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

Perth Children's Hospital

CAHS Research Education Program

Research Skills Seminar

Ethics Processes for Clinical Research in WA

21 November 2023

Presented by

Dr Natalie Giles

Manager, Ethics and Compliance,

CAHS Research Department

Child and Adolescent Health Service, Department of Research

Department of Health, Government of Western Australia

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

Perth Children's Hospital

Ethics Processes for Clinical Research in WA

PRESENTATION SLIDES

CAHS Research Education Program Research Skills Seminar Series
✉ ResearchEducationProgram@health.wa.gov.au
cahs.health.wa.gov.au/ResearchEducationProgram

Government of Western Australia
Department of Health

Perth Children's Hospital

CAHS Research Education Program

2023 Research Skills Seminar Series

Ethics Processes for Clinical Research in WA

Presented by

17th November 2023

Dr Natalie Giles

Manager, Research Ethics & Governance,
CAHS Research Department

Perth Children's Hospital Foundation

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Acknowledgement of Country

The Child and Adolescent Health Service acknowledge Aboriginal people of the many traditional lands and language groups of Western Australia.
We acknowledge the wisdom of Aboriginal Elders both past and present and pay respect to Aboriginal communities of today.

2

CAHS Research Education Program

Research Skills Seminar Series

A free, open-access resource designed to upskill busy clinical staff and students and improve research quality and impact.

- Over 20 topics across the research process
  - 1h overview
  - Handouts are provided
- Recorded and uploaded
- Feedback
  - Back of handout
  - Emailed link
- Please hold questions to the end
  - Use provided microphone

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Overview

1. Ethics principles
2. National Statement
3. Ethics review pathways
4. Practical requirements
5. Monitoring requirements

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Ethics Principles

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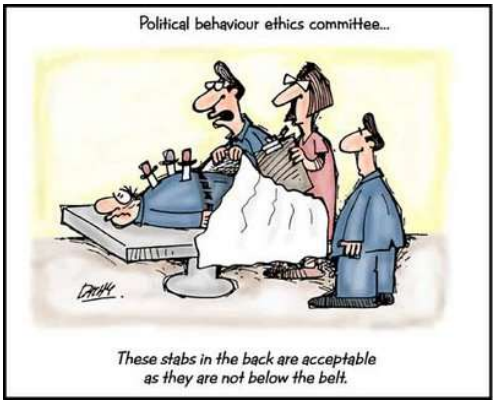
Ethics?

- A social, religious or civil code of conduct
- The philosophical study of the moral value of human conduct and its governing rules
- The principles of conduct governing an individual or group

"A man without ethics is a wild beast loosed upon the world"
Albert Camus



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Why?

Historical

- Inhumane medical experimentation
  - Nazi Germany human experimentation (1940-1945)
  - Tuskegee study (1932-1973)
- Themes
  - Involuntary participation
  - Vulnerable groups
  - Dependant relationships
  - Significant harm
  - No benefit

https://www.cdc.gov/tuskegee/timeline.htm

Why?

- Establishing standards of acceptable research conduct
  - Scientific rigor
  - Accountability (researchers and institutions)
  - Protection of participants i.e. risk vs benefit
- Development of international regulations
  - Nuremberg Code (1947)
  - Declaration of Helsinki (1964)
- NHMRC Act 1992 established the Australian Health Ethics Committee (AHEC) to guide the research community
- NHMRC National Statement on Ethical Conduct in Human Research (1999)

National Health & Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

- **Human Research** is research involving people, their tissue and/or their data
- Ethical approval must be obtained **prior** to commencing any research involving humans

Core principles

- Research merit and integrity
- Justice
- Beneficence
- Respect

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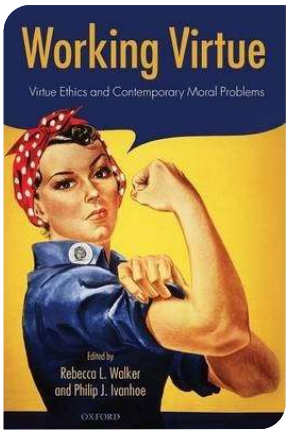
Research Merit

