researchers must register their conflict of interest in the Declarations section of RGS at the time of completing their Ethics and/or site authorisation application.
2. For LREC, CTS or HREC identified conflict: The committee that identified the conflict will review the researcher's response and evaluate whether the researcher has adequately addressed its concerns.
3. If the committee still feels that a conflict exists, the researcher may be asked to attend a meeting of the committee to discuss the issues.
4. For RGO identified conflict: The RGO will review the researcher's response and evaluate whether the researcher has adequately addressed its concerns. If the RGO still believes that a conflict exists the researcher may be asked to attend a meeting with the RGO and the Manager, REG.
5. The research will not be given approval until the committee or RGO is satisfied that the conflict has been addressed.

Related internal policies, procedures and guidelines
CAHS Procedure - Management of Conflicts of Interest for CAHS staff https://cahs-healthpoint.hdwa.health.wa.gov.au/integrity/info_managers_staff/Conflict%20of%20Interest%20Library/CAHS.PM.ManagementOfConflictsOfInterest.pdf
CAHS Fact Sheet - Conflict of interest https://cahs-healthpoint.hdwa.health.wa.gov.au/integrity/info_managers_staff/Conflict%20of%20Interest%20Library/CAHS%20Conflict%20of%20Interest%20Factsheet_PDF.pdf

Related external policies, procedures, guidelines and resources
MP 0138/20 Managing Conflicts of Interest Managing Conflicts of Interest Policy (health.wa.gov.au)
Integrity Coordinating Group: Conflicts of Interests Guidelines for the Western Australia Public Sector. Conflct of interest - Guidelines for the WA public sector (www.wa.gov.au)
WA Health Conflict of Interest register Conflict of Interest Form - Conflict of Interest (health.wa.gov.au)
NHMRC - Identifying and managing conflicts of interest Identifying and managing conflicts of interest | NHMRC

103 - Submission Deadline, Meeting Schedules, and Timelines

PROCEDURE – 103	
Submission Deadline, Meeting Schedules, and Timelines Submission deadlines and meeting dates for the Child and Adolescent Health Service review committees.	
Scope (Staff):	All researchers wishing to undertake research within CAHS.
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information and/or CAHS facilities.

Aim

To outline the submission deadlines and meeting schedule for CAHS CTS and CAHS HREC meetings.

Background

The CAHS CTS and HREC meet eleven times a year. First meeting for the year is held in February. There is no meeting in January.

The year's submission deadline and meeting schedule is developed and published the previous year, usually by September.

Procedure

1. The meeting schedule is determined by the REG office following consultation with CTS and HREC members.
2. The submission deadline for new applications, substantial amendments and relevant reports is at COB (4pm) approximately one week before the scheduled CTS meeting.
3. The submission deadline applies to all submissions except for those qualifying for a low risk review. There is no deadline date for low-risk review. Feedback is provided to the CPI for low risk submission within seven (7) working days of submission.
4. The HREC meeting is held approximately one (1) week after the CTS meeting.
5. Feedback is provided to the CPI within three (3) working days of a scheduled HREC meeting.

Related internal policies, procedures and guidelines
CAHS Low Risk Ethics Committee (LREC) Terms of Reference CAHS Human Research Ethics Committee (HREC) Terms of Reference CAHS Clinical Trials Subcommittee (CTS) Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC
Schedule of CAHS CTS and HREC Meetings Child and Adolescent Health Service | CAHS - Meetings

104 - Conflicts of interest: Members of research review committees

PROCEDURE - 104	
Conflicts of interest: Members of the LREC, CTS & HREC The guideline to identify and declare conflicts of interests with Committee members and how these conflicts are handled.	
Scope (Staff):	All researchers wishing to undertake research within CAHS.
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information and/or CAHS facilities.

Aim

The guideline to identify and declare conflicts of interests with Committee members and how these conflicts are handled.

Background

The principles and values expressed in the Western Australian Public Sector Code of Ethics and the WA Health Code of Conduct describe the standards of behaviour expected of people working in the public health sector. The Code of Conduct expressly states that employees of WA Health will: "Disclose any personal or professional matters that may lead to actual or perceived conflicts of interest".

A conflict of interest can be:

- actual – a conflict exists
- perceived – a conflict is only believed to exist
- potential – a conflict is a future possibility

Procedure

1. All Committee members are required to sign a confidentiality form and conflict of interest declaration upon the commencement of their term of appointment.
2. If a committee member identifies a conflict of interest before or during a meeting, they must verbally declare that interest to the Committee at the meeting and this is to be recorded in the minutes of the meeting. Conflicts of Interested will be managed in accordance with the DoH 'Managing Conflict of Interest Guidelines'.
3. The Committee member must leave the room and not participate in any discussion or decision-making associated with the research application for which they have an identified actual or potential conflict of interest. Scientific experts invited to meetings to assist in the review of research will also be subject to the same requirements and must declare any known conflict of interest.
4. Where a committee member is involved in a study under review, they will be required to declare a conflict of interest. At the time when the project is reviewed at the Committee meeting, the member must leave the room whilst the Committee discusses the project and makes its deliberation on whether to recommend approval of the study. This is to be recorded in the minutes of the meeting stating that "It is noted that (name of member) declared his/her Conflict of Interest and stepped out of the room during the discussion and decision of this study". Any further investigation or procedures associated with the management of the conflict of interest must be documented in the Conflict of Interest Registry by the executive officer minuting the meeting.
5. The member who declared a conflict must not be informed of the Committee's decision at the time of the meeting but will be advised in writing by the Ethics Office after the minutes of that meeting have been reviewed and approved by the Chair of the meeting.
6. For LREC members, if there is a conflict of interest, it is the responsibility of the LREC member to declare the conflict of interest when invited to review an ethics application.

Related internal policies, procedures and guidelines
Procedure - Management of Conflicts of Interest for CAHS staff https://cahs-healthpoint.hdwa.health.wa.gov.au/integrity/info_managers_staff/Conflict%20of%20Interest%20Library/CAHS.PM.ManagementOfConflictsOfInterest.pdf
CAHS Fact Sheet - Conflict of interest https://cahs-healthpoint.hdwa.health.wa.gov.au/integrity/info_managers_staff/Conflict%20of%20Interest%20Library/CAHS%20Conflict%20of%20Interest%20Factsheet_PDF.pdf

Related external policies, procedures, guidelines and resources
WA Health Policy MP0138/20: Managing Conflicts of Interest Managing Conflicts of Interest Policy (health.wa.gov.au)
Integrity Coordinating Group: Conflicts of Interests Guidelines for the Western Australia Public Sector. Conflct of interest - Guidelines for the WA public sector (www.wa.gov.au)
NHMRC - Identifying and managing conflicts of interest Identifying and managing conflicts of interest | NHMRC

105 – Review Process for New Ethics Submissions

PROCEDURE - 105	
Review Process for New Ethics Submissions To provide researchers with information about the review process for ethics submissions.	
Scope (Staff):	All researchers wishing to undertake research within CAHS.
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information and/or CAHS facilities for research.

Aim

The guideline to inform interested parties of the protocols and processes of the ethics review process.

Background

Low risk research is categorised as defined by the National Statement (Chapter 2.1) where research will cause no more than discomfort. Discomforts include, for example, minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview. Where potential risk to participants exceeds discomfort and could become distress, research cannot be deemed low risk. If research projects involve taking blood samples from participants in addition to a clinical requirement, they will not be considered low risk due to potential risk that is beyond what can be considered discomfort.

The National Statement allows a non-HREC review process to be used for the review and approval of lower risk research. Low risk approval pathways are also accepted by the National Mutual Acceptance Scheme.

All research involving humans, which is deemed to be more than low risk, according to the National Statement definition provided in Chapter 2.1 will be reviewed through the standard review stream. This includes single-site research as well as research for which the CAHS HREC will act as the lead HREC.

Clinical trial / interventional studies will be reviewed by both Clinical Trials Sub-committee (CTS and the HREC at a scheduled meeting.

Meeting dates for CTS and HREC meetings are scheduled in advance and are available on the CAHS REG webpage.

Procedure

1. Applications must be submitted via the RGS to the REG office by the submission deadline date.
2. Upon the receipt of the application submission via RGS, the REG Office will review the received documents.
3. If the submission is complete, the application will be added to the relevant meeting agenda.
4. If the application is incomplete, a REG office staff member will contact the CPI to request further information/clarification or additional documents.

Low Risk Review

1. Once finalised, the application will be reviewed by two LREC members and the Manager, REG or three LREC members according to the LREC Terms of Reference.
2. There are no submission deadlines for low risk research and applications may be submitted at any time. Once received, an application will be reviewed within seven (7) working days.
3. The decisions available to the committee include:
    a. Approval granted
    b. Additional information required.
    c. Full HREC review recommended.

4. Once approved, ethics applications approved by LREC are added to the agenda for the next scheduled HREC meeting for noting by the HREC.

Review of Clinical Trials

1. If the study is a clinical trial/interventional study, review will be conducted by both CTS and HREC.
2. Ethics applications involving clinical trials must be submitted on the WASM + HREA, not the WAHEAF.
2. Once finalised, the CTS meeting agenda items will be sent out to the members approximately seven (7) days before the Committee meeting to allow enough time for review of the applications.
3. CTS meetings are conducted in accordance with its Terms of Reference and CTS members reviews each clinical trial proposal for scientific validity and ethical integrity.
4. The decisions available to the CTS include, but are not limited to, the following:
    a) Recommended by CTS for the application to progress to HREC for review. The CPI will be notified by the REG office via email. Any comments and recommendations made by CTS members will be added to HREC comments and recommendations.
    b) Resubmission required. Where CTS members have identified significant issues, the CPI will be notified via RGS that the application will not proceed to HREC review and requires a resubmission to CTS with substantial changes made prior.
5. Once the CTS meeting minutes has been reviewed and approved by the CTS Chair, the minutes will be added to the HREC meeting agenda along with the clinical trial applications recommended to proceed to HREC review.

HREC review

1. Once finalised, the HREC meeting agenda items will be sent out to the members seven (7) days before the meeting to allow enough time for review of the applications.
2. HREC meetings are conducted in accordance with its Terms of Reference and members review each research proposal for scientific validity and ethical integrity.
3. The HREC will comply with the membership requirements prescribed in the National Statement (5.1.29 – 5.1.30) and the Terms of Reference. Consistent with the National Statement, if at a meeting of the HREC there is less than full attendance of the minimum membership, the Chair should be satisfied that the views of those absent have been considered before a decision is reached. This may be through the provision of written or verbal comments.
4. The HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by general agreement. Any significant minority view shall be noted in the minutes.
5. The decisions available to the committee include:
    a. Approval granted
    b. Additional information required. These queries may be resolved out of session.
    c. Approval not granted.
6. Investigators will be notified of the outcome of the HREC meeting within three (3) working days.
7. The minutes of each meeting will be recorded by the Ethics Administrative Officer and provided to the HREC members for ratification.

Related internal policies, procedures and guidelines
CAHS HREC and CTS Meeting Dates and Deadlines Child and Adolescent Health Service | CAHS - Meetings
CAHS Low Risk Ethics Committee (LREC) Terms of Reference

Child and Adolescent Health Service | CAHS - Applying to HREC
CAHS Clinical Trials Subcommittee (CTS) Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC
CAHS Human Research Ethics Committee (HREC) Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
WA Department of Health – Research Governance Service (RGS) https://rgs.health.wa.gov.au/
ICH Guidelines ICH Official web site: ICH

106 - Expert reviewer

PROCEDURE - 106	
Expert reviewer Where the CTS and/or HREC requests an independent opinion of an expert in relation to the review of a particular project.	
Scope (Staff):	All researchers wishing to undertake research within CAHS.
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information and/or CAHS facilities.

Aim

To provide researchers with information about the expertise of the Committee member reviewing projects within the CAHS HREC and CTS.

Background

This procedure is written in accordance with Chapter 5.2 of the *National Statement*.

As outlined in the terms of reference both the HREC and CTS, if they deem it necessary, request the independent opinion of experts when reviewing a research application.

Procedure

1. Where the CTS or HREC requests the independent opinion of experts for a particular research project, the CPI will be asked to nominate 3 individuals. Taking account of the nominations, the committee Chair will determine the expert/s to be approached for the review.
2. The committee Chair or delegate will contact the potential reviewer/s and request they review the clinical trial proposal.
3. If the potential reviewer/s declines, an alternate reviewer will be asked as outlined above.
4. If a reviewer accepts an invitation to provide expert review, they will be given the following:
   a) A copy of the research application
   b) A review form (as used by committee with the required components for review highlighted) to complete
   c) An outline of any specific concerns or queries that the committee would like an opinion on
   d) Confidentiality Agreement Form to complete
   e) Due date for the review
5. The committee Chair or delegate will ensure that the expert(s) have no conflicts of interest in relation to the project under review, any financial interest in the outcome or any involvement in competing research.
6. The signed Confidentiality Agreement will be kept electronically with the research project file and with the minutes for the relevant committee meeting.
7. The expert opinion will be submitted to the relevant committee for consideration.

Related internal policies, procedures and guidelines
CAHS Low Risk Ethics Committee (LREC) Terms of Reference CAHS Human Research Ethics Committee (HREC) Terms of Reference

CAHS Clinical Trials Subcommittee (CTS) Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC

107 - Resubmission of a previously reviewed research application

PROCEDURE - 107	
Resubmission of a previously reviewed research application. To describe the process of submission, review and approval of an application that was not granted approval upon initial review.	
Scope (Staff):	All researchers requiring a resubmission of a research project to CTS or HREC
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information and/or CAHS facilities.

Aim

To provide researchers with information about projects that is required to be resubmitted to the CTS or CAHS HREC for reconsideration.

Background

This SOP is written in accordance with Sections 5.2.11 to 5.2.14 of the *National Statement*, regarding communication with researchers.

Procedure

1. If a research application has been reviewed by CTS and/or HREC and has not been granted approval, a letter will be sent to the CPI via RGS notifying them of the Committee's decision. This letter will outline the issues that the Committee identified during its review and request the researcher to address these issued and have the application resubmitted for further consideration.

2. Upon receipt of this letter, the researcher has two options:

    a) The researcher can make the changes requested by the Committee. Once the changes have been made, the researcher is required to submit the amended documentation to the REG office via RGS by the relevant submission date for the next round of meetings.

    b) If the researcher has an objection to one or more of the requested changes, they can submit these objections in a covering letter to the Committee with sufficient justification for disregarding the Committee's recommendations, along with any amended paperwork via RGS on or before the submission deadline for review at the upcoming meeting. The Committee may invite the researcher to attend the meeting to discuss these objections.

3. Once received by the REG office, the resubmitted application will be circulated to the Committee members with other agenda items for the next Committee meeting.

4. Resubmitted applications are the first applications reviewed in any Committee meeting.

5. The Committee will review the resubmission and ensure the requested changes have been made.

6. In the case of a researcher raising objection to the Committee's requests, the Committee will decide on the validity of the objections. If the Investigator has been invited to attend the meeting, then the researcher will be asked to answer questions and discuss the objections they have to the requested changes. The researcher is required to leave the meeting prior to the Committee making its decision.

7. The arrival and departure of the researcher will be minuted, and they will not be present during discussions regarding any application other than their own.

8. If the Committee approves the resubmission, then the application can progress to the HREC (from CTS), or the approval letter can be issued (in the case of HREC).

9. If the Committee has not recommended approval, then the process outlined above is repeated. This will continue until the Committee and the researcher come to an agreement and the HREC approves the application, or the researcher withdraws the application.

Related internal policies, procedures and guidelines
CAHS Low Risk Ethics Committee (LREC) Terms of Reference CAHS Human Research Ethics Committee (HREC) Terms of Reference CAHS Clinical Trials Subcommittee (CTS) Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and useful resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
WA Department of Health – Research Governance Service (RGS) https://rgs.health.wa.gov.au/

108 - CAHS HREC approval

PROCEDURE - 108	
CAHS HREC approval To describe the process of issuing a letter of ethics approval to conduct a project.	
Scope (Staff):	All researchers submitting either a new research application or amendment for review
Scope (Area):	CAHS and external institutes undertaking research with CAHS patients, patient samples or information.

Aim

To describe the process of issuing a letter of ethics approval to conduct a project from the CAHS HREC.

Background

The HREC is responsible for reviewing a research project in accordance with *the National Statement*. CAHS HREC has appointed a Clinical Trials Subcommittee (CTS) to advise on clinical trial proposals presented to CAHS HREC. In addition, the HREC has appointed a Low Risk ethics committee (LREC) to approve low risk research in accordance with NS 5.1.10 – 5.1.14.

Procedure

1. Once any changes required by the LREC, HREC or CTS/HREC have been made to project documentation and it has determined that the project can be approved, a HREC approval letter will be generated by the REG Office via RGS to the CPI of the project.
2. The letter will include the following information:
    a) The RGS number as issued to the project workspace by the RGS (the study code for COG projects)
    b) Name of the Co-ordinating Principal Investigator (CPI) and their department
    c) Project title
    d) Date of the meeting at which the project was reviewed, approved or noted
    e) List of all approved study documents
    f) Approval expiry date
    g) List of all approved public health participating sites
    h) Advice that the letter constitutes ethics approval only
    i) Advice that the project cannot proceed at any site until site authorisation has been obtained from a member of the CAHS Executive or Delegate of the site under whose auspices the research will be conducted.
    j) References to the *National Statement* as follows:
        i. “The above research project meets the requirements of the *National Statement on Ethical Conduct in Human Research* (2023) and ethics approval for this research project has been granted by Child and Adolescent Health Service HREC.”
    k) Other specific references to the *National Statement* where relevant:
        i. e.g., “A waiver of consent has been approved by the Child and Adolescent Health Service Human Research Ethics Committee in accordance with the *National Statement on Ethical Conduct in Human Research* (2023), Section 2.3.10.

3. The HREC conditions of approval will be attached to the letter to outline the research team's responsibilities and obligations.
4. The RGS generated HREC approval letter will be digitally signed by the HREC Chair or their Delegate on behalf of the HREC.
5. For a multi-centre research project, where the CAHS HREC is acting as the Lead HREC, the approval letter can be provided to other sites as evidence of approval from the CAHS HREC.

Related internal policies, procedures and guidelines
CAHS Low Risk Ethics Committee (LREC) Terms of Reference CAHS Human Research Ethics Committee (HREC) Terms of Reference CAHS Clinical Trials Subcommittee (CTS) Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
Research Governance Service https://rgs.health.wa.gov.au/Pages/Research-Governance-Framework.aspx

109 – Participant Information Sheet and Consent Form

PROCEDURE - 109	
Participant Information Sheet and Consent Form To describe the requirements of the Participant Information Sheet and Consent Form (PICF) for research.	
Scope (Staff):	All researchers submitting either a new research application or amendment for review
Scope (Area):	CAHS and external institutes undertaking research with CAHS patients, patient samples or information.

Aim

To outline the requirements for information to be included in the Participant Information Sheet and the Consent Form (PICF) used for research projects in accordance with the National Statement (2023).

Background

According to the National Statement, participation in research must be the result of a voluntary choice based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it (Chapter 2.2).

- The Participant Information Sheet (PIS) is the explanatory information provided to potential research project participants. The PIS should be written in plain language that is accessible for all nonprofessional or lay people to understand.
- The Consent Form (CF) is a document that research participants sign to indicate informed consent for research project participation.
- CAHS investigators are strongly encouraged to use the NHMRC standardised PICF templates which can be customised for specific projects.

Research with children and young people under 18 years of age raises issues around informed consent. Usually, consent must be obtained from:

- the child or young person and
- the parent or guardian

When seeking consent from a child or young person, the following must be considered:

- their capacity to understand what the research involves and
- the complexity of the research, and its potential risks and benefit.

The developing capacity of children and young people to be involved in decisions about their participation in research must be respected. If the child cannot consent, they should still be involved in appropriate discussions about the research. A Child Information Sheet should be provided wherever appropriate.

In some cases, parental consent may not be necessary. For example, a 17 year-old with good literacy skills may be able to consent to low-risk research e.g., online survey not of a sensitive nature.

Chapter 4.2 of the National Statement (2023) provides guidance regarding involving children and young people in research, including information and consent requirements.

Procedure

- CAHS HREC strongly recommends use of the NHMRC templates to ensure that all the required sections and information to satisfy the National Statement Chapter 2.2 conditions are included. These templates can be customised to specific research projects.
- PICFs must be written in plain, everyday language aimed at a literacy level of Year 8.

- The overall presentation should be neat, easy to read, with correct spelling and grammar. Using headings and sub-headings and spacing out short paragraphs assists in making the document user-friendly.
- The version number and date of the document must be included in the footer to track changes to the document over the life of the project. Ensure the version and date corresponds with the version and date you enter in RGS during document upload.
- All involved investigators should be named with their affiliations. At the very least, the CPI and PI for the site must be included.
- The opening paragraph should be an invitation to participate with a clear explanation as to why the individual is invited.
- It should clearly state who the Sponsor of the research project is and who is the funding body (if relevant).
- The name of the HREC who has approved the research project must be included.
- Information must clearly outline what will be expected of participants. A step-by-step explanation or use of bullet points is recommended wherever possible.
- If relevant, a schedule of visits should be presented in a table, which includes the number of visits, timing of visits, what will occur at the visits and an estimation of time involved for each visit.
- Potential risks to participants must be clearly listed and explained, including both the severity of the risk and the frequency. Information regarding how the potential risks will be minimised and managed must be clearly explained.
- When communicating volumes of fluid taken as samples, it is recommended that a comparison to teaspoons/tablespoons be used.
- Any optional additional investigations (e.g., storage of remaining biospecimens for future research purposes or to be stored in a biobank) must be explained as such with separate clauses in the consent form.
- Contact details for an appropriate member of the research team must be provided for participants to contact should they have any questions or concerns.
- The following sentence and contact details for complaints must be included:

  If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

  Reviewing HREC approving this research:

Reviewing HREC name	Child & Adolescent Health Service (CAHS)
Position	HREC Chair
Telephone	(08) 6456 8639
Email	CAHS.Ethics@health.wa.gov.au

  Site contact:

Name	CAHS Research Ethics & Governance Office
Position	Manager
Telephone	(08) 6456 8639
Email	CAHS.RGO@health.wa.gov.au

Master and Site-specific PICF

- Multi-site research projects usually require a master PICF as well as a site specific PICF. The master PICF contains all the information relevant to the research project, except any site-specific information. The master will instead include placeholders for site-specific information e.g. [insert PI name] [insert site name].

- The master PICF is reviewed by the lead HREC and the site-specific PICF is reviewed by the site's RGO only.
- The footer of the master PICF must specify that the document is the master PICF e.g.

RGSXXXX Main PICF Master version 1.0 dated 15 August 2023	page 1 of 10

- The footer of the site-specific PICF specifies that the document is a site-specific version and indicates which master version it is based on.

RGSXXXX PCH Main PICF version 1.0 dated 15 August 2023 based on RGSXXXX Main PICF Master version 1.0 dated 1 August 2023	page 1 of 10

Related internal policies, procedures and guidelines
CAHS Communications – Branding and Logos Branding and logos (health.wa.gov.au)
CAHS – Submission requirements Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
NHMRC Standardised Participant Information and Consent Forms Ethical issues and resources | NHMRC
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
Research Governance Service https://rgs.health.wa.gov.au/Pages/Research-Governance-Framework.aspx

110 - Schedule of review fees

PROCEDURE - 110	
Schedule of review fees To notify researchers and industry of the fees that the Child and Adolescent Health Service charge for research review.	
Scope (Staff):	All researchers submitting either a new research application or amendment for review.
Scope (Area):	CAHS and external institutes undertaking research with CAHS facilities, patients, patient samples or information.

Aim

To notify researchers and sponsors of the fees that the CAHS HREC charge for research review.

Background

The CAHS REG office spends significant amounts of time reviewing research projects to ensure they are safe, realistic, appropriate for the intended outcome, and within the requirements of the NHMRC guidelines and governance requirements. Fees may be considered in-kind if there is no external funding or competitive grant funding provided for the research study. If the research study is commercially funded or initiated, then review fees will be charged. If the study is not a commercially funded project but has significant external funding, please contact the governance office to confirm if there will be a fee or if in-kind support will be available.

Key Points

- Industry and non-industry submissions of incomplete applications requiring significant additional administrative workload may be subject to additional fees both for sponsored and non-sponsored studies.
- Substantial amendments that introduce major new aims (i.e., a new primary or secondary objective) or which introduce major new safety considerations, and which require extended scientific and/or ethics review may attract a higher fee. This includes new sub-studies.

Procedure

1. Applications for studies that are fully sponsored by external commercial agencies, e.g., pharmaceutical companies or other commercial bodies incur a submission fee.
2. Fees must be paid on submission, prior to review using the form available on the CAHS research website and uploaded to RGS.
3. Commercial sponsorship may be financial or in-kind (e.g., provision of drugs or devices). Fees for in-kind support by commercial agencies may be waived for research-initiated studies if the following conditions are included in a WA Health approved clinical trial agreement:
    a) The IP arising from the project is not restricted by the commercial agency.
    b) The data arising from the project is not provided to the commercial agency for marketing or publicity purposes.
    c) The researcher retains full publication rights. There should not be a right-of-review restriction by the commercial agency.
    d) Applications by individual researchers for non-sponsored projects or for competitive grant applications will not attract a fee.
4. All substantial amendments for studies that are fully sponsored by external commercial agencies incur a submission fee, payable on submission.
5. Applications by researchers for non-sponsored research do not attract a submission fee.

6. Competitive research grant funded applications do not incur a fee.
7. If the research is not considered to be a commercially funded project but has significant external funding, please contact the governance office to confirm if there will be a fee or if in-kind support will be available.

Related internal policies, procedures and guidelines
Application fees to the HREC Child and Adolescent Health Service | CAHS - Application fees to HREC
Application fees for site authorisation Child and Adolescent Health Service | CAHS - Application fees to Research Governance Office (RGO)

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201 - Research governance review process

PROCEDURE - 201	
Research governance review process Outlines the process of an independent systematic evaluation of a research project by the research governance office.	
Scope (Staff):	All researchers wishing to undertake research within CAHS
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information and/or CAHS facilities.

Aim

To ensure all applicable research is captured, reviewed and approved by CAHS prior to project commencement.

Background

For all research governance approvals, site authorisation forms and supporting documentation must be submitted using RGS. Site approval cannot be finalised until the project has been approved by a WA Health or NHMRC certified Lead HREC.

Key Points

Upon approval of a project workspace in RGS a RGS number is generated and will be used to identify the corresponding research project. This number must be included in all correspondence to Research Governance Office (RGO) regarding the research and will be quoted on all correspondence from the RGO and CAHS.

The RGO is required to ensure that researchers are aware of and compliant with relevant laws, policies and codes of conduct.

As well as scientific and ethics review by an approving HREC, the research protocol is also reviewed by the RGO in detail. This is to ensure that the research activities described in the protocol are adequately communicated in the other project documents and all project tasks and CAHS resources to be utilised are accurately reflected in the Site Specific Assessment (SSA)/Budget forms or Access Request form (ARF) section of the RGS application.

Process/Procedure

1. Researchers must register for RGS access using the “New User Sign Up” accessible on the RGS website (refer to link below).

2. Once both RGS access and subsequent project workspace approval have been granted, researchers must complete a RGS submission (made up of ethics and site authorisation components for each project), including the provision of requested information.

3. The site Principal Investigator (PI) or their delegate is responsible for submitting the site authorisation application in RGS, while the Coordinating Principal Investigator (CPI) or delegate is responsible for the submission of the ethics application.

4. Once a completed application has been submitted, the RGO will assess it to ensure that all required documentation has been submitted and the application is complete (occurs at validation stage in RGS). Incomplete submissions cannot be fully reviewed until the missing/completed documentation is received.

5. To complete a full assessment of the project, RGO staff will review and assess the following:

    a) Site Specific Assessment (SSA)

    b) Budget form

c) Access Request form (if relevant)

d) Documents approved by HREC

And where applicable (uploaded as documents in RGS, under Site authorisation):

e) Draft Clinical Trial Research Agreement (CTRA)

f) Draft Indemnity form

g) Insurance Certificate (and policy wording if provided)

h) Student Research and Confidentiality Declaration (for investigators who are students and utilising project data as part of a higher degree, including WA Health staff).

6. In addition to the above requirements, for projects that are reviewed by a non-CAHS HREC and include a clinical intervention, a checklist for management of adverse events should be included in the application. This document is available on the CAHS website.

7. When a HREC has approved a project and the RGO has recommended approval a request for site authorisation will be forwarded in RGS to the CAHS Chief Executive (or Delegate – currently Executive Director Medical Services) – to approve the project and sign the approval letter. Where applicable the CE Delegate will also sign the CTRA and Indemnity form. For multicentre research the site authorisation approval letter will list the site specific documents that are approved for use at the CAHS site(s).

8. The PI (and delegate) will be notified via RGS when site approval has been finalised and will have access to a signed copy of the approval letter, together with a copy of the signed CTRA and Indemnity if applicable. Original signed copies can also be provided.

Related internal policies, procedures and guidelines
CAHS Research Governance process https://cahs.health.wa.gov.au/Research/For-researchers/Ethics-and-governance-approval

Related external policies, procedures, guidelines and resources
WA Health Research Governance Framework Research (health.wa.gov.au)
WA Health – Research Governance Service (RGS) https://rgs.health.wa.gov.au/
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
WA Health – RGS Document templates (including CTRA, Indemnity) https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx
Medicines Australia - Clinical Trials https://medicinesaustralia.com.au/policy/clinical-trials/
Australian Clinical Trials Handbook https://www.tga.gov.au/publication/australian-clinical-trial-handbook

Government of Western Australia - WA Government IP Policy 2023 https://www.wa.gov.au/organisation/department-of-jobs-tourism-science-and-innovation/western-australian-government-intellectual-property-policy
Radiation Safety Act 1975 (WA) https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_784_homepage.html
Working with Children Checks https://workingwithchildren.wa.gov.au

202 - Research governance review process for multi-centre projects (with non-CAHS HREC)

PROCEDURE - 202	
Research governance review process for multi-centre projects (with non-CAHS HREC) Outlines the process of the site evaluation of a multi-centre research project that has received ethics approval from a NHMRC certified Lead HREC.	
Scope (Staff):	All researchers wishing to undertake research within the CAHS whose project has been approved by a non-CAHS, NHMRC certified HREC.
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information or CAHS facilities.

Aim

To ensure all applicable research is captured, reviewed and approved by CAHS prior to project commencement.

Background

From August 2017 multi-centre projects to be undertaken at CAHS are only required to have ethics review from a single NHMRC certified Lead HREC. For all single and multi-centre projects, a site authorisation application (for research governance review and site approval) must be submitted using the online system.

Key Points

Any project that is to be undertaken within CAHS must be submitted via the RGS. The WA Specific Module (to accompany the HREA for the HREC application) must be completed in RGS and forms part of the application submitted to the reviewing HREC. Once the project has received ethics approval all HREC approved documents and approval letters are provided to the RGO to undertake the site authorisation review. HREC approval from an external lead HREC will not be accepted if the WASM has not been reviewed as part of the HREC submission.

The RGO review will follow the same process as for any project.

Process/Procedure

1. A project workspace approval must be requested from the CAHS RGO prior to HREC approval for the project being sought.

2. The WA Specific Module (WASM) is completed in the Ethics approval section of the workspace and submitted to the reviewing HREC by the researcher as part of the ethics application. This can be printed from RGS and submitted as a PDF document.

3. If the project has already been approved by a NHMRC certified HREC then an amendment to include one of the CAHS sites will require approval by the reviewing HREC. Such an amendment application must include the WASM (generated in the RGS) for review by the approving HREC.

4. Once the HREC has approved the project, including the relevant CAHS site(s), the approved protocol, Master information and consent forms, other HREC approved documents and the HREC approval letter should be uploaded to the Ethics approval section of the RGS project workspace and submitted to the RGO.

5. The site authorisation forms (Site Specific Assessment and Budget forms) are then completed, as for any project to be undertaken within CAHS. Once complete these are submitted to the RGO together with any site specific documents e.g., site versions of the information and consent forms (based on the Master versions approved by the HREC). All site specific documents should be submitted in the site authorisation section of the RGS project workspace.

6. Site specific documents based on HREC approved Masters should ensure that the version control is clearly outlined in the footer of the document – include the site specific version no. and date 'based on Master version # date'.

7. The research governance review will then follow the usual process.

Related internal policies, procedures and guidelines
CAHS – Applying to RGO Child and Adolescent Health Service | CAHS - Applying to RGO

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
RGS – Multi-centre Research https://rgs.health.wa.gov.au/Pages/Multi-centre-Research.aspx
National Mutual Acceptance Scheme National Mutual Acceptance - Clinical Trials and Research

203 - Site Specific Assessment (SSA) & Authorisation

PROCEDURE - 203	
Site Specific Assessment (SSA) and Budget forms Outlines the functions and review process of the Site Specific Assessment and Budget Forms by the Research Governance Office (RGO)	
Scope (Staff):	All researchers wishing to undertake research within CAHS
Scope (Area):	CAHS and external institutes utilising CAHS patient and patient information and CAHS facilities.

Aim

Outline the functions and review process of the forms required for research utilising CAHS patients, patient information as well as staff and/or facilities.

Background

The Site Specific Assessment (SSA) and Budget forms are the documents within the RGS that ensure that all CAHS Departments that are required to provide a service for a research study have been informed of the protocol requirements and agree to participate (including any necessary funding or support to be provided). The SSA and Budget forms are confirmation of this approval.