- Justifiable by its potential benefit
- Designed and developed using appropriate methods for achieving the aim
- Conducted and supervised by qualified people
- Conducted in an appropriate setting
- Following recognized principles of research conduct
- Research & methods must be appropriate to the participant group



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Researcher Integrity

- Search for knowledge
- Honesty, lack of bias in conduct
- Communicate findings without bias
- Allow <u>scrutiny</u>

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3136032/

"Scientists who publish their research have an ethical responsibility to ensure the highest standards of research design, data collection, data analysis, data reporting, and interpretation of findings; *there can be no compromises because any error, any deceit, can result in harm to patients as well as harm to the cause of science*"

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Respect for Persons

- Persons are autonomous
- People cannot be used as a means to an end
- Protect those of diminished autonomy

<u>Informed Consent must be</u>:

1. Fully informed
2. Voluntary decision

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Justice

- Who benefits?
- Who bears the burden?
- Public *versus* private
- Adults *versus* children
- Minority *versus* majority

- If unable to consent can only include children if:
  - Research is likely to provide knowledge relevant to children, or
  - Use of children is unavoidable

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Beneficence

- Maximize benefit
- Minimize harm

- Includes procedures for:
  - Minimising risks, e.g. increased monitoring
  - Managing risks and adverse events should they occur e.g. distress

- Reimbursement for costs and time
  - Proportionate to time spent
  - Not an inducement to participate

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Components of the National Statement

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The National Statement

- Section 1 - Values and principles of ethical conduct
- Section 2 - Themes in research ethics: risk and benefit, consent
- Section 3 - Ethical considerations in the design, development, review and conduct of research.
- Section 4 - Ethical considerations specific to participants e.g. Children
- Section 5 - Processes of research governance and ethical review

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Chapter 3.1 The Elements of Research

- Element 1: Research Scope, Aims, Themes, Questions and Methods
- Element 2: Recruitment
- Element 3: Consent
- Element 4: Collection, Use and Management of Data and Information
- Element 5: Communication of Research Findings or Results to Participants
- Element 6: Dissemination of Research Outputs and Outcomes
- Element 7: After the Project

Element 1: Research Scope, Aims, Themes, Questions and Methods

- What is the research theme or question that this project is designed to explore?
- Why is the exploration of this theme or answer to this question worth pursuing?
- How will the planned methods explore the theme or achieve the aims of the research?

Element 2: Recruitment

- Who will be recruited?
- How will participants be identified and recruited?
- Will the potential participants be screened?
- What is the impact of any relationship between researchers and potential participants on recruitment?
- How will the recruitment strategy facilitate obtaining the consent of participants?
- How will the recruitment strategy ensure that participants can make an informed decision about participation?
- Are there any risks associated with the recruitment strategy for potential participants or for the viability of the project?

Element 3: Consent

- What strategy(ies) for obtaining consent, or alternatives to consent are appropriate for the specific project?
- Does the nature of the project design, the participants or the context necessitate the use of more than one strategy?
- Do the proposed strategy(ies) satisfy the relevant requirements of Chapters 2.2 and 2.3?
- Are there any project-specific matters that warrant specific attention e.g.
  - whether the research could generate results of significance to participants
  - whether the data will be added to an open or mediated access repository or
  - whether the data or materials will be used for any other purpose?

Participant Information*

- Letter head, Title of Project,
- "This is for you to keep"
- Invitation – Researcher names, contacts
- Background/Aims
- Process - visits
- Risks and benefits
- Consent and withdrawal options
- Privacy protection
- Concerns and complaints mechanism

Plain language!

Flip charts
Videos
Group discussions
Letters
Posters
Photos

Version number!!!