Key Points

Researchers should be aware that the completion of the SSA and Budget forms may take some time and so should commence the process as soon as possible. More time will be required where multiple Departments need to sign off and where the study involves radiation exposure, possible dosimetry assessment and Radiological Council approval.

Procedure for review

1. In the Site Authorisation section of the RGS project workspace researchers must draft both a SSA and Budget form (much of the information for the former will populate from the information already entered in the Project Details). It is the responsibility and the role of the site Principal Investigator (PI) or their delegate (as roles specified in the RGS) to submit the site authorisation application to the Research Governance Office (RGO) in RGS. Advice regarding the completion of these forms can be found in the RGS Help Wiki or contacting CAHS Research Support CAHS.ResearchSupport@health.wa.gov.au.

2. In the Budget form the main CAHS department (where the PI is based or where most project activities will occur) will be nominated as the 'Research' department while other departments will be nominated as 'Support' departments. All applications must include a Research department. Once details of the project activity are completed for a department it is recommended the researcher contact the head of department to discuss the project with them and advise that they would receive an invitation within RGS to authorise the department's involvement in the project. Researchers must give the authorisers of the relevant departments sufficient time to read through the study information to

    a) assess the feasibility of delivering services,

    b) assess any additional costs incurred to their department for services,

    c) determine the impact on their department,

    d) document in the Budget form any funding or other support required, and

    e) confirm their ability to participate by authorising the Budget form within RGS.

3. Three categories will automatically appear within the 'Research' department table of the Budget form (these are all Project specific costs):

    a) Clinical services – An overhead charge of 25% will be levied on commercially funded research, 10% for non-commercial funders not listed with the Australian Charities or Not for Profit Commission (ACNC). No overhead charge will be levied for funders listed with the ACNC.

b) Ethics approval – Ethics review; While the cost is the same for all projects (refer to fees in SOP 112 or CAHS website) the sponsor for commercially funded projects is listed as the funder in the relevant Budget form column in section 3 of 3. For non-commercial projects the CAHS Executive funds the fees as in-kind support, which is reflected in the relevant Budget column in section 3 of 3. The relevant sponsor name or the CAHS Executive need to be listed under Governance Information section 7 of the Project Details for them to be included in the Budget form.

c) Site specific assessment – Site process and review; As for Ethics approval (section 3.2 above).

4. It should be noted that where the Head of Department is an investigator on the project, they are not able to authorise the department on the Budget form. In such instances the relevant Divisional Director should be invited to authorise that department.

5. Once the Budget form is drafted and the heads of department have been invited and authorised the relevant section of the Budget form the SSA form should be completed. The SSA form consists of several sections

   a) Project and investigator details.

   b) Funding: The study team needs to provide details of the source of the funding for the research study as well as who will be managing these funds. Details of the relevant CAHS cost centre should also be provided (if applicable).

   c) Agreement, intellectual property, insurance and indemnity details (if applicable).

   d) Business Manager to sign in section 18.1. This is mandatory.

   e) Divisional Director to sign in section 18.1. This is mandatory unless the Divisional Director has signed the Budget form (where the Head of Department is an investigator).

   f) The Business Manager from PathWest will also need to sign in section 18.1 if PathWest is listed as a supporting department in the budget.

   g) CAHS Investigator Responsibilities (section 18.2) – CAHS Investigator is to read the declaration and sign. This is mandatory.

6. The SSA and Budget forms ensure that the PI, Head/s of Department, Business Manager and the Divisional Director under whose auspices the research is taking place have all signed to show they understand the financial, human resource, logistical and other resource implications a particular project will have upon their Departments. The Business Manager and Divisional Director will not sign the SSA form until all signatures, have been obtained in the Budget form – ensure the Budget form is complete prior to inviting these personnel to sign the SSA in the RGS.

7. The RGO will review all the required documents in the research application and determine that each Department that is required to be involved in the project has been identified, approached and given approval for the use of their resources by way of signing the Budget form. If a research application utilises the services of a department, even if it is considered ‘standard of care’ by the researcher, the researcher must still contact the Head of Department to discuss the research requirements and obtain sign-off. The same should occur if the researcher intends to recruit participants from a particular department e.g., Emergency.

8. It should be noted that all research applications that involve the use of a pharmaceutical or device for delivery of a pharmaceutical (or both) must obtain sign off from Pharmacy. Pharmacy must be responsible for the handling of all Investigational Medicinal Products (IMP) and associated devices. In exceptional circumstances where it is not possible for pharmacy to manage the IMP (for example standard medications administered in operating theatres as part of a research protocol), the researcher should ensure that they have liaised with Pharmacy regarding the project. Confirmation within the Budget form by the Clinical Trials pharmacist is required to indicate they have reviewed and approved the handling procedures for management and documentation of IMP by the PI.

9. If there is uncertainty whether a department needs to sign off for a particular project, the researcher should contact the Department or the RGO to discuss.

Procedure for approval

1. After a project has been reviewed and approved by a lead HREC (CAHS or another certified HREC under the NMA), the application for site approval will be reviewed by the RGO. The RGO will, if appropriate,

recommend to the authorised member of the CAHS Executive or Delegate that the project be given site approval.

2. The authorised member of the CAHS Executive or Delegate provides overall authorisation for a research project to commence at CAHS.
3. When site approval is been granted by the Institution, the Principal Investigator (PI) will be notified by letter via the RGS that the project has been granted approval. The project may then commence.
4. The terms of approval will be attached to the site approval letter, and these must be adhered to prevent withdrawal of the approval as stated in SOP 313.

Related internal policies, procedures and guidelines
CAHS – Applying to RGO Child and Adolescent Health Service | CAHS - Applying to RGO

Related external policies, procedures, guidelines and resources
WA Department of Health – Research Governance Service (RGS) https://rgs.health.wa.gov.au/
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
WA Health – RGS Document templates (including CTRA, Indemnity) https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx

204 - Access request form

PROCEDURE - 204	
Access request form Outlines the functions and review process of the online Access Request Form (ARF) by Research Governance Office (RGO)	
Scope (Staff):	All researchers wishing to undertake research within CAHS.
Scope (Area):	CAHS and external institutes utilising CAHS patient information or samples or recruiting CAHS patients/staff.

Aim

Outlines the functions and review process of accessing CAHS patients, information or patient samples for research use.

Background

The WA Health Access Request Form (ARF) is a form within the RGS which allows for the governance review of single-centre and multi-centre research projects, irrespective of risk, that require support from a Health Service Provider (HSP) in the form of access to participants, tissue or data, but does not involve CAHS staff as investigators and will not be conducted on site of that HSP.

Key Points

The ARF must be completed for all the sites (single or multiple) requiring access for the research within the jurisdiction of an HSP.

Examples of such projects are:

- Participant recruitment through posters, leaflets, handouts and letter of invitation - but not recruitment through direct contact with potential participants.
- Distribution of surveys and questionnaires to CAHS patients via CAHS staff - but not collation and analysis of responses at CAHS or by CAHS investigators.
- Access to data or tissue held at CAHS - but not processed, tested or analysed at CAHS or by CAHS investigators.

Procedure

1. If the project is approved by a WA Health HREC or certified HREC under the NMA scheme, documents should be uploaded in RGS via the usual process.
2. The documents to be uploaded in RGS are:
    a) Evidence of approval from a recognised HREC
    b) A copy of the HREA (if a NMA project)
    c) A copy of the advertising material and other documents to be distributed through CAHS sites (e.g., poster, recruitment letter, survey). These must clearly identify the research site and not CAHS.
    d) Access Request Form
3. RGO staff will review the application and determine if all the required documentation has been submitted. It will also ensure that each CAHS Department that has been asked to provide access to participants, data or tissue has been identified, approached and agreed (as evidenced by sign off in section 3.2 of the ARF).

4. If there is uncertainty as to whether a department needs to provide confirmation for access, the investigator should contact the Department or RGO staff to discuss.
5. Once the RGO review is complete and all requirements are met, a recommendation will be made to the CAHS Executive or delegate to approve the access requested.
6. If a project is approved by another NHMRC-registered HREC that is not WA Health or certified under the NMA scheme (e.g. university HREC), further review may be exempted and access may be granted on a case-by-case basis depending on what the requirements are. Investigators should contact the Manager, REG for advice.

Related internal policies, procedures and guidelines
CAHS – Applying to RGO Child and Adolescent Health Service | CAHS - Applying to RGO

Related external policies, procedures, guidelines and resources
WA Department of Health – Research Governance Service (RGS) https://rgs.health.wa.gov.au/
WA Health – RGS Document templates https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx

205 - Clinical Trials Notifications (CTN) & Clinical Trials Approvals (CTA)

PROCEDURE - 205	
Clinical trials notifications (CTN) and Clinical Trials Approvals (CTA) Outlines the requirements for conducting clinical trials under the CTN/CTA Scheme.	
Scope (Staff):	All researchers whose research involves the use of a medication or device that is not registered with the TGA or is to be used outside its registered indications.
Scope (Area):	CAHS and external institutes undertaking research within CAHS or utilising CAHS patients in research.

Aim

To outline the purpose and procedure for applying or notifying the TGA of a clinical trial involving an unapproved medication or device.

Background

The Therapeutic Goods Administration (TGA) is the organisation in Australia which is responsible for the regulation of therapeutic goods (medications and devices). The TGA administers two schemes under which clinical trials involving unapproved therapeutic goods may be conducted - The Clinical Trial Notification (CTN) scheme and the Clinical Trial Approval (CTA) scheme. While the former is a notification to the TGA of a project taking place with approval from a HREC and the site, the latter is an approval process in which the TGA evaluates the project in place of the HREC.

Key Points

A notification or application to the TGA is required for all clinical investigational use of a product in Australia, where that use involves:

- a product not entered on the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or
- the use of a registered or listed product outside the conditions of its marketing approval.

Process/Procedure - CTN

1. For projects being conducted under a CTN, all material relating to the proposed trial is submitted via RGS for approval in the usual way (by a HREC and CAHS site).
2. For commercial projects or when the project is sponsored by an external entity (e.g., Collaborative Research Group), the sponsor will submit the CTN once HREC and institutional approval for the project has been provided. The project team must ensure the CTN ID is included in the RGS Project Details, and a copy of the acknowledgment is submitted to RGO via RGS.
3. For investigator led or collaborative group projects where CAHS is the sponsor, the PI should draft the CTN. Researchers requiring drafter access to the TGA online system and the details to be included in the CTN form should contact the CAHS RGO.
4. Once such projects have received HREC approval and the governance review is completed the RGO will submit the CTN to the TGA. A CTN invoice will be generated by the TGA which will be sent to the RGO who will forward to the project team to organise payment. On receipt of payment the TGA will process the CTN, provide an acknowledgement and the RGO can then finalise the site authorisation approval.

Process/Procedure – CTA

1. Any researchers considering conducting a trial under the CTA scheme must contact the REG office in the first instance.
2. If a proposed clinical trial is a first time in human clinical trial proposal, a CTA approval is required prior to submission to CAHS.

3. The investigator will submit all trial material to the TGA for evaluation, together with the necessary fee payment.
4. The ethics and governance submission application should be made once the TGA has approved the use of the investigational product.

Related internal policies, procedures and guidelines
CAHS Research Governance process https://cahs.health.wa.gov.au/Research/For-researchers/Ethics-and-governance-approval

Related external policies, procedures, guidelines and resources
TGA Clinical Trials information Clinical trials | Therapeutic Goods Administration (TGA)
Australian Clinical Trials For researchers | Australian Clinical Trials
Medicines Australia - Clinical Trials https://medicinesaustralia.com.au/policy/clinical-trials/
Australian Clinical Trials Handbook https://www.tga.gov.au/publication/australian-clinical-trial-handbook

206 – Research Collaboration Agreements

PROCEDURE – 206	
Research Collaboration Agreements Outlines the process for administrative review of research collaboration agreements.	
Scope (Staff):	All researchers wishing to undertake research within CAHS that involves an external entity.
Scope (Area):	CAHS and external institutes undertaking research with CAHS patients or patient samples or information or utilising CAHS facilities.

Aim

To outline the requirements for agreements when conducting collaborative research at CAHS.

Key Points

Collaborative research between institutions can take various forms and includes research partners in industry, universities, other health service providers and not-for-profit organisations. Specific issues related to collaborative research must be negotiated before commencing.

A formal research agreement is a requirement of the Code. The Code states that organisations involved in a joint research project should ensure that an agreement is reached with the partners on the management of the research. This agreement should follow the general principles of this Code, including integrity, honesty and a commitment to excellence. The agreement should be in writing, covering the following:

- intellectual property
- confidentiality
- copyright issues
- sharing commercial returns
- responsibility for ethics and safety clearances
- reporting to appropriate agencies
- protocols to be followed by the partners when disseminating the research outcomes
- management of primary research materials and research data

The type of agreement or contract required for a specific project may vary and some research projects may require multiple agreements. Researchers should seek advice from the CAHS RGO regarding what agreements may be required. In many cases, researchers will be required to utilise approved template agreements.

Commercially Sponsored Research

For commercially sponsored pharmaceutical clinical trials, the following WA Health approved templates must be used and are available on RGS:

- WA Health - MA Clinical Trial Research Agreement – Standard (Form A)
- WA Health - MA Clinical Trial Research Agreement – Contract Research Organisation acting as Local Sponsor (Form D)
- WA Health - MA Clinical Trial Research Agreement – Phase IV Clinical Trial (Form E)
- WA Health - MA Clinical Trial Research Agreement - Phase IV Clinical Trial Contract Research Organisation acting as Local Sponsor (Form F)
- WA Health – Sponsor, CRO & Institution CTRA (Form B)

For commercially sponsored medical device clinical trials, the following WA Health approved templates must be used and is available on RGS:

WA Health - MTAA Clinical Investigation Research Agreement - Standard (CIRA)

Non-commercial Collaborative Research Groups

WA Health - MA Clinical Trial Research Agreement – Collaborative or Cooperative Research Group (CRG) Studies (Form C)

Investigator-Initiated Clinical Trials

Researchers should seek advice from the CAHS RGO regarding which Research agreement template should be used on a case by case basis.

Several sponsors and CRGs have negotiated specific CTRAs for use with CAHS (or other WA Health Services) and the RGO can provide further information about this to researchers if required.

The CAHS legal name for the purposes of a Research Agreement is:

Name of Institution: Child and Adolescent Health Service a body corporate established under section 32 of the *Health Services Act* 2016

Address: Perth Children's Hospital, 15 Hospital Avenue, Perth, 6009, Western Australia

ABN: 37 180 581 224.

Beneath the CAHS signatory block the following must be included:

*"*for and on behalf of Child and Adolescent Health Service in accordance with section 41 of the *Health Services Act 2016."*

Other available Research agreement templates (see under 'Document Templates' in RGS) are:

1. Confidentiality Disclosure Agreement
2. Data Transfer Agreement
3. Material Transfer Agreement
4. Funding Agreement
5. Service Agreement – WA Health providing the service
6. Service Agreement – WA Health receiving the service

Procedure

1. The RGO will review the CTRA and determine that the correct details are included in the document and that these details correspond with information contained in the application. This includes:

   a) The Institution's legal name (as a party to the CTRA),

   b) The title of the trial,

   c) The Sponsor entity corresponds with the entity name on the indemnity, CTN and other vital documents,

   d) The funding details outlined in Schedule 2 correspond with the information provided in the RGS Budget form.

2. The RGO will review the submitted CTRA to ensure it meets the WA Health Guidelines for Clinical Trial Research Agreements.

3. Where a Sponsor or CRG submits, without amendment, the current version of an approved CTRA, that document will be accepted by the RGO.

4. If a Sponsor or CRG submits a CTRA containing material changes, the RGO will need to assess the effect of those changes on the integrity of the CTRA. This may involve requesting advice from LLS. In such instances the Sponsor/CRG will be expected to provide an electronic (Word) version of the CTRA to facilitate editing and tracking changes.

5. Amendments to the CTRA must be set out in a schedule to the agreement and not in the actual body of the CTRA. Schedule 7 in the Medicines Australia CTRA (Forms A, B & D) and Schedule 4 of the CRG

CTRA (Form C) are used specifically for this purpose. Sponsors, CROs and CRGs are strongly encouraged to accept the WA Health approved versions without change. Where changes are requested by those parties, they should not seek to substantially amend the CTRA or introduce provisions that contradict or undermine the intent of the CTRA.

6. For Investigator-initiated clinical trials where funding or other support is provided by an external party, the RGO must be contacted regarding the type of contract to be used.

7. By virtue of his or her employment status, the Principal Investigator (PI) cannot be a party to a CTRA. The CTRA is a legal document between the Institution and the Sponsor/CRG. The PI can acknowledge, by way of signing, their obligations as set out in the terms and conditions of the CTRA.

8. Once a CTRA has been reviewed and approved by the RGO and if the Sponsor wishes to have a signed hard copy document the Sponsor/CRG should send 3-4 complete and signed copies to the RGO for signing (usually one original for the RGO, one for the study team and one for Sponsor and CRO if required). The CTRA, along with other relevant approval documentation, is then signed and dated by a member of the Executive, acting as a delegate of the CAHS Chief Executive.

9. Once signed (with other approval documentation) the CTRA will be given to the site study personnel for distribution to the Sponsor/CRG as relevant (either as a scanned copy via RGS or original hard copy according to Sponsor preference).

10. Any subsequent changes to an approved CTRA will be required to be submitted to the RGO as an amendment for review and approval. A Governance only Amendment form should accompany a copy of the CTRA amendment. If the changes are substantial the review may include the involvement of LLS.

Related internal policies, procedures and guidelines
CAHS Research Governance process https://cahs.health.wa.gov.au/Research/For-researchers/Ethics-and-governance-approval

Related external policies, procedures, guidelines and resources
Medicines Australia - Clinical Trial Research Agreements https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements
RGS Document templates https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx
WA Health Research Governance Framework Research (health.wa.gov.au)

207 - Indemnity for Clinical Trials

PROCEDURE - 207	
Indemnity for Clinical Trials Outlines the process for the administrative review of the Indemnity Form	
Scope (Staff):	All researchers wishing to undertake research within the CAHS which requires a clinical trial research agreement (CTRA).
Scope (Area):	CAHS and external institutes undertaking research which requires a clinical trial research agreement (CTRA) or utilising the CAHS Human Research Ethics Committee for review of a commercially funded project.

Aim

To outline the requirements for indemnity when conducting commercially sponsored research at CAHS.

Key Points

In all projects where the following CTRA (including amended versions) are used, the Sponsor and/or the Contract Research Organisation (CRO) must provide indemnity to the Institution and members of the Responsible HREC against claims arising from the project on the terms and conditions set out in the relevant Medicines Australia Form of Indemnity for Clinical Trials:

- CTRA - Medicines Australia Standard Form (Form A)
- CTRA - Medicines Australia Form - Contract Research Organisation acting as the Local Sponsor (Form D)
- WA CTRA Standard Form B – involving a Sponsor and a Contract Research Organisation

Projects conducted under the Clinical Trial Agreement - Collaborative or Cooperative Research Group (CRG) Studies – Standard Form (Form C) do not require the CRG to provide the Institution and HREC with an indemnity. If a CRG offers to provide an indemnity it should be in the form of the Medicines Australia version.

There are two versions of Medicines Australia (MA) Form of Indemnity for Clinical Trials:

1. Standard Form of Indemnity (for use where the Indemnified Party (CAHS) is providing premises for the conduct of the project and HREC Review, or is providing premises only)
2. HREC review only (for use where the Indemnified Party (CAHS) is providing HREC review ONLY of the project)

For most projects, the Standard Form of Indemnity will be submitted. The current version can be downloaded from the RGS or Medicines Australia.

As the Form of Indemnity is a legal document, the indemnifying party (e.g., the Sponsor) must ensure that the correct legal name appears for both ‘the Indemnified Party” and “the Sponsor”.

Note: the ABN [Australian Business Number] and address are included as part of the legal name. Researchers are advised to check ABN Lookup for the correct entity names and ABN.

Prior to submitting these documents to the RGO, researchers are to ensure that all project details, including the project number and study title are consistent with the study title and number on the Protocol.

Other details that are to be confirmed on page 1 include identification of the “the Subjects” and “the Investigator” in paragraph 1.

Depending on the type of CTRA, a signed Form of Indemnity must be provided to each of the parties to the Agreement.

Where CAHS HREC is the lead HREC for a multicentre project there will be a requirement for both a Standard Indemnity (for the site) and a HREC review only Indemnity (for the HREC approval of all sites).

The latter should be signed at the time of HREC approval, while the former will be reviewed as part of the RGO review.

Process/Procedure

1. Following submission to the RGO via RGS, the draft Form of Indemnity will be checked to verify that the details for each party are correct, that “the Subjects” and “the Principal Investigator” (PI) have been identified in paragraph 1, and that none of the wording has been altered, deleted or inadvertently omitted when completing the document details.

2. Any proposed changes to the wording of the Form of Indemnity by any party to the project, aside from those required above, must be made separate to this document. Generally, this is done in Schedule 3 of the respective CTRA.

3. If the indemnifying party makes any changes to the text of the Form of Indemnity, the RGO will need to have these reviewed by Legal & Legislative Services (LLS) at the DoH.

4. Once the Form of Indemnity is in order, a copy signed by the Sponsor and provided either in hard or electronic copy will be included as part of the documents submitted for Institutional sign-off. At that time, they will be signed and dated by a member of the CAHS Executive, acting as a delegate of the CAHS Chief Executive.

5. The RGO will retain an original CAHS signed MA Form of Indemnity. If hard copies provided by the Sponsor an original Form will be returned to the PI for distribution to the relevant Sponsor /Contract Research Organisation with the other approval documentation. A scanned copy will also be attached to the signed site approval letter sent via RGS.

Related internal policies, procedures and guidelines (if required)
Procedure 206: Clinical Trial Research Agreements (CTRA)

Useful resources (including related forms)
Medicines Australia - Clinical Trial Research Agreements https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements
RGS Document templates https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx

208 - Insurance for research

PROCEDURE - 208	
Insurance for research Outlines the process of review of insurance provisions provided for a research project by the RGO	
Scope (Staff):	All researchers wishing to undertake research within CAHS
Scope (Area):	CAHS and external institutes utilising CAHS patient and patient information and CAHS facilities.

Aim

To ensure the insurance provisions for research are adequate.

Background

Reviewing other parties' insurance is a risk management strategy which seeks to ensure that research activities are adequately covered by robust insurance provisions. This not only protects the interests of WA public hospitals but importantly also protects the interests of research participants, as well as Sponsors and supporting Clinical Research Organisations (CROs).

Key Points

The Insurance Commission of Western Australia (ICWA) manages the Western Australian Government's self-insurance arrangements, which incorporate the WA Health system including research activities. ICWA protects public institutions under the legal liability cover and provides insurance and risk management advice to its public clients. Where a hospital employed researcher initiates a research project, the proposal must be reviewed by the RGO, including examination of any external parties' insurances. ICWA provides a support service in scrutiny and advice regarding these insurances, for consideration by the RGO.

The Clinical Trial Research Agreement (CTRA) stipulates what insurance requirements must be met.

Process/Procedure

1. Where insurance is required, an insurance certificate at the very least must be provided with the submission documentation. A full copy of the insurance policy wording is preferable and research staff are encouraged to request this document from the Sponsor. The RGO will assess the insurance information provided against the 13 points of insurance that have been outlined by ICWA as the minimum amount of information that needs to be provided. These are listed in Schedule 4 of the WA CTRA's (Forms A, B and D) and are as follows:

    a) Name and address of the insurer, including its Internet website address.

    b) Name and address of the insured. If the insurance extends to other parties relevant to the agreement, details must be provided. The Institution needs to be satisfied that the Sponsor is an insured under the policy.

    c) Policy number.

    d) Period of insurance.

    e) Class of insurance.

    f) Sum insured per event including any sub limits.

    g) Aggregate sum insured.

    h) If applicable, any excess of loss/umbrella policy information.

    i) Deductibles/excesses.

    j) Whether the policy is constructed on an "occurrence" or "claims made" wording.

k) Scope of cover. For example, “Legal liability of the insured for death and bodily injury arising from clinical trials, including products liability risks”. There may be a need to quote the operative clause of the policy to capture the correct interpretation.

l) Territorial limits of the policy. It is essential that the policy respond to claims lodged and processed in an Australian jurisdiction. Notwithstanding that the cover may apply anywhere in the World, if there are any restrictions on claims in an Australian jurisdiction, these must be detailed (if an overseas sponsor is providing insurance, it needs to be clarified that if a claim were to be made that it would not be required to be heard in a court overseas).

m) Relevant policy exclusions and conditions must be listed and detailed if appropriate. Exclusions relating to contractual liabilities, specific drugs and implements may be important (this is important as the RGO has found examples where the very product being trialled is listed as an exclusion on the insurance policy, rendering the insurance policy provided for that research study as useless, leaving WA Health open to a claim).

2. The Institution will review insurance limits with reference to the risks of the project however the minimum requirements for a sponsor and/or CRO are:

   a) public liability insurance for the minimum sum insured of AUD $5,000,000 any one occurrence: and

   b) liability insurance covering:

      - clinical trial / product liability (or equivalent) and professional indemnity; and
      - the contractual obligations of the Sponsor and the CRO contained in the Agreement,
        - without limiting the indemnity obligations of the Sponsor and the CRO set out in Schedule 3 of the Agreement.
        - for minimum sum insured of AUD $10,000,000 any one claim and in the aggregate during any one twelve (12) month period of insurance and which does not contain an excess/deductible or self-insured retention amount greater than AUD $25,000 for each claim or series of claims arising out of one originating cause.

3. Where the 13 points of insurance information have not been provided, the project team will be sent a request by the RGO for the balance of information that is to be obtained from the Sponsor/CRO. Once this information is received by the RGO and deemed to be in order, then the insurance review is complete.

4. If a CRO is acting as a local sponsor it should be either named as an additional insured on the sponsor’s insurance policy or provide evidence of its company’s policy.

5. Any employee of an external institution attending site for research purposes (e.g., CRO for site initiation or monitoring visits) should be covered by public liability insurance. Evidence of such insurance should be provided with the submission documentation.

6. When the RGO receives information regarding insurance that does not comply with ICWA’s recommendations or is difficult to understand or analyse, ICWA will be contacted for further advice.

7. If a policy has been provided that does not comply with requirements and no further information/documentation is forthcoming from the sponsor/CRO, then the RGO will take the information to the CAHS Executive to decide if the trial can proceed based on the insurance provisions provided.

Related external policies, procedures, guidelines and resources
Medicines Australia - Clinical Trial Research Agreements Clinical Trials – Medicines Australia
Insurance Commission of Western Australia – Risk Cover Government Insurance - Insurance Commission of Western Australia (icwa.wa.gov.au)
Australian Prudential Regulation Authority – Register of Institutions authorised to provide general insurance (including for clinical trials)

Register of general insurance | APRA

209 - Intellectual property in research

PROCEDURE – 209	
Intellectual property in research Outlines the process for the protection and management of Intellectual Property in research studies.	
Scope (Staff):	All researchers wishing to undertake research within CAHS.
Scope (Area):	CAHS and external institutes undertaking research with CAHS patients or patient samples or information.

Aim

Outlines the process for the protection and management of Intellectual Property in research studies.

Background

Intellectual Property (IP) is the tangible representation of intellect and creativity, which has value and is protectable by law. There is wide diversity in the types of IP that are generated in WA Health. These include new drugs, medical devices, data, software, teaching and training materials, reports or business processes. In some cases, these products can have actual or potential commercial value, and may require some form of protection. In WA Health this is generally through Copyright and Patenting.

Copyright refers to a series of rights granted to the author or creator of an original work, including the right to copy, distribute and adapt the work. Copyright does not protect ideas, only their expression or fixation. Under the Copyright Act (Commonwealth 1968) copyright arises upon fixation and does not need to be formally registered.

Patents are applicable to inventions or innovations that potentially lead to new and improved products or processes. They provide a time-limited monopoly over commercialisation, and require formal registration procedures, that are complex, costly and require specialist advice. Care must be taken with respect to documentation, prior use or public disclosure, and the establishment of 'first to invent' status may apply.

Key Points

- The State of WA owns IP rights created by CAHS employees in the course of their employment. However, in some circumstances, agreements may be entered into to vary these arrangements.
- Relevant employment, secondment and consultancy contracts shall expressly address any research, invention and other such duties of employees.
- IP ownership shall be addressed in contracts between CAHS, other agencies and third parties that involve pre-existing IP or new IP. This includes procurement, grant, funding, research and collaboration contracts.
- Where possible, business critical or IP required for core functions owned by the State of WA should be retained.
- Where the State of WA will not own the IP, the State of WA's right to use the IP (licence terms) must be specifically addressed in all relevant contracts. The right to use the IP should be broad enough to cover the State of WA's and CAHS operational needs.
- All IP and IP agreements involving CAHS must comply with the following WA State Government and Department of Health policies and procedures:
    - WA Government Intellectual Property Policy
    - WA Health Intellectual Property Policy - MP 0156/21
    - Intellectual Property Management in the WA Health System
    - CAHS Intellectual Property Policy

Significant IP is that which:

- has potential strategic, financial, operational or public value or requires statutory registration and renewal; and
- risks being unlawfully copied or otherwise misappropriated or misused by external parties.

Process/Procedure

1. When a CAHS employee is involved in a research project that has been approved by the Institution, the Institution supports this project by providing indemnity and insurance. If there are reasonable grounds to anticipate that significant IP could be developed in the study, the employee must notify the CAHS IP Contact Point through formal written notification as early as practicable. The CAHS IP Contact Point shall review the reported IP with the employee and where appropriate, record the IP on the CAHS IP Register. The employee will be requested to acknowledge the ownership of this IP by the State of WA, represented by CAHS.

2. CAHS staff must make every effort to identify and acknowledge any third-party IP that they might use and avoid any infringement of the IP rights of the other party. This also applies to material that carries no evident ownership disclaimers, such as can be downloaded from the internet.

3. The ownership and use of both Background (pre-existing) IP and newly developed (Project) IP in collaborative research should be specified in written contractual agreements between the participating parties. These agreements will need to be approved by the RGO, which may consult with the CAHS IP Contact Point and the Office of Medical Research (OMRI), DoH. Background and Project IP can, in some circumstances, be assigned to another party, but only upon specific approval by the RGO, in consultation with the CAHS IP Contact Point and OMRI.

4. Patent protection or commercialisation of CAHS IP must not be undertaken without prior authorisation and guidance from the RGO which may consult with the CAHS IP Contact Point and OMRI, DoH.

5. Brandon BioCatalyst can offer WA Health researchers the opportunity to apply for funding for early stage development and commercialisation of intellectual property.

6. The possible benefits to WA Health employees resulting from the commercialisation of IP are considered in the policy: WA Government Intellectual Property Policy 2023.

7. Authorship of scientific publications resulting from research projects will be governed by the guidelines of the International Committee of Medical Journal Editors. Most scientific, technical and medical publications require that the IP rights to published articles be assigned to the Journal, although some open-access publications do not require this.

8. Unless IP assignment is required by the publisher, any publication, whether in print or electronic form, arising from WA Health activities must carry the copyright disclaimer available on the DoH IP Management website.

9. Any queries in relation to IP matters in WA Health/CAHS must be directed in the first instance to the IP Contact Point at CAHS. If required these may be then referred to the OMRI.

Related internal policies, procedures and guidelines
CAHS – Intellectual Property Policy

Related external policies, procedures, guidelines and resources

Department of Health – Intellectual Property Policy https://www.health.wa.gov.au/About-us/Policy-frameworks/Research/Mandatory-requirements/Intellectual-Property-Policy
Department of Health - Procedures for the protection and commercialisation of WA Health IP https://ww2.health.wa.gov.au/Articles/F_I/IP-Management-in-WA-Health
Government of Western Australia - WA Government IP Policy 2023 https://www.wa.gov.au/organisation/department-of-jobs-tourism-science-and-innovation/western-australian-government-intellectual-property-policy
Brandon BioCatalyst https://brandonbiocatalyst.com/
NHMRC - National principles of IP management for publicly funded research https://www.nhmrc.gov.au/about-us/resources/national-principles-ip-management-publicly-funded-research
Department of Health - Code of Conduct https://www.health.wa.gov.au/About-us/Policy-frameworks/Integrity/Mandatory-requirements/Code-of-Conduct-Policy
International Committee of Medical Journal Editors - Recommendations http://www.icmje.org/recommendations

210 - Adult Research Participants

Procedure - 210	
Adult Research Participants To explain the process for seeking research approval for a study onsite at CAHS involving adult participants.	
Scope (Staff):	All researchers undertaking research within CAHS.
Scope (Area):	CAHS and external institutes undertaking research with CAHS staff, facilities, patients, patient samples or information.

Aim

To explain the process for seeking research approval for a study involving adult participants.

Background

As the CAHS most research activity will be focused predominantly on children and adolescents as well as their families. It is expected that clinicians and associated staff at CAHS conducting research will be appropriately experienced and/or supervised in appropriate oversight with the paediatric cohort of participants. However, there are additional considerations specific to conducting adult research in a paediatric facility - as opposed to an adult facility at another WA Health service.

CAHS HREC supports CAHS research in adults involving:

- parents/guardians of participants
- siblings of participants
- adolescent and young adults up to 25 years of age
- pregnant adults
- healthcare workers / staff participants (e.g., CAHS, Telethon Kids Institute and/or Universities)

For research involving adult participants that fall outside the parameters described in this procedure, investigators should seek advice from the Manager, REG prior to submitting a research application to CAHS.