Forms all on RGS

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Participant Consent

- Voluntary
- ***Ongoing*** process
- Plain language:
  - Aim language at 12 year old level
- Allow ***time***

"Consent should be a voluntary choice, and should be based on sufficient information and an adequate understanding of both the proposed research and the implications of participation"

National Statement on Ethical Conduct in Human Research (2007)

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Element 4: Collection, Use and Management of Data and Information

- What data or information are required to achieve the objectives of the project?
- How and by whom will the data or information be generated, collected and/or accessed?
- How and by whom will the data or information be used and analysed?
- Will the data or information be disclosed or shared and, if so, with whom?
- How will the data or information be stored and disposed of?
- What are the risks associated with the collection, use and management of data or information and how can they be minimised?
- What is the likelihood and severity of any harm/s that might result?
- How will the collection and management of the data or information adhere to the ethical principles in Section 1 of this National Statement?

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Element 5: Communication of research findings or results to participants

- Could the research generate findings or results of interest to participants?
- Could the findings or results be of significance to the current or future welfare or wellbeing of participants or others?
- Are potential participants in the research forewarned of this possibility?
- Will the consent of participants be obtained to enable any planned or necessary disclosure of findings or results?
- Who will communicate the findings or results and how?
- Will the findings or results be disclosed to third parties?

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Element 6: Dissemination of project outputs and outcomes

- What is the plan for reporting, publishing or otherwise disseminating the outputs/outcomes of the research?
- Will participants in the research be offered a timely and appropriate summary of the project outputs/outcomes?
- How will the planned dissemination of the outputs/outcomes contribute to knowledge or practice or serve the public?

Element 7: After the project

- Will the data or information be retained only for the minimum period required by relevant policy?
- Do the data or information have cultural, historical or other significance that could warrant longer, or perpetual retention?
- Are the arrangements regarding intellectual property (individual, community, organisational, commercial) and copyright related to the outputs of the research clearly understood and communicated?
- Will the data or information be banked or added to a repository, such as an open or mediated access facility, for future use?
- Is any follow up or monitoring of research participants required and is this clear in the research plan and consent information?

Other Guidelines

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Good Clinical Practice

- The international ethical, scientific and practical standard to which all clinical research involving human subjects is conducted
- ICH Guidelines
- Regular training essential to maintain awareness and compliance with relevant laws, policies and codes of conduct
- In WA Health, GCP certification is required to conduct research
- Onus is on the researcher to be up to date

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NHMRC Australian Code for the Responsible Conduct of Research

Describes principles of responsible research conduct, responsibilities of institutions, and responsibilities of researchers.

Contains information on:

- Research governance
- Data management requirements
- Peer review
- Conflicts of interest
- Dissemination of results

https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

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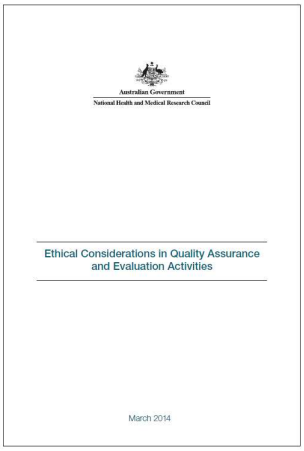
NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities



Guidance document that assists in determining whether an activity is research, evaluation or QA.

- Quality assurance, evaluation and research can exist on a continuum.
- *"Irrespective of whether an activity is called research or QA or evaluation, those conducting the activity must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy"* (NHMRC, 2014)

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

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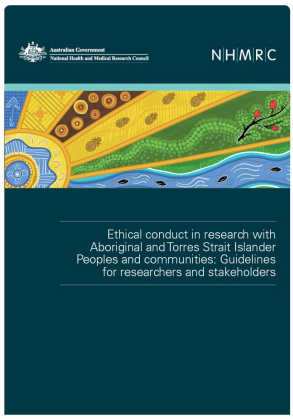
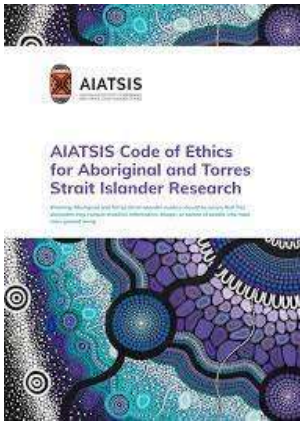
NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities



https://www.nhmrc.gov.au/about-us/resources/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities

AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research



https://aiatsis.gov.au/sites/default/files/2020-10/aiatsis-code-ethics.pdf

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Ethics Review Pathways

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Triaging Risk

Risk profiles of Research (National Statement 2023 – Chapter 2.1)

Lower Risk		Higher Risk (individual, group, community, societal, global)	
Minimal	**Low**	**Greater than Low**	**High**
No risk of harm or discomfort Potential for minor burden or inconvenience	No risk of harm Risk of discomfort +/- foreseeable burden	Risk of harm +/- foreseeable burden	Risk of significant harm +/- foreseeable burden

- Applications are submitted the same way in RGS
- National Statement guides institutions to develop expedited process for the review of low and negligible risk research
- Your Research Ethics & Governance (REG) Office will triage the study

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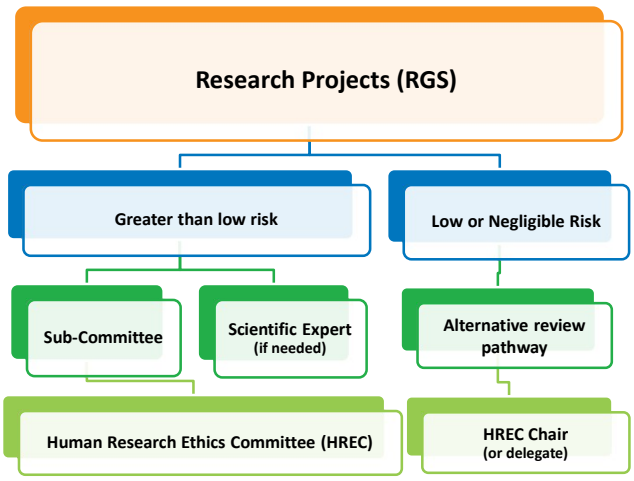
Proportionate (Risk-based) review pathway



- Projects triaged by REG office
- Alternative review pathways
  - CAHS LREC
  - SMHS HREC members

Can refer to full HREC review if required

- Some HSPs have sub-committees
  - SASC
  - CTS

  Then reviewed by full HREC
- Other greater than low risk will proceed to HREC.

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Role of Ethics Overview?

- To ensure best possible research practice
- To protect
  - research participants
  - researchers
  - organisations
- Will result in a better study

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Role of Researchers?

- To ensure best possible research practice
- To protect
  - research participants
  - researchers
  - organisations

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What is “Low Risk” research?

- Low risk research is defined in National Statement as *research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk* (Section 2.1.6).
- Negligible risk is defined in the National Statement as *research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience* (Section 2.1.7).
- The National Statement allows a non-HREC review process to be used for the review and approval of low or negligible risk research (Sections 5.1.18-5.1.21).
- Low risk approval pathways are also accepted by the National Mutual Acceptance Scheme (NMA Standard Principles for Operation).

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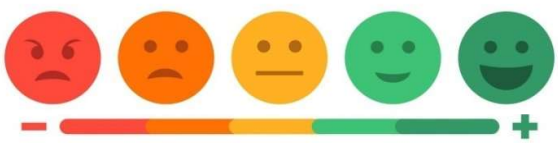
Suitable Projects - Low and Negligible Risk

- Most qualitative research protocols
- Studies where data is collected by questionnaire/via focus groups and the target population is not vulnerable as per National Statement

Example:
Experiences and needs of families with a Type 1 Diabetes involving an anonymous online questionnaire



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NOT suitable for Alternative Review Pathway

- All interventions
- All “opt out” or “waiver consent”
- Collection of biospecimens outside of standard care
- Vulnerable individuals e.g:
  - dependent relationship with medical personnel,
  - mental illness, cognitive or intellectual impairment
  - gender identity issues
- Aboriginal /Torres Strait Islanders as the target population
- Genetic testing
- Stem cells or their products
- Creation of a databank, biobank or registry
- Examination of sensitive personal or cultural issues
- Pregnant women or their foetuses

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GEKO – Quality Improvement Activities

- Governance Evidence Knowledge Outcomes
- Electronic submissions, **new guidance forms** 2019
- Rapid turn around
- Perth Metro public health sites
- Separate committees based on Dept/discipline
- Generally sit within Safety and Performance /Quality Assurance

“Without research we cannot know the most effective practice. Without audit we cannot know it if is being practised”

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Quality Improvement or Research?