Procedure

1. It is the Investigator's responsibility to ensure all possible risks associated with the study have been considered, minimised and are appropriately managed specific to the adult population.
2. When the study involves adult participants receiving an intervention, a safety monitoring plan is required specific to the adult cohort. The plan should include the following:
    a) Details of any Data Safety Monitoring Committee or independent adult clinician who has the expertise in the research area to review the protocol and monitor the ongoing safety of the study.
    b) The procedure to monitor the outcome of the study intervention including duration and frequency of monitoring of the intervention throughout the study period.
    c) Details of the process to determine whether an adult participant should continue the study; the contact details of a clinician who is able to authorise discharge following the interventional activity; and an outline of the information and resources that will be supplied to study participants on discharge.
    d) The Procedure that will be followed if an adverse event occurs while an adult participant is on site at CAHS.
    e) A description of the availability and accessibility of a suitable clinician(s) in the event of an adverse safety issue.

f) A description of the skills and qualifications of the fully trained staff who will be managing the study on site at CAHS.

3. Investigators need to establish a separate webPAS clinic code to separate the adult participants and ensure medical records are not automatically called or created for this cohort.

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
NHMRC - Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods; November 2016 https://nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

ETHICS AND GOVERNANCE POST APPROVAL PROCEDURES

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301 - Expiry of approval

PROCEDURE - 301	
Expiry of approval To explain the administrative process for granting an extension to the approval to conduct research.	
Scope (Staff):	CAHS and external institutes undertaking research with CAHS patients, patient samples or information and /or CAHS facilities.
Scope (Area):	CAHS and external institutes undertaking research with CAHS patients, patient samples or information and/or CAHS facilities.

Aim

To explain the administrative process for granting an extension to the HREC approval to conduct research.

Background

CAHS HREC issues approval for a period of three (3) years. Institutional approval at CAHS is valid, once granted, while there is ongoing HREC approval. Approval granted from an external Lead HREC under NMA may be for a different period. It is the responsibility of the researcher to be aware of any requirements from the approving HREC for continued approval.

Key Points

- CAHS HREC, and thus institutional approval is valid for a period of three (3) years. This can be extended for a further period of up to 3 years.
- Beyond a six (6) year timeframe, if further HREC approval is required, acceptable justification must be provided with the request to be reviewed by HREC.
- Continued HREC endorsement is conditional on the receipt of annual progress reports.
- The HREC has the discretion to recommend immediate suspension or termination of a project to the institution.
- The expiry date of HREC approval will be included in the initial HREC approval letter and in the annual progress report reminders sent to the CPI and their delegate.
- The research must not continue beyond the HREC approval expiry date without an extension being granted.

Procedure

1. To request an extension of HREC approval, the CPI (or their delegate) must submit an Amendment form to the HREC via the RGS.
2. HREC approval can be extended for up to a further 3 years at the discretion of the REG office. Approvals within the 6-year timeframe can be approved by the REG office staff as delegate of the HREC.
3. Once approved by the HREC, the request should be submitted to CAHS RGO to determine if the continuation of the project has any implications to the site.
4. Further extension requests beyond 6 years can be submitted by the same process. Justification is required and the request will be reviewed by the HREC at a HREC meeting. Approval of each subsequent extension request will be at the discretion of the HREC. In some instances, a new application may be required.
5. The HREC may set a project specific approval period depending on the level of risk and complexity of the project.

Related internal policies, procedures and guidelines
CAHS Human Research Ethics Committee (HREC) Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
RGS User Guide Monitoring – Amendments https://rgs.health.wa.gov.au/rgshelp/Pages/Amendments.aspx

302 - Amendments for review by CAHS HREC

PROCEDURE - 302	
Amendments for review by CAHS HREC To describe the process for the submission and approval of amendments to the CAHS HREC.	
Scope (Staff):	Researchers submitting amendments to approved research projects to the CAHS HREC.
Scope (Area):	CAHS and external institutes undertaking research with CAHS patients, patient samples or information and/or CAHS facilities.

Aim

To describe the procedures for the submission and CAHS HREC review of requests for amendment and renewal (extension) of HREC approval for approved projects.

Key Points

An ethics amendment application is required when there has been a change to a project following initial HREC approval.

Minor amendments - minimal changes or corrections to participant documents, addition or removal of a study team member, addition or removal of a study site, extension of HREC approval request.

Substantial amendments – addition of outcome measures/tests, significant changes to study design and methodology, addition of a sub-study, significant changes to participant documents e.g., information regarding risk has changed, important addition of information that elevates the risk and safety profile of the study.

- The REG office has been delegated authority by the HREC to review and approve minor amendments and requests for HREC approval extensions.
- The LREC has been delegated the authority by the HREC to review and approve substantial amendments for research deemed low risk.
- The CTS has been delegated the authority by the HREC to review and approve substantial amendments for clinical trial projects.
- REG office, LREC and CTS have the discretionary ability to refer any amendment to the full HREC for review.

Procedure

1. Proposed changes to approved research projects and requests for extensions to HREC approval must be submitted by the CPI or CPI delegate via RGS for ethics review and approval.
2. Amendments must outline the nature of the proposed changes and/or request for extension, reason/s for the request, and an assessment of any ethical implications arising from the request on the conduct of the research. All amended documents must have tracked changes, a clean copy and contain revised version number and date.
3. Minor amendments will be reviewed and approved by the REG office.
    - Approval letters listing the approved amendments or new date for HREC expiry will be sent to the CPI via RGS.
    - The amendment application will be listed on the agenda of the next scheduled HREC meeting for noting by HREC.
4. Substantial amendments for low risk projects can be reviewed via the low risk review pathway.
    - If LREC members determine that further information, clarification or corrections are required, correspondence will be provided to the CPI clearly articulating the reasons for this determination.
    - Approval letters listing the approved amendments will be sent from a REG office delegate to the CPI via RGS.

- The amendment application will be listed on the agenda of the next scheduled HREC meeting for noting by HREC.

5. Substantial amendments for clinical trials will be reviewed by the CTS at a scheduled CTS meeting.
   - If CTS members determine that further information, clarification or corrections are required, correspondence will be provided to the CPI clearly articulating the reasons for this determination.
   - Approval letters listing the approved amendments will be sent from a REG office delegate of the CTS to the CPI via RGS.
6. Substantial amendments for projects not low risk and not a clinical trial will be reviewed by the HREC at a scheduled HREC meeting.
   - If HREC members determine that further information, clarification or corrections are required, correspondence will be provided to the CPI clearly articulating the reasons for this determination.
   - Approval letters listing the approved amendments will be sent from a REG office delegate of the HREC to the CPI via RGS.
7. All reviewed and approved requests for amendment and extensions are recorded, and the status of the project is updated within the project RGS workspace.
8. An approval letter from CAHS HREC or delegate constitutes ethics approval only. Submission and approval must also be sought from the site RGO.
9. For projects approved by another WA Health HREC or another lead HREC under NMA, amendments need only to be submitted to the CAHS RGO and not to the CAHS HREC.
10. For projects approved by CAHS HREC, conducted only at a CAHS site (single site CAHS project), amendments need only to be submitted to the CAHS HREC and not to CAHS RGO.
11. Memos and notification letters from external sponsors regarding temporary closure, partial closure, early termination affecting a specific site, due to safety concerns, should be submitted on an amendment form for review by the CTS.
12. Other types of memos and notification letters from external sponsors that does not correspond with an amendment to the approved research project, does not require review or approval by HREC or delegate. If notification from the HREC is requested by the external sponsor, the REG office will issue an acknowledgment letter via RGS and the documents will be listed in the agenda for the next scheduled HREC for noting by HREC.

Related internal policies, procedures and guidelines
CAHS Low Risk Ethics Committee (LREC) Terms of Reference CAHS Human Research Ethics Committee (HREC) Terms of Reference CAHS Clinical Trials Subcommittee (CTS) Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
RGS User Guide Monitoring – Amendments https://rgs.health.wa.gov.au/rgshelp/Pages/Amendments.aspx

303 - Amendments for review by CAHS RGO

PROCEDURE - 303	
Amendments for review by CAHS RGO To describe the process for the submission and approval of substantial amendments to the CAHS RGO.	
Scope (Staff):	Researchers submitting substantial amendments to the CAHS RGO.
Scope (Area):	CAHS and external institutes undertaking research with CAHS patients, patient samples or information and/or CAHS facilities.

Aim

To describe the procedures for the submission and CAHS RGO review of requests for amendments for HREC approval for approved projects.

Key Points

1. An amendment must satisfy both ethics and institutional requirements to be approved. The latter is achieved by a governance review to safeguard the continuation of the ethical, legal and professional standards of the project and ensures that the amendment does not impact on the safety of project participants or increase the risk to the staff and Institution.
2. Please refer to RGS for guidelines on the preparation and submission of your amendment (See link to RGS listed under 'useful resources' at the end of this document).

Procedure

An amendment is required to be submitted to CAHS RGO via RGS, following HREC approval in the following instances:

1. For multi-centre project within WA Health only – lead HREC is not CAHS

Following HREC approval under the WA health single site review scheme, the approved amendment form is required to be submitted to CAHS RGO for site approval for the following changes:

a) Changes to the project protocol

b) Change to site-specific documents

c) Changes to the research team affecting the CAHS site

2. For multi-centre projects under the NMA scheme – lead HREC is CAHS

Following CAHS HREC approval, the approved amendment form is required to be submitted to CAHS RGO for site approval for the following changes:

a) Changes to the project protocol

b) Changes to site-specific documents

c) Updates to an Insurance Policy

d) Changes to any agreement in place e.g., Clinical Trial Agreement

e) Changes to the budget

f) Changes to the research team affecting the CAHS site

3. For multi-centre projects under the NMA scheme -Lead HREC is not CAHS

Following lead HREC approval, then the following documentation must be submitted via a Governance Only Amendment form:

a) Changes to the project protocol
b) Changes to site-specific documents
c) Updates to an Insurance Policy
d) Changes to any agreement in place e.g., Clinical Trial Agreement
e) Changes to the budget
f) Changes to the research team affecting the CAHS site
g) A copy of the Lead HREC Approval letter

3. Once submitted via RGS, the amendment application will be validated and reviewed by RGO staff. The RGO review will:
   a) Determine if the amendment will result in any changes to the research project's vital documents e.g., CTRA or CTN.
   b) Assess if the amendment will be included under the existing insurance provisions.
   c) Conduct a site-specific assessment to determine if the amendment has additional impact on any department within CAHS.
   d) Assess whether the amendment documentation includes all the required changes and updated documents.
4. The RGO may request further information or clarification and/or updates to documents where necessary from the researcher before approving the amendment. Any such request will be communicated to the researcher via RGS.
5. Official responses and/or amended documentation are to be submitted through the RGS.
6. Once recommended for approval approved by the RGO, an institutional approval letter will be sent via RGS to the PI by the RGO.
7. Memos and notification letters from external sponsors regarding temporary closure, partial closure, early termination affecting a specific site, for reasons other than safety concerns, should be submitted on a Governance only amendment form for action.

Related internal policies, procedures and guidelines
CAHS – Applying to RGO Child and Adolescent Health Service | CAHS - Applying to RGO

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
RGS homepage: https://rgs.health.wa.gov.au/Pages/Home.aspx
RGS User Guide – Amendments User Guides (health.wa.gov.au)

304 – Safety and Adverse Event Reporting

PROCEDURE - 304	
Safety and Adverse Event Reporting	
Scope (Staff):	All researchers undertaking research within CAHS.
Scope (Area):	CAHS and external institutes undertaking research with CAHS staff, facilities, patients, patient samples or information.

Aim

To outline the safety reporting requirements associated with clinical trials involving investigational medicinal products and investigational medical devices conducted at CAHS. The reporting requirements are indicated as they apply where CAHS is the approving HREC, approving institution and/or CAHS is the named Sponsor.

Background

All sponsors of clinical trials conducted in Australia are responsible for ensuring that clinical trials conducted under their auspices are designed, managed and monitored in a way that ensures participants are protected and the trial data generated are both reliable and robust. This is equally important for commercial and non-commercial clinical trials, as both types of trial have the potential to significantly impact on the future clinical care of patients.

CAHS safety reporting is in line with the NHMRC *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (2016) and the WA Health Research Governance Policy and Procedure.

For commercially sponsored clinical trials, the sponsor is responsible for safety reporting. For investigator-led, CAHS sponsored clinical trials, the Principal Investigator is responsible for Safety reporting. Refer to Table 304.1

All researchers are responsible for ensuring that all clinical incidents related to research are reported in line with the MP 0122/19 - Clinical Incident Management Policy and all associated procedures and guidelines.

All safety reports are submitted via RGS using the Safety Report form under the monitoring tab.

Procedure

The sponsor via the CPI or PI is responsible for the following:

- Proactively monitoring the ongoing risk versus benefit ratio of the clinical trial.
- Ensuring there is appropriate independent oversight of the safety of the clinical trial by use of a Data Safety Monitoring Board (DSMB) or independent individuals (e.g., a medical monitor) to review accruing safety data.
- Providing the lead HREC with an annual safety report, which includes an outline of relevant findings to date, an updated Investigator Brochure (IB) if relevant, a discussion of the implications of the safety data, any measures taken to minimise risk and confirmation that the research project is being adequately monitored (the Executive Summary of a Development Safety Update Report (DSUR) or DSMB report may be used where applicable)
- Reporting serious breaches of the protocol or the Australian Code, that may affect participant safety and/or the reliability of the data to the:
    - lead HREC within seven days
    - RGO at the site the breach occurred within 72 hours
- Reporting all significant safety issues (SSIs) that adversely affect the safety of the participant to the:
    - lead HREC within 72 hours
    - RGO at the site the issue occurred within 72 hours

- Reporting all local Suspected Unexpected Serious Adverse Reaction (SUSAR) and Unanticipated Serious Adverse Device Effect (USADE) to the RGO of the site where the issue occurred within 72 hours.
- Where CAHS is listed as the sponsor, the CAHS CPI (acting as Sponsor-Investigator) is responsible for assessing and categorising the safety reports received from investigators at all participating sites. The CPI must then report all SUSAR and USADE occurring in Australian participants to Research Department who will confirm the assessment and category and complete reporting to the Therapeutic Goods Administration (TGA) within the time frames specified by the TGA.
- Reports of safety issues or breaches must be accompanied by a Corrective and Preventative Action (CAPA) plan uploaded to the Safety Report form as an attachment
- In line with relevant national guidelines, investigators are **not required** to report:
  - adverse events which do not meet the definition of a local SUSAR/USADE
  - SUSAR line listings
  - hospitalisation, injury or sickness in trial participants not related to the research project
  - full DSUR or DSMB reports (executive summaries may be used as the annual safety report).

Table 304.1 Reporting table

For research that is either ethically approved by the CAHS HREC, or where CAHS has issued governance authorisation only, the following reporting structure applies:

Report Type	Report to	Responsibility	Time Frame
Serious Breach *	RGO at the site the breach occurred	PI	72 hours
	Lead HREC	CPI	7 calendar days
Significant Safety Issue (SSI) #	RGO at any site the issue will impact	PI	72 hours
	Lead HREC	CPI	Initial report 72 hours Follow up 15 days
Suspected Unexpected Serious Adverse Reaction (SUSAR) ^	RGO at the site the event occurred	PI	72 hours
Annual Safety Report	Lead HREC	CPI	Annual
Temporary Halt or Termination notification	Lead HREC	CPI	15 calendar days
Updated Investigator Brochure (IB) - No protocol / PICF change	Lead HREC	CPI	When received from Sponsor
Updated IB - with Protocol / PICF change	Lead HREC	CPI	When received from Sponsor
	All RGOs	PI	

* A serious breach of the protocol or the Code that is something that is likely to affect the safety or rights of a participant, or the reliability and robustness of the data generated in the research. This includes breaches in privacy and confidentiality of the research data.

A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

^ An adverse reaction that is both serious and unexpected and related to the research.

Related internal policies, procedures and guidelines
CAHS Research – Applying to HREC – Amendments and Monitoring Child and Adolescent Health Service | CAHS - Applying to HREC
CAHS Clinical Incident Management Guideline Clinical Incident Management (health.wa.gov.au)

Related external policies, procedures, guidelines and resources
NHMRC - Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) Safety monitoring and reporting in clinical trials involving therapeutic goods | NHMRC
NHMRC – Data Safety Monitoring Boards (2018) Safety monitoring and reporting in clinical trials involving therapeutic goods | NHMRC
WA Health Clinical Incident Management Policy (MP 0122/19) Clinical Incident Management Policy 2019 (health.wa.gov.au)
WA Health Research Governance Policy Research Governance Policy (health.wa.gov.au)
WA Health Research Governance Procedures DoH Multi-page Template (health.wa.gov.au)
Therapeutic Goods Administration - Report a medical device adverse event (sponsor/manufacturer) http://www.tga.gov.au/form/report-medical-device-adverse-event-sponsormanufacturer
Therapeutic Goods Administration - Users Medical Device Incident Report https://apps.tga.gov.au/prod/mdir/udir03.aspx?sid=-57210438
Therapeutic Goods Administration – Sponsor / Manufacturer Medical Device Incident Report http://www.tga.gov.au/form/report-medical-device-adverse-event-sponsormanufacturer

305 – Corrective Action and Preventative Action Plan (CAPA)

Procedure - 305	
Corrective Action and Preventative Action Plan (CAPA) To outline the requirements of when to complete a CAPA to address a research-related issue that has occurred.	
Scope (Staff):	All researchers undertaking a clinical trial within CAHS.
Scope (Area):	CAHS and external institutes undertaking a clinical trial utilising CAHS patients and facilities.