Criterion	Quality Improvement	Research
Aim of Study	• Measurement of performance to assess or improve a process, program or system and evaluate against current evidence-based practice / standards	• To test a hypothesis • To establish new practice standards • To establish best practice by the creation of new knowledge
Questions	• Are we doing the right thing? • Are we doing what we think we are?	• What is the right thing to do? • Why does this happen?
Treatment type	• Standard routine care	• Experimental or comparing standards of care
Breadth of study	• Service • Ward • Department	• Has broader health implications; state, national international
Methodology	• Improvement methodology: Plan Do Study Act (PDSA); Six Sigma; LEAN etc. • Surveys/ questionnaires • Observational audits • Clinical audit using an audit tool	• Research methodology such as Quantitative, Qualitative, Mixed Methods, Delphi study etc. • Surveys / questionnaires • Interviews / focus groups • Clinical Trials • Observational studies • Laboratory work

Is my project Quality Improvement or Research? Guideline - SMHS RSDU

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Other Requirements – Data Collection

WA Health Data Collections

- Research requiring access to centrally held WA Health data collections and/or involves data linkage
- Submit to the Department of Health WA HREC

https://www.datalinkageservices.health.wa.gov.au/

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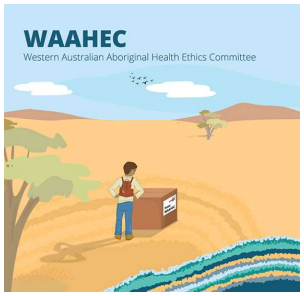
WA Aboriginal Health Ethics Committee

Within the Aboriginal Health Council of WA

- Aboriginal and/or Torres Strait Islander status is a key determinant
- Data collection directed at Aboriginal people
- Aboriginal people to be examined separately – sub analysis
- Outcome may impact Aboriginal communities
- Aboriginal health funds are a source of funding
- Likely to be over-represented in the study



WAAHEC: https://www.ahcwa.org.au/sector-support/waahec/
and NHMRC values and ethics: guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research 2003"

Other Requirements – Clinical Trials

- Follow the CONSORT statement
- Must be registered in order to be publishable
  i.e. International Committee of Medical Journal Editors
- Australian New Zealand Clinical Trials Registry
  www.anzctr.org.au
- Industry often requires registration details for participants
- CTRA, indemnity, insurance etc.

Practical Requirements – HREC Submission

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WA Health Research Governance Framework

The Department of Health research governance framework governs the scientific, ethical and governance review, approval, conduct and monitoring of human research within WA public health organisations.

The Research Policy Framework specifies the research requirements that all Health Service Providers (HSPs) must comply with in order to ensure effective and consistent research activity across the WA health system.

Under this policy framework HSPs and the Department of Health must comply with all mandatory requirements related to the Department of Health Research Governance Policy and the Research Governance Procedures.

The Research Governance Service (RGS) supports the framework and single ethical review of multi-centre research, by hosting standard ethics and governance forms and agreements, as well as facilitating the research governance approval and monitoring process of projects.

http://rgs.health.wa.gov.au

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WA Health Single Ethical Review Scheme

For intra-jurisdictional (within WA) single-centre or multi-centre research

- Approval by one WA Health HREC
- Research involving children – CAHS HREC Paediatric specialist
- Research involving mental health – NMHS mental health specialist

- Either the WAHEAF or the HREA accompanied by the WASM can be used for an ethics application.