Aim

The purpose of this document is to outline the requirements of completing a Corrective and Preventive Action Plan (CAPA) to address a research-related issue.

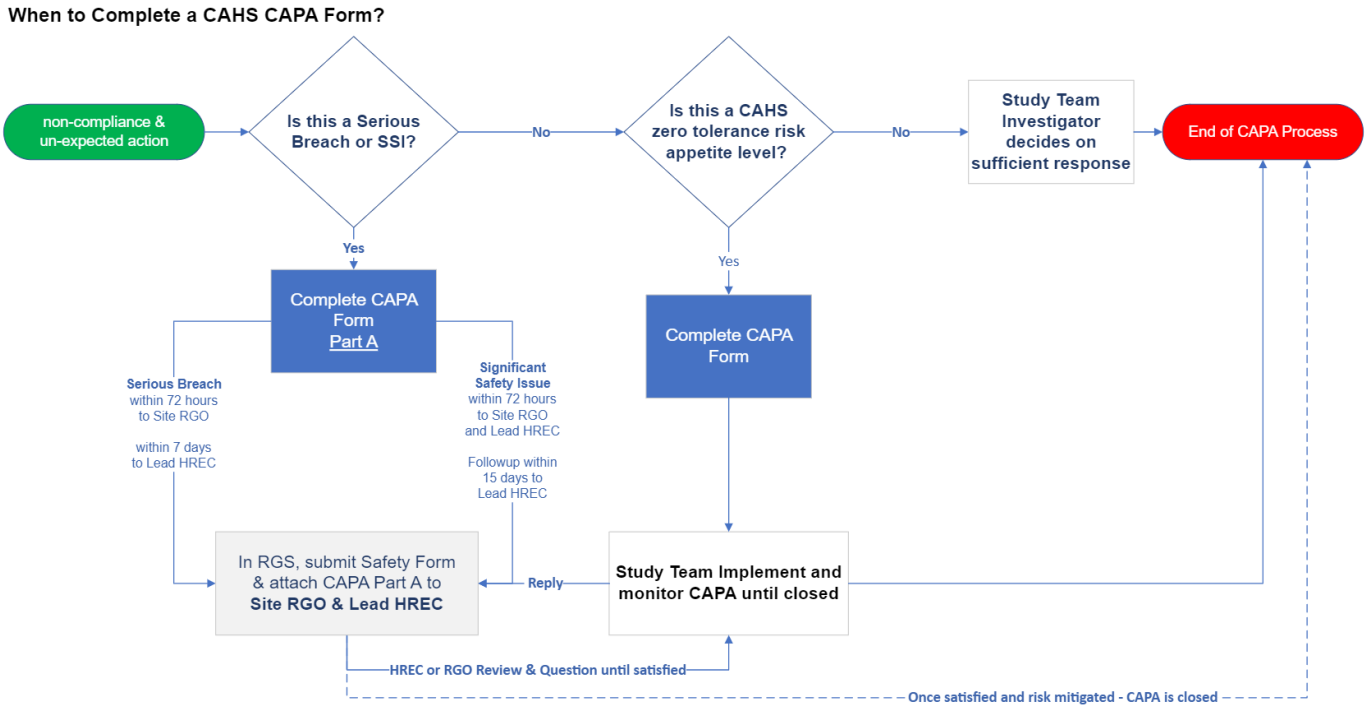
Background

A CAPA is a quality system plan used to address a research-related issue that has occurred. It incorporates:
1. Identifying the root cause of the issue;
2. Identifying actions to prevent recurrence of the issue (corrective action) or, identify actions to prevent an issue from occurring (preventive action);
3. Documenting that the required actions were completed.

Some examples of research-related issues include: injury of clinical trial participants or a high potential for this to occur; repeated violations of the protocol; serious breaches of privacy and significant data integrity problems.

The CAPA process is an important part of ensuring quality and ethical research practice and ensuring that systems used in research are continuously improved.

Process Map:



Procedure

1. Identification of an issue

Potential and/or actual issues that arise during the conduct of research can be identified through several sources. For example:

- A specific incident has occurred;
- Observations/concerns are made by a research staff member about a potential issue;
- Concerns are raised during/after monitoring, auditing, external/third party audits, or regulatory authority inspection of the research;
- A concern raised by another body such as a data safety monitoring committee, HREC or Governance.

Please note that these may or may not be a deviation from the protocol.

If the issue is a Serious Breach or a Significant Safety Issue (SSI), you are required to complete the CAHS Research CAPA form along with the required Safety Report and submit them both to Lead HREC or Site RGO. See procedure 304 – Safety and Adverse Event Reporting for information on the required Safety Report.

- A serious breach of the protocol or the Code is something that is likely to affect the safety or rights of a participant, or the reliability and robustness of the data generated in the research. This includes breaches in privacy and confidentiality of the research data.
- A safety issue is an action that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

2. Assessing the Risk

A CAPA is required in cases where a corrective action and/or preventative action is necessary to appropriately address a risk. Risk assessments improve quality and compliance. They are a proactive, anticipatory approach to improve quality management.
CAHS considers the different levels of risk appetite a more practical and realistic view of risk to be taken in the workplace. Appetite exists on a continuum starting with No Appetite and then moves into the 'considered appetite' levels of Limited, Balanced and Enhanced.

If an activity has been assessed as having No Risk Appetite with a 0 Tolerance Level, then a CAPA must be completed. See B1 Risk Assessment below for further information.

3. Developing the CAPA Plan

The steps are listed below in how the CAHS Research CAPA Form should be completed.

Complete Part A

- **A1 Quality Issue Identification:** The study team shall identify and decide who will take overall responsibility for the CAPA plan. This person is called the CAPA Owner. This includes development of the CAPA plan, its implementation, training of staff on the CAPA plan, and evaluation of the results of the CAPA plan.
- **A2 Quality Description:** Complete details relating to the quality issue. Provide action taken in response to issue.

Note: If issue is a Serious Breach or SSI, at a minimum, complete part A1 & A2 and submit to RGS with your Safety Report within the time frames listed in Table 304.1.

Complete Part B

- **B1 Risk Assessment:** Indicate what is the Risk Tolerance Level of this issue. Choose an appetite statement below that reflects CAHS Tolerance Levels if this event should happen again.

Table 1: Extracted from CAHS Risk Appetite Statement 2021 - 2024

CAHS has the lowest appetite for risks related to:

- safety and health of children and adolescents;
- workplace health and safety of its staff;
- security of confidential and personal information;
- fraud and corruption; and
- regulatory compliance.

Element	Detailed risk appetite definitions			
	NO APPETITE	LIMITED	BALANCED	ENHANCED
Descriptor	Unwillingness to knowingly accepting any level of risk and holds no consideration for opportunities or returns. These activities are to be avoided and robust controls are required to ensure these activities do not occur.	Takes a cautious approach ensuring that risk management objectives are prioritised over benefits. Treatments are premised on lowest acceptable levels of risk.	Takes a balanced approach where risk reduction and pursuing benefits are given equal consideration. Treatment decisions are based on strategic priorities.	Taking risk is considered essential within agreed thresholds in order to pursue benefits. Treatments are designed to support innovation and opportunity.
Risk Tolerance Level	Zero Tolerance	Low Tolerance	Medium Tolerance	High Tolerance
Approach	Avoid	Cautious	Balanced	Pursue

- **B2 Root Cause Analysis:** Evaluate the extent of the problem: identify/characterise the problem; determine the scope and impact; investigate data, process, operations and other sources of information; investigate the impact of the issue on the overall research.

  Focus on determining the root cause(s): Investigate how/why the incident occurred (i.e. are there specific causes or sources of the problem; why is this problem occurring; is the problem due to training, design, manufacture, management, documentation, etc.). After identifying the root cause(s), break the solution into discrete, measurable actions that address the root cause(s).

- **B3 Action Item Tracker:** Organise each action and include the following attributes:
  a. What will be done – identify action(s) needed to correct and prevent recurrence (e.g. amending documents, changing systems, staff training)
  b. Who is assigned responsibility to manage or make amendments & perform the corrective actions?
  c. Establish an achievable target date for completion.
  d. Update the action tracker with a completion date once completed.

- **B4 CAPA Effectiveness and Monitoring:** Indicate if the effectiveness of the CAPA actions need to be monitored. If yes, decide on how the effectiveness of the actions will be determined. For example, will spot checks be required or will surveys or questionnaires need to be completed. Update this section once an assessment has been made and indicate whether the CAPA was effective or not effective. If not effective, enter a reason why in the comment box.

- **B5 CAPA Owner Signature:** The Principal Investigator, as the CAPA Owner, is required to acknowledge completion of CAPA, effectiveness outcome and confirming the CAPA can be closed.

Related internal policies, procedures and guidelines
CAHS Research – Applying to HREC – Amendments and Monitoring Child and Adolescent Health Service | CAHS - Applying to HREC
CAHS Research CAPA Form Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
NHMRC - Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) Safety monitoring and reporting in clinical trials involving therapeutic goods | NHMRC
NHMRC – Data Safety Monitoring Boards (2018) Safety monitoring and reporting in clinical trials involving therapeutic goods | NHMRC
WA Health Clinical Incident Management Policy (MP 0122/19) Clinical Incident Management Policy 2019 (health.wa.gov.au)
WA Health Research Governance Policy Research Governance Policy (health.wa.gov.au)
WA Health Research Governance Procedures DoH Multi-page Template (health.wa.gov.au)

306 - Data and Safety Monitoring Requirements

Procedure - 306	
Data and Safety Monitoring Plan Requirements To outline the requirements of a data safety monitoring plan and a data and safety review process in interventional research.	
Scope (Staff):	All researchers undertaking a clinical trial within CAHS.
Scope (Area):	CAHS and external institutes undertaking a clinical trial utilising CAHS patients and facilities.

Aim

The purpose of this document is to outline the requirements of a data safety monitoring plan and review process to researchers within the CAHS.

Background

A data and safety monitoring plan is the minimum requirement in all clinical interventional research to ensure participant safety. The plan should include the following information:

1. Protocol or procedure to monitor trial progress and safety
2. A plan to assess data quality, timeliness, participant recruitment, accrual and retention
3. A plan to assure data accuracy and protocol compliance
4. Definition of specific triggers or stopping rules that will dictate the required follow up actions
5. A plan to assure compliance with CAHS HREC safety and adverse events reporting requirements (SOP 307) which should include:
    a. A process or procedure for detecting and reporting severe adverse event (SAE) and/or problems involving risk to participants
    b. Nominated persons to monitor, collect, and report adverse events
6. Details of the Data Safety Monitoring Board (DSMB)

Procedure

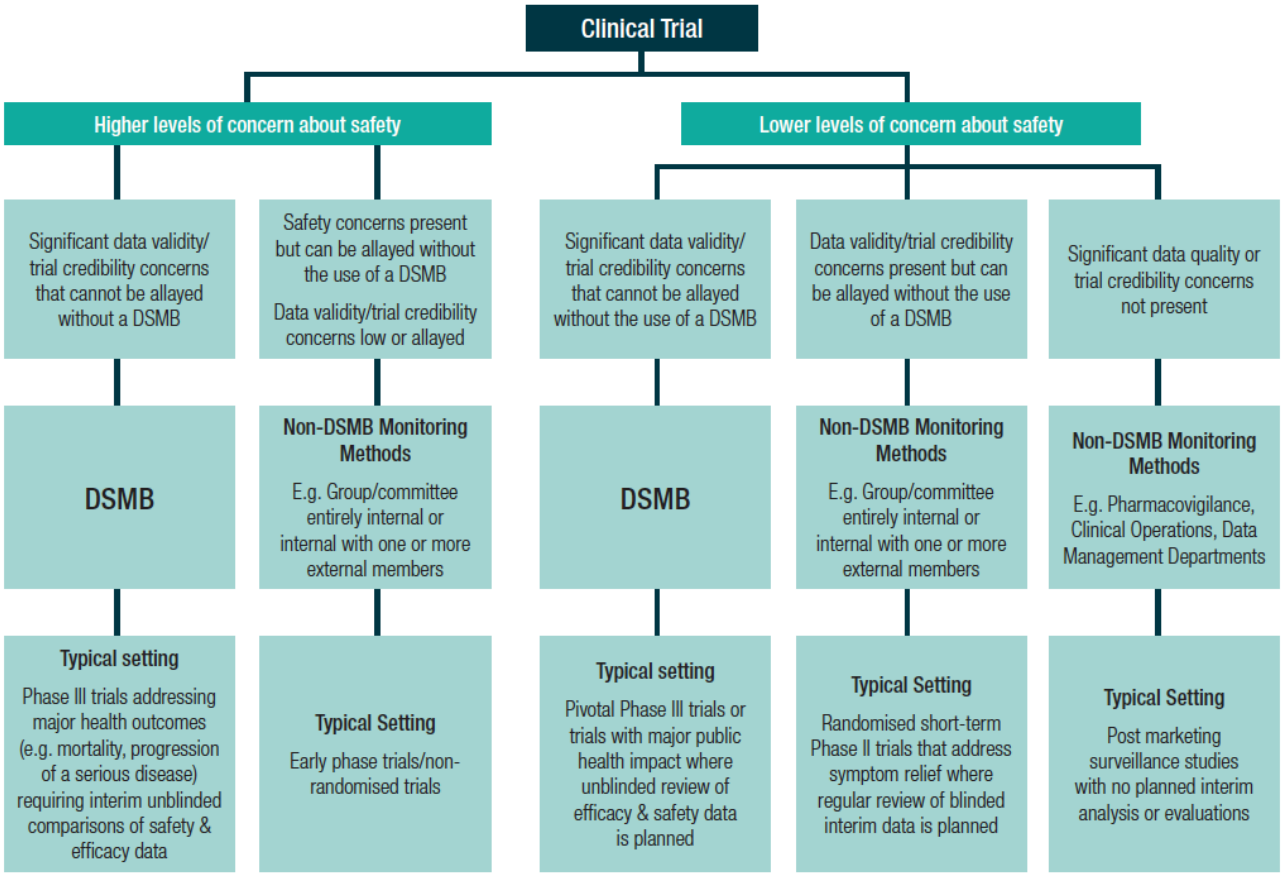
1. The DSMB is considered a critical component to determine safe and effective conduct of an interventional trial. It is an independent group of experts which provide their expertise and recommendations to the study investigators, sponsors and the approving HREC. All clinical trials require safety monitoring, but not all trials require monitoring by a formal committee that may be external to the trial sponsors and investigators (Diagram 305.1).
2. NHMRC has published the ‘Data Safety Monitoring Boards (DSMBs)’ in 2018. This document provides the scope of guidance on DSMB and covers the following key topics:
    a) What is a DSMB and what is its role
    b) Does the DSMB need to be independent
    c) How is a DSMB established
    d) What training and experience should DSMB members have
    e) How is the role and function of the DSMB documents
    f) Alternatives to DSMBs

3. Researchers are required to follow the guidance provided by the NHMRC. See Diagram 308.1- Decision Making Tree for Establishment of a DSMB provided by NHMRC

4. Where CAHS is the sponsor, the investigators must ensure appropriate arrangements are in place to monitor the safety of participants during the trial by implementing a data safety monitoring plan that is clearly described in the protocol and ethics application.

5. In the absence of an independent DSMB for an investigator initiated single centre study, it is recommended that the Investigators consider, discuss and present accumulated study data and adverse events at the departmental meetings on a regular basis. Where the investigator is also Head of Department then it is advisable to have at least one independent clinician at the departmental meeting.

Diagram 306.1 Decision marking tree for establishment of a DSMB[1]



Related external policies, procedures, guidelines and resources
NHMRC - Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) Safety monitoring and reporting in clinical trials involving therapeutic goods | NHMRC
NHMRC – Data Safety Monitoring Boards (2018) Safety monitoring and reporting in clinical trials involving therapeutic goods | NHMRC

307 - Annual Progress Report

PROCEDURE - 307	
Annual Progress Report To outline the procedure for the submission of annual progress reports.	
Scope (Staff):	All researchers who have had research approved by CAHS.
Scope (Area):	CAHS and external institutes undertaking research with CAHS facilities, patients, patient samples or information.