Note: the WAHEAF is shorter than the HREA and includes the same WASM questions.

http://rgs.health.wa.gov.au

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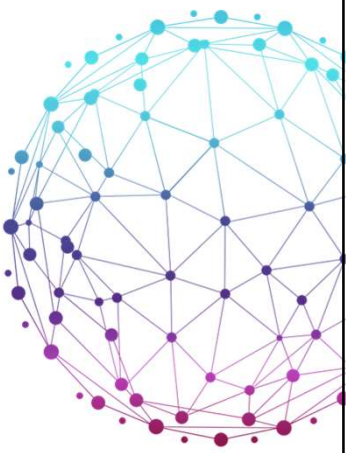
Multi-Site Research in Australia



National Mutual Acceptance (NMA) Scheme

- To improve quality and streamline the ethics review process across Australia
- Single ethical review by certified HRECs (in WA - SMHS, CAHS, SCGHOPG)
- All multi-site research, not just clinical trials

HREA must be used for all ethics applications

If ethical review is by a WA HREC: CPI should complete the HREA via the NHMRC website and uploaded to the RGS website as a pdf supporting document. It should be submitted with the WASM via RGS.

If ethical review is by:
QLD or VIC HREC - complete and submit the HREA via the ERM website with VSM
ACT or NSW HREC - complete and submit the HREA via the REGIS website
SA HREC - complete and submit the HREA via Research GEMS website

https://www.clinicaltrialsandresearch.vic.gov.au/national-mutual-acceptance

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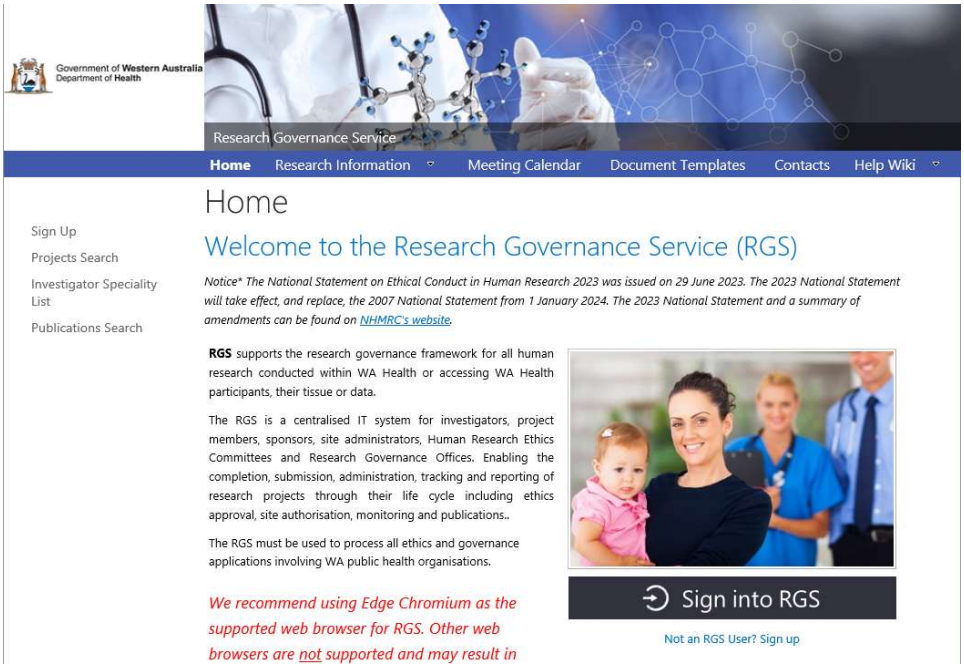

HREC Composition

- Composition determined by *National Statement S5.1.29*.
- Minimum 8, males = females
  - One third from outside the institution
  - 2 community representatives; one male, one female
    - no affiliation to the institution
    - not engaged in medical, scientific, legal or academic work
  - 1 person with experience in professional care e.g. doctor, nurse
  - 1 pastoral carer
  - 1 lawyer
  - 2 with current relevant research experience (pool)

HREC Chair expectations

- Attendance: (5-6) meetings a year
- Reading: 4-8 hours per month prior to the meeting
- Contribution: in line with member role, all equally important
- Respect:
  - listening and consideration of views
  - clarity when presenting own views, linked to ethical principles.
- Conflict of Interest:
  - Must be disclosed and managed.
  - Financial, relationships (positive and negative), and other biases