Aim

To outline the requirements to researchers for submitting annual progress reports to CAHS where CAHS is the approving HREC or Institution.

Background

Chapter 5.5 of the *National Statement* states that the progress of a research project should be reported to HREC at least on an annual basis.

Key Points

- This SOP is written in accordance with Section 5.5. of the *National Statement* and the CAHS HREC Terms of Reference. All research approved by CAHS must continue to meet these standards.
- Annual progress reports are due on the anniversary of HREC approval.
- REG office staff have delegated authority by the HREC to review and approve annual progress reports. These are then provided to the HREC for noting at a scheduled HREC meeting.
- Annual progress reports are not required to be submitted to the CAHS RGO, unless CAHS HREC is not the lead HREC.

Procedure

1. Progress reports are submitted to CAHS by the due date via a Progress Report form in RGS.
2. For multi-centre research, where CAHS is the lead HREC, a progress report is required to be submitted to CAHS HREC plus site-specific progress reports to each site's RGO.
3. For CAHS single site research, where CAHS is the lead HREC, a progress report can be submitted to CAHS HREC only. Approval will be provided on behalf of both HREC and RGO.
4. For multi-centre research where CAHS is not the lead HREC, a progress report is submitted by the CAHS site PI to CAHS RGO.
5. For CAHS HREC approved projects, a reminder email will be sent via RGS to the CPI and CPI Delegate one month and then one week prior to the due date of the annual report.
6. One week past the due date, a third and final reminder by RGS will be sent. Failing to submit an annual report can lead to suspension or termination of approval for the project.
7. Annual progress reports will be reviewed and approved by REG office staff as delegates of CAHS HREC. REG Office staff may request review by the HREC at a HREC meeting if any issues have been identified.
8. Once approved, a letter referencing to the relevant sections of *National Statement*, will be sent to the researcher and the approval will be noted at the next scheduled HREC meeting.

Related internal policies, procedures and guidelines

CAHS HREC Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
RGS homepage: https://rgs.health.wa.gov.au/Pages/Home.aspx
RGS User Guide – Progress Reports User Guides (health.wa.gov.au)
National Mutual Acceptance Single Ethical Review of Multi-centre Human Research Projects Monitoring and Reporting Tables https://rgs.health.wa.gov.au/Documents/NMA%20Monitoring%20and%20Reporting%20Tables.pdf

308 - Final Report

PROCEDURE - 308	
Final Report To outline the procedure for the submission of a final report.	
Scope (Staff):	All researchers undertaking research within the CAHS.
Scope (Area):	CAHS and external institutes undertaking research with CAHS facilities, patients, patient samples or information.

Aim

To inform researchers of their responsibilities for submitting a final report to CAHS where CAHS is the approving HREC or institution.

Background

Chapter 5.5 of the *National Statement* states that the outcomes of research should be reported to HREC upon research completion.

Key Points

- This SOP is written in accordance with Section 5.5 of the *National Statement* and the CAHS HREC Terms of Reference. All research approved by CAHS must continue to meet these standards.
- A final report is required to notify the Lead HREC that the project is completed, and all sites are closed.
- Each site listed in the project must be closed via a site final report before the final report is to be submitted to the HREC and the project can be closed.
- REG office staff have delegated authority by the HREC to review and approve final reports. These are then provided to the HREC for noting at a scheduled HREC meeting.

Procedure

1. Once a research project has been closed and/or the final close out visit with the sponsor has been completed, a final report with project summary is to be submitted to the Lead HREC. It is the responsibility of the CPI to complete and submit final reports.
2. A final report is only to be submitted to the HREC once all sites have been closed and all involvement with the project has been finalised. A report will not be listed as final in the case of recruitment completion or at the close of any activity other than the final stage of the project. The project outcomes should be included in the final report submitted to the HREC.
3. A site final report is required to close the project at a WA Health site. Where CAHS is a site, a site final report is to be submitted to the CAHS RGO in the monitoring section via RGS within 30 calendar days of the project completion at the site.
4. Final reports are to be submitted to CAHS HREC via the RGS within the monitoring section (access link below in the useful references section) following project completion and project closure at all sites.
5. For single-site projects, a site final report can be accepted as the overall final report for the project.
6. After the final report is received and approved, this final report and the acknowledgement letter from the lead HREC is to be sent to all other institutions (sites) where the research has been conducted.
7. Where a project is discontinued before the expected completion date the researcher must inform the approving HREC of the reasons for this in writing and complete a final report.

Related internal policies, procedures and guidelines
CAHS HREC Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) – National Statement on Ethical Conduct in Human Research 2023 | NHMRC
RGS homepage https://rgs.health.wa.gov.au/Pages/Home.aspx
RGS User Guides: Project Final Reports, Site Final Reports User Guides (health.wa.gov.au)

309 - Suspension or Early Termination of a Project

PROCEDURE - 309	
Suspension or Early Termination of a Project To outline the procedures for reporting the suspension or early termination of a research project	
Scope (Staff):	All researchers undertaking research within the CAHS.
Scope (Area):	CAHS and external institutes undertaking research with CAHS facilities, patients, patient samples or information.

Aim

To inform researchers of their responsibility for notifying CAHS, where CAHS is the approving HREC or institution, if a project is suspended or terminated early.

Background

From 01 December 2018 notifications of suspension or early termination of a project are to be completed and submitted online via the RGS.

Key Points

This SOP is written in accordance with Sections 5.5.7of the *National Statement* and the CAHS HREC Terms of Reference. All research approved by CAHS must continue to meet the standards described in the *National Statement* as well as the terms of approval set down by CAHS.

Procedure

1. If a project is suspended or terminated, as decided by the researcher or sponsor, the Lead HREC must be informed. Where CAHS is the Lead HREC and/or approving site the researcher must provide the HREC and the RGO with the reasons for the decision (as stated in the Terms of Approval).
2. Notification of suspension or early termination pertaining to safety reasons is to be submitted to CAHS via a Safety Report in RGS.
3. The report will then be forwarded to the delegated person for review and tabled for review at the next CTS meeting.
4. If the research is terminated, the HREC will request a final report and information (if not provided) of what action is being taken to ensure the safety and ongoing care of participants.
5. If the research is suspended, the HREC will request information (if not provided) of what action is being taken to ensure the safety and ongoing care of participants.
6. If a suspended project is to be recommenced, the CPI/PI is required to notify the CAHS HREC and receive written notification/approval prior to restarting the project within the CAHS.

Related internal policies, procedures and guidelines
CAHS HREC Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources

National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
RGS homepage https://rgs.health.wa.gov.au/Pages/Home.aspx
RGS User Guides: Project Final Reports, Site Final Reports User Guides (health.wa.gov.au)

310 - Withdrawal or Termination of Approval

PROCEDURE - 310	
Withdrawal or Termination of Approval	
Scope (Staff):	All researchers undertaking research within CAHS whose research has failed to meet the terms of approval or whose conduct has breached the *National Statement*
Scope (Area):	CAHS and external institutes undertaking research with CAHS facilities, patients, patient samples or information.

Aim

To describe the process CAHS will undertake if a project breaches the CAHS Terms of Approval and the *National Statement*.

Key Points

- This SOP is written in accordance with sections 5.4.14 - 5.4.19 of the *National Statement* and the CAHS HREC Terms of Reference.
- All projects approved by the CAHS where CAHS is the approving HREC, or institution must continue to meet the standards described in the *National Statement* as well as the terms of approval set down by the CAHS. If the project does not meet these requirements, then the HREC or REG Office may recommend suspension of the approval of a research project to the CAHS.
- The CAHS reserves the right to suspend institutional approval of any previously approved research project without recommendation from the HREC or RGO.
- This process must ensure that the researchers and all those associated with the project are treated with fairness and respect.

Procedure

1. CAHS may withdraw approval for research in accordance with section 5.4.14 of the *National Statement*. The researcher will be notified in writing by the CAHS that approval has been withdrawn with the reasons for this decision.
2. If approval is withdrawn from a research project, the researcher must immediately suspend the research.
3. Researchers and the institution must make arrangements to meet the needs of the participants in the research in accordance with Section 5.4.17 of the *National Statement*.
4. If CAHS considers that urgent suspension of research is necessary, this notification will come via Director, RO in the form of a telephone call or email. Such suspension will be confirmed in writing, referencing to the relevant sections of *National Statement*, within 24 hours.
5. Researchers will be given the opportunity to assure the CAHS that the conditions set out in 5.4.17(c) have been met. This will be reviewed by the HREC and Research Governance and a recommendation, referencing to the relevant sections of *National Statement*, made to the Director, RO as to whether the research should recommence.
6. If the case for recommencement of the research is accepted by the Director, RO, the researcher will be notified in writing by the CAHS that the project can resume.
7. If the case for recommencement of the project is not accepted by the CAHS Executive, the withdrawal of approval will stand, and the project will be closed.
8. One month and then one week prior to the HREC approval expiry date, an RGS auto-generated email will be sent to the Coordinating Principal Investigator (CPI) and CPI Delegate advising that the approval for the research project is due to expire. If the project is to be continued, an amendment to the HREC requesting an extension of approval requires submission via RGS. If the project has ceased, a final report requires submission via RGS (access link below in the useful references section).

9. If neither the extension request nor a final report is received by the approval expiry date further reminders with a specified due date, will be sent by the REG office and researchers will be advised that the project may be terminated.
10. If neither the extension request nor a final report is received by the specified due date, the project will be closed in RGS by the REG office.
11. All documentation relating to a closed study will be archived.

Related internal policies, procedures and guidelines
CAHS HREC Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
The RGS homepage: https://rgs.health.wa.gov.au/Pages/Home.aspx

311 – Site Monitoring Visits of Research Projects

PROCEDURE- 311	
Site Monitoring Visits of Research Projects	
Scope (Staff):	All research staff involved with clinical trials as per below scope
Scope (Area):	All approved clinical trials approved by CAHS HREC or conducted on site at CAHS facilities.

Aim

To outline the purpose and procedure for clinical trial monitoring at CAHS.

Background

The purpose of clinical trial monitoring is to oversee the progress of a trial, to protect the rights and well-being of trial participants and to give reassurance that the trial protocol and procedures are being followed, that legal/governance requirements are being complied with, and that the critical data collected are reliable.

The Responsibility for ensuring that research is reliably monitored lies with the institution under which the research is conducted. CAHS as an institution approves research that occurs on site according to the WA Health Research Governance and Single Ethics Review Operating Procedures.

Mechanisms for monitoring can include:

- Review of annual and final reports
- Review of safety reports informing of safety issues
- Review of annual safety reports
- Review of Sponsor notifications
- Site Visit Monitoring
- Complaints process

The CAHS HREC approval letter includes a statement in the conditions of approval advising the research team that study monitoring and audits could be undertaken to assess compliance.

Key Points

A REG office staff member, acting as a monitor, may perform routine site monitoring visit or central (remote) monitoring using systematic methods to evaluate compliance with the *National Statement*, Good Clinical Practice, National Clinical Trials Governance Framework and WA Health and CAHS policies and procedures and to verify that research is conducted in accordance with the HREC and site approved protocols. Monitoring will mainly focus on investigator-led research projects which are not already monitored by a commercial sponsor.

Procedures

1. Initiating a Site Visit

1.1 Projects are selected for monitoring based on criteria which includes, but is not limited to, the following:

a) HREC request following approval of a new project

b) Studies involving procedures that are considered high risk to participants

c) Investigator-Initiated drug/device studies

d) Investigators conducting a large number of studies

e) Random selection

f) A complaint was made

g) Progress report verification

h) Self selection

1.2 Initial communication with the PI will provide information on the purpose of the visit and what is expected. A monitoring outline will be provided to the PI.

1.3 The Monitor will collect information regarding the status of the project including the following:

a) HREC and RGO specific conditions of approval

b) Protocol, including any amended versions

c) Progress and safety reporting

d) Documentation regarding any relevant adverse event reporting.

1.4 The Monitor will confirm a time and location for the visit and inform the PI which documents are required for review. (See 1.3 regarding participant records). The PI must make these documents available at the time of the visit. Any other materials deemed necessary to accurately understand the research process under investigation shall be made available by the PI upon request.

2. Preparing for a Site visit

2.1 The study team can prepare for a visit by making sure the monitor has access to:

- study files and documents, including electronic versions
- participant data files, including medical records*, for the three subjects specified in the initial letter
- list of participants
- the signed consent form for every participant enrolled in the study
- a member of the research team to answer any questions
- the database** containing the study data

*If medical records need to be requested from Health Information Services with advanced notice, the researchers must account for this to make sure the correct and complete records are available.

**A researcher with authorised access who is familiar with the database is required to assist the monitor on the database.

3. Site Visit

3.1 Using the CAHS monitoring worksheets and the investigator self-assessment checklist (if completed), the reviewer examines some or all the aspects of the research records. The completed checklists may become part of the final written report or may be referenced in the report.

3.2 The monitor will conduct inspect relevant documents and areas and will interview study team members as relevant.

4. Post-visit follow-up and report

4.1 The collected data is than analysed and a report generated. The written report is sent to the Director, RO and where CAHS is the approving HREC, to the Chairs of CTS and HREC.

4.2 If the monitoring does not identify any problems, no action is taken. A letter confirming compliance will be issued by the Manager, Clinical Trials Governance.

4.3 If the monitoring/audit identifies problems or deficiencies, the report will include appropriate corrective and preventive actions.

4.4 A follow up meeting may be required to discuss the findings of the monitoring/audit.

4.5 The PI will be asked to respond in writing to each finding in the report, offering additional supporting evidence and confirming that the required actions and recommendations specified in the report will be complied with.

4.6 The PI is expected to comply with the corrective and preventive actions in the time frame provided in the report. The monitor will follow up with the PI to ensure that the corrective and preventive actions are completed.

4.4 If the corrective and preventive actions are not completed or an immediate risk is detected, the monitor will consult with the CTS and HREC Chairs. If their opinion concurs, the study may be placed on a temporary halt until the recommendations are implemented. Any requirement for study halt will be notified in writing to the investigator. Where CAHS is not the approving HREC, a formal letter will be sent to the lead HREC notifying them of the findings and site decision.

4.5 The temporary halt will not be removed until the matters of concern can be resolved effectively.

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
Australian Code for the Responsible Conduct of Research Australian Code for the Responsible Conduct of Research, 2018 | NHMRC
WA Health Research Governance Policy Research Governance Policy (health.wa.gov.au)
WA Health Research Governance Procedures DoH Multi-page Template (health.wa.gov.au)
Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods (australianclinicaltrials.gov.au)

312 – Auditing of Research Projects

PROCEDURE- 312	
Auditing of Research Projects	
Scope (Staff):	All research staff involved with clinical trials as per below scope
Scope (Area):	All clinical trials approved by CAHS HREC or conducted on site at CAHS facilities.

Aim

To outline the purpose and procedure for a clinical trials audit at CAHS.

Background

Clinical Investigator site audits are a critical component of clinical research, serving as a quality assurance tool to ensure that the rights, safety, and well-being of human subjects are protected, and that the data generated from clinical trials are accurate, reliable, and verifiable.

Clinical Investigator site audits are formal examinations of how clinical trials are conducted at the research sites. Audits can be performed at various stages of a clinical trial and can be triggered by specific events or concerns by CAHS. CAHS as an institution **governs** research that occurs on site according to the WA Health Research Governance and Single Ethics Review Operating Procedures.

If a specific non-compliance activity occurs, which has been assessed as a concern to patient safety, then CAHS CTS or HREC can request any of the following types of audits

- For-cause audit, triggered by specific events or concerns that arise during the trial.
- Pre-study audit, before a trial commences, to ensure the study team & processes are capable of conducting the trial.

Audits conducted will be follow a risk based approach to determine the timing and focus of the audit. Auditors will concentrate on elements that affect patient safety, ethical considerations, and data integrity, guided by data analysis and risk assessment.

Key Points

A REG office staff member, acting as an auditor, may perform for-cause or pre-study audit, using systematic methods to evaluate compliance with the *National Statement*, Good Clinical Practice, National Clinical Trials Governance Framework and WA Health and CAHS policies and procedures and to verify that research is conducted in accordance with the HREC and site approved protocols.

Auditing can be requested by the HREC, CTS or on behalf of a commercial sponsor .

Procedures

1. Initiating a Site Visit

1.1 Projects are selected for an audit based on criteria which includes, but is not limited to, the following:

a) HREC request following a non-compliance event

b) Investigator-Initiated drug/device studies with a safety reported concern.

c) Investigators conducting a large number of studies

d) A complaint was made

e) Commercial Sponsor requested

1.2 Initial communication with the PI will provide information on the purpose of the audit and what is expected.

1.3 The Auditor will confirm a time and location for the visit and inform the PI which documents are required for review. The PI must make these documents available at the time of the visit. Any other materials deemed necessary to accurately understand the research process under investigation shall be made available by the PI upon request.

2. Preparing for an audit

2.1 The study team can prepare for an audit by making sure the auditor has access to:

- study files and documents, including electronic versions
- participant data files, including medical records*, for the three subjects specified in the initial letter
- list of participants
- the signed consent form for every participant enrolled in the study
- a member of the research team to answer any questions
- the database** containing the study data

*If medical records need to be requested from Health Information Services with advanced notice, the researchers must account for this to make sure the correct and complete records are available.

**A researcher with authorised access who is familiar with the database is required to assist the monitor on the database.

3. Audit Visit

3.1 Using the CAHS audit worksheets and the CAPA Plan (if completed), the reviewer examines some or all the aspects of the research records. The completed checklists may become part of the final written report or may be referenced in the report.

3.2 The auditor will inspect relevant documents and areas and will interview study team members as relevant.

4. Post-visit follow-up and report

4.1 The collected data is then analysed and a report generated. The written report is reviewed by the Director, RO or delegate. Any comments or recommendations from the Director, RO or delegate are included prior to the report being sent to the PI, and the requestor of the audit.

4.2 A follow up meeting may be required to discuss the findings of the audit.

4.5 The PI will be asked to respond in writing to each finding in the report, offering additional supporting evidence and confirming that the required actions and recommendations specified in the report will be complied with.

4.6 The PI is expected to comply with the corrective and preventive actions in the time frame provided in the report. The auditor will follow up with the PI to ensure that the corrective and preventive actions are completed.

4.4 If the corrective and preventive actions are not completed or an immediate risk is detected, the study may be placed on a temporary halt until the recommendations are implemented. Any requirement for study halt will be notified in writing to the investigator.

4.5 The temporary halt will not be removed until the matters of concern can be resolved effectively.

4.5 If the audit identifies non-compliance, such as lack of oversight, deliberate falsification or omission, failure to comply with the requirements and determinations of the HREC, significant protocol violations, or deviations or frequent occurrences of such, additional corrective and preventive actions may be required and/or an investigation may be initiated to investigate a possible breach of the Code.

Related external policies, procedures, guidelines and resources
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
Australian Code for the Responsible Conduct of Research Australian Code for the Responsible Conduct of Research, 2018 | NHMRC

WA Health Research Governance Policy Research Governance Policy (health.wa.gov.au)
WA Health Research Governance Procedures DoH Multi-page Template (health.wa.gov.au)
Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods (australianclinicaltrials.gov.au)

COMPLAINTS AND OTHER PROCEDURES

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401 - Complaints on the Conduct of Research

PROCEDURE - 401	
Complaints on the Conduct of Research To outline the process for to the management of complaints concerning the conduct of an approved research project.	
Scope (Staff):	Research participants, researchers, staff of institutions and other stakeholders.
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information and/or CAHS facilities.

Aim

To describe the process for receiving, managing and responding to complaints concerning the conduct of an approved project.

Background

A complaint about a potential breach of the Code occurs when a concern is raised or identified that one or more researchers have conducted research that is not in accordance with the principles and responsibilities of the Code. This procedure is written in accordance with Chapter 5.7 of the *National Statement* and the *Australian Code*.

A breach is defined as a failure to meet the principles and responsibilities of the Code and may refer to a single breach or multiple breaches. Examples of breaches of the Code include, but are not limited to, the following:

- Not meeting required research standards e.g., conducting research without approval, misuse of research funds
- Fabrication, falsification, misrepresentation e.g., fabrication or falsification of research data or source material
- Plagiarism e.g., plagiarising someone else's work
- Research data management e.g., failure to appropriately maintain research records

A complaint can be made by a research participant, potential research participant, researchers, CAHS staff, or external stakeholders.

Key Points

Regardless of which NHMRC Certified HRECs provided ethics approval for the project, either under National Mutual Acceptance (NMA) or single-ethics review, the complaint must initially be directed to the institution the complainant attended and/or the complaint is regarding.

Risk

- Potential for a serious breach in relation to the integrity of the research data or safety of the participants
- Non-compliance with CAHS research policy and procedures

Procedure

1. Prior to initiating a complaint, a person who believes they may have a complaint in relation to a CAHS researcher and/or research conducted at CAHS about a potential breach of the Code should seek advice from the Manager, REG.

2. All complaints in relation to CAHS researchers and/or research conducted at a CAHS site should be referred to the Manager, REG in writing.

3. Complaints should include all information relevant to the alleged breach and any available evidence to support the complaint.
4. Anonymous complaints or complaints lodged by a third party will be accepted and considered, although progression of an assessment will depend on the nature of the complaint and the evidence presented.
5. Complainants have the right for their complaint to be:
    a) received and treated in confidence
    b) treated with respect and dignity
    c) dealt with in a manner that includes appropriate communication and progress updates
6. The Manager, REG will send a letter of acknowledgement to the complainant within 5 working days.
7. The Manager, REG, will advise the Director, RO of the complaint and together, determine whether the complaint relates to a potential breach in the Code.
    a) If determined that it does, the matter proceeds to a preliminary assessment.
    b) If it does not, the complaint may be dismissed or referred to other CAHS processes.
8. The preliminary assessment involves collecting and evaluating facts and information to assess the complaint. This involves, but is not limited, to the following:
    a) Consultation with the REG office staff others at CAHS and experts where necessary
    b) Liaising with the respondent and other relevant parties as appropriate
    c) Securing evidence
    d) Providing recommendations for further action
9. Following the preliminary assessment, the matter may be:
    a) Dismissed
    b) Resolved locally with or without corrective actions
    c) Referred for investigation
    d) Referred to other institutional processes
10. The Manager, REG will provide the outcomes, if appropriate, to the respondent and complainant at the conclusion of the preliminary assessment in a timely manner.
11. If it is determined that there is merit for a further investigation, then the Director, RO will convene a suitable panel to conduct a formal investigation of the matter in accordance with the NHMRC Guide *Managing potential breaches of the Australian Code for the responsible conduct of research*.
12. The purpose of the investigation is to make findings of fact to allow the Director, RO to assess whether a breach of the Code has occurred, the extent of the breach and the recommended actions. This is done by examining the facts and information from the preliminary assessment and gathering and examining further relevant evidence if required.
13. Following the investigation, the Panel will draft a written report containing a summary of all the relevant information, findings of fact and any recommendations.
14. The Director, RO will consider the findings of fact, evidence presented and any recommendations made in the report. The Director, RO will also consider the extent of the breach, the appropriate corrective actions and if referral to disciplinary procedures is required. The Director, RO will then provide to the EDMS for finalisation.
15. The report will be finalised with the inclusion of the Director, RO decision. The decision may be one of the following:
    a) Finding no breach of the Code
    b) Finding a breach of the Code

16. When the EDMS has considered the Panel's report, any decisions or actions are to be communicated to the respondent and the complainant. Subsequent actions may include informing relevant parties (such as funding bodies, other relevant authorities or other institutions) of the outcome.

Related internal policies, procedures and guidelines
CAHS Research Policy Research Policy (health.wa.gov.au)
CAHS Investigator Responsibilities – Research Investigator Responsibilities (health.wa.gov.au)
CAHS Managing Potential Breaches – Research Conduct Managing Potential Breaches (health.wa.gov.au)
CAHS Fraud and Corruption Control Plan https://cahs-healthpoint.hdwa.health.wa.gov.au/integrity/Documents/CAHS%20Fraud%20and%20Corruption%20Control%20Plan.pdf
CAHS Risk Management CAHS.PM.RiskManagementClinicalandCorporate (health.wa.gov.au)
CAHS Gifts, Benefits and Hospitality Declarations CAHS Universal Policy Template (health.wa.gov.au)
CAHS Discipline Guide CAHS Universal Policy Template (health.wa.gov.au)

Related external policies, procedures, guidelines and resources
WA Health Complaints Management Policy MP 0130/20 Complaints Management Policy (health.wa.gov.au)
WA Health Code of Conduct Policy - MP 0124/19 Code of Conduct Policy (health.wa.gov.au)
WA Health Discipline Policy - MP 0127/20 Discipline Policy (health.wa.gov.au)
WA Health Fraud and Corruption Control Policy - MP 0105/19 Fraud and Corruption Control Policy (health.wa.gov.au)
WA Health Gifts Benefits and Hospitality Policy - MP 0136/20 Gifts Benefits and Hospitality Policy (health.wa.gov.au)
WA Health Integrity Governance Policy - MP 0114/19

Integrity Governance Policy (health.wa.gov.au)
WA Health Managing Conflicts of Interest Policy - MP 0138/20 Managing Conflicts of Interest Policy (health.wa.gov.au)
WA Health Notifiable and Reportable Conduct Policy - MP 0125/19 Notifiable and Reportable Conduct Policy (health.wa.gov.au)
WA Health Pre-Employment Integrity Check Policy - MP 0126/19 Pre-employment Integrity Check Policy (health.wa.gov.au)
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
Australian Code for the Responsible Conduct of Research Australian Code for the Responsible Conduct of Research, 2018 | NHMRC
Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018) Australian Code for the Responsible Conduct of Research, 2018 | NHMRC

402 - Complaints on the Conduct of the Human Research Ethics Committee (HREC)

PROCEDURE – 402	
Complaints on the Conduct of the Human Research Ethics Committee (HREC)	
Scope (Staff):	All participants, researchers, staff of institutions and other interested persons
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information and/or CAHS facilities.

Aim

To describe the procedure for receiving and handling concerns or complaints from investigators relating to the HREC's review process.

Procedure

1. Any concern or complaint received about HREC's review process will be sent to the REG Office. The information can be received by letter, email or phone, detailing the grounds of the concern or complaint.
2. Such complaints must be directed to the attention of the Manager, REG.
3. The Manager, REG will send a letter of acknowledgement to the complainant within 5 working days outlining the following mechanism that will be followed.
4. The Manager, REG will work with the HREC Chair to investigate the complaint and its validity and make a recommendation to the HREC on the appropriate course of action. This investigation shall take no longer than 30 working days from the time the notification of the complaint or concern.
5. Out-of-session meetings may be arranged if deemed necessary by the HREC Chair.
6. The complainant will be informed of the outcomes of the investigation.
7. If the complainant is not satisfied with the outcome of the investigation, then the complainant can refer the complaint to the Director, RO.
8. The Director, Research Operations will determine whether there is to be a further investigation of the complaint. Where no further investigation is to occur, the Director, RO will inform the complainant and the HREC Chair and provide justification for the decision.
9. If the Director, RO determines that there is merit for a further investigation, then the Director, RO will convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded the opportunity to make submissions.
10. In conducting its review, the panel will determine whether the HREC acted in accordance with the *National Statement* and its Terms of Reference and whether the HREC acted in a fair or unbiased manner.
11. The Director, Research Operations will notify the complainant and the HREC of the outcome of the further investigation.

Related internal policies, procedures and guidelines
CAHS HREC Terms of Reference Child and Adolescent Health Service | CAHS - Applying to HREC

Related external policies, procedures, guidelines and resources

National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
Australian Code for the Responsible Conduct of Research Australian Code for the Responsible Conduct of Research, 2018 | NHMRC

403 - Authorised Prescriber

PROCEDURE - 403	
Authorised Prescriber	
Scope (Staff):	Clinicians wishing to become Therapeutic Goods Administration (TGA) Authorised Prescriber of an unregistered drug or device.
Scope (Area):	CAHS staff

Aim

To describe the process and facilitate clinicians to become TGA Authorised Prescribers. Authorised Prescribers are medical practitioners who are approved by the TGA to prescribe unapproved therapeutic goods for a particular condition or class of patients in their immediate care without further approval".

Procedure

1. Applicants submit the following documents to both Drug and Therapeutics Committee (DTC) and HREC:
    a) Cover letter addressed to both DTC and HREC: including an explanation and justification for why the drug/device is required and description of the qualifications/expertise of the applicant.
    b) Product Information
    c) Efficacy and safety data
    d) Information and Consent form for patients
2. DTC will review the application and the therapeutic justification.
3. If DTC endorses the therapeutic use, DTC will provide the REG Office with a letter of endorsement for the HREC.
4. If DTC requires further information/clarification from the applicant, feedback would be requested by DTC and resolved if practical. If DTC is unable to progress the request, this will be communicated to the applicant.
5. The application will be reviewed by the HREC Chair. If endorsed by the HREC Chair, REG Office will issue a letter of HREC endorsement to the applicant.
6. The applicant then submits their authorised prescriber application with the TGA using the TGA online platform.
7. A list of authorised prescriber endorsements will be noted at the next scheduled HREC meeting.

Related internal policies, procedures and guidelines
CAHS Drug and Therapeutics Committee (Terms of Reference) CAHS Drug & Therapeutics Committee (health.wa.gov.au)

Related external policies, procedures, guidelines and resources
Therapeutic Goods Administration – Prescription medicines registrations Prescription medicines registrations | Therapeutic Goods Administration (TGA)

Therapeutic Goods Administration – Authorised Prescriber Scheme Guideline Authorised Prescriber Scheme (tga.gov.au)
Therapeutic Goods Administration – Applying Unapproved products for multiple patients (Authorised Prescriber) | Therapeutic Goods Administration (TGA)
Therapeutic Goods Act 1989 and the Poisons Standard The Therapeutic Goods Act 1989 & the Poisons Standard | Therapeutic Goods Administration (TGA)

404 - Case Report or Case Series

PROCEDURE - 404	
Case Report or Case Series To describe the process for the publication of a case report or case series.	
Scope (Staff):	Any clinician who is interested in publishing a case report or case series.
Scope (Area):	CAHS clinicians.

Aim

To describe the process for the publication of a case report.

Key Points

Case Study: A detailed report of the diagnosis, treatment, and follow-up of an individual patient. Case reports may contain some demographic information about the patient (e.g., age, gender, ethnic origin) and describe an unusual or novel occurrence or association.

Case Series: A group or series of case reports involving multiple patients who were given similar treatments. Reports of case series usually contain detailed information about the individual patients (e.g., age, gender, and ethnic origin) and information on diagnosis, treatment, response to treatment, and follow-up after treatment.

The review of patients to report as a case study or case series is considered anecdotal. These reviews may proceed without Human Research Ethics Committee (HREC) review or approval however one of HREC's important roles is to safeguard patients, researchers, institutions, and the public, clarifying and reviewing a researchers' duty of confidentiality to their patient–participants.

Procedure

1. If publishing a case report is identified as a possibility, clinicians must discuss the publication with the parent/guardian and, where appropriate, the patient.
2. It is the clinician's responsibility to obtain a signed consent form from a participant's parent/guardian prior to submission of case report for publication.
3. The signed consent form must be filed in the patient's medical record.
4. Where consent is not able to be obtained (for example the patient has been discharged from the health service and contact details are out of date) then guidance must be sought from the HREC Chair via the REG Office. The matter may be referred to the HREC if deemed necessary by the HREC Chair.
5. A completed declaration form should be provided to the REG office confirming:
    a) Informed consent from the parent/guardian and where appropriate agreement from the child has been obtained to allow the completion of this report, this may be verbal or preferably in writing.
    b) Consent has been documented as obtained and filed in the patient medical record.
    c) The treating clinician has provided consent to review the patient records.
    d) Any identifying information in relation to the child or family has been removed from written text, diagrams and photos.
    e) The patient/family have been given the opportunity to receive a copy of the outcomes/publication from this review.
    f) The requirements for journal publication have been met.
    g) A copy of the manuscript is attached for review and filing at the REG office.

6. The Case Report submission will be reviewed by the HREC Chair or their delegate and any follow up requested from the author via e-mail from the REG office.
7. The REG Office will then prepare a letter to investigators to confirm the following:
8. The Authors have obtained informed consent from the parent/guardian and patient for publication of de-identified information contained in this report according to approved Institutional Procedures and in accordance with the *National Statement* Section 2.2.5.

Related external policies, procedures, guidelines and resources
International Committee of Medical Journal Editors - Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals ICMJE | Recommendations
National Statement on Ethical Conduct in Human Research (2023) National Statement on Ethical Conduct in Human Research 2023 | NHMRC
CARE – case report guidelines CARE Case Report Guidelines (care-statement.org)

This document can be made available in alternative formats on request for a person with a disability.

Document Owner:	Manager, Research Ethics & Governance		
Amendments:	Updated from 2016 Version – transferred to new template and updated NHMRC, Research Governance Service and National Mutual Acceptance requirements incorporated.	Version:	2020
	Updated from 2020 version – incorporate new proportionate review processes and updated National Statement (2023) information	Version:	2023
	Updated from 2023 version – Included National Clinical Governance Framework (NCTGF) reference. Added NCTGF Standards 1. & 2 in metadata section called Standards Applicable.	Version:	2024
Last Reviewed:	November 2024	Next Review:	2027
Approved by:	Director, Research Operations	Date:	19/11/2024
Endorsed by:	Executive Director, Medical Services	Date:	19/11/2024
Standards Applicable:	NSQHS Standards:  NCTGF Standards: 1 & 2 NSMHS: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10.1, 10.2, 10.3, 10.4, 10.5, 10.6,		
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