HREC Meeting format

- Face-to-face or MS Teams
- Discussion – ensuring all perspectives heard
- Voting – majority, not unanimous
- Comments and suggestions minuted
- Feedback to applicant clearly articulated

Application Forms – Standard Requirements

- Application form – WAHEAF or WASM + HREA
- Protocol – use WA health template
- Recruitment documents – email, flyer, advertisement, letter
- Participant Information Sheet & Consent Form (PICF) – may have adult participant, child participant, parent/guardian
- Data collection tools – survey, interview questions, observation checklist
- Other documents – Investigator Brochure, Radiation dose assessment, patient ID card, VSM etc
- Other approvals – supporting departments, WAAHEC, university HREC

Application Review Process

- Apply within RGS
- CPI receives acknowledgement
- REG staff validate submission and triage
- HREC review
- Notification through RGS with outcome of review
- Options: Approve, Approve with conditions, Resubmit to HREC
- Submit SSA and Budget or Access Request form simultaneously for review

Ethics Submissions – General Approach

Use appropriate language!

- Aims, objectives, methods
  - Participants, privacy, consent
  - Data management
  - Consultation, feedback
- Names and titles of investigators - responsibilities
- Conflict of interest, risks and benefit
- Start date – <u>after</u> ethics approval

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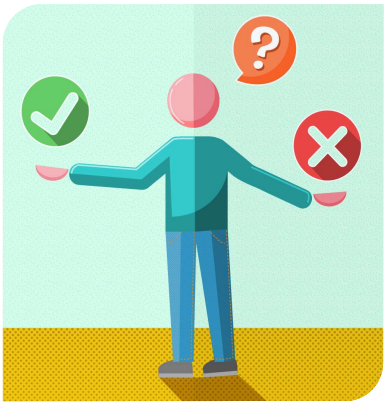
Research Ethics & Governance Offices

Staffing - <u>generally small</u>
e.g. 5-6 FTE total



Duties covered may include:

- Ethics Officer
- Research Governance Officer
- Clinical Trials Liaison Officer
- Monitoring & Compliance officer

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How best to prepare?

- Start early, allow sufficient time *supervisors
- Community involvement
- Speak to in-house research support staff:
  REG Office, Biostats, Head of Department, data manager, business manager
- Look at successful applications/ talk to successful researchers
- Peer review

Resubmission means delay of final approvals

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Monitoring and Safety

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Compliance

- Submit amendments
- Report adverse events
- Submit progress reports – annual, final
- NHMRC: "Safety monitoring and reporting in clinical trials involving therapeutic goods"
- Monitoring visit by REG Office, Data safety monitoring boards (DSMBs) etc

"Filling in a form well does not mean a study will be ethical unless ethical conduct follows"

Annual and Final Reports

- RGS will automatically notify via reminders
- Content
  - Publications
  - Adverse events + changes required
  - Staffing changes
  - Findings
  - Recruitment and progress
  - Results
  - Final : aims met?

Adverse Event Reporting

NHMRC - Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods (2016)

Serious Breach

- within 72h to site RGO
- within 7 days to lead HREC

Significant Safety issue

- within 72h to site RGO
- within 7 days to lead HREC, follow-up up to 15days

SUSAR/USADE

- within 72h to site RGO

Key Messages

- Understand the principles and processes
- Onus is on you, the researcher
- Use the WA Health website
- Allow sufficient time
- Get help, Look at successful examples
- Use the NHMRC National Statement
- Plain language
- Be fussy about detail

"Improvement begins with I."
Arnold H. Glasow

- Questions?
- Comments?

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Next Research Skills Sessions

21 Nov – WORKSHOP

Navigating Research Ethics + Governance in WA

Dr Natalie Giles + CAHS Ethics and Governance team

24 Nov – SEMINAR Qualitative Research Methods

- Dr Lorna Davin, Notre Dame University

Register → **researcheducationprogram.eventbrite.com.au**

We love feedback

A survey is included in the back of your handout, or complete online
https://tinyurl.com/SurveyEthicsProcesses

✉ ResearchEducationProgram@health.wa.gov.au cahs.health.wa.gov.au/ResearchEducationProgram

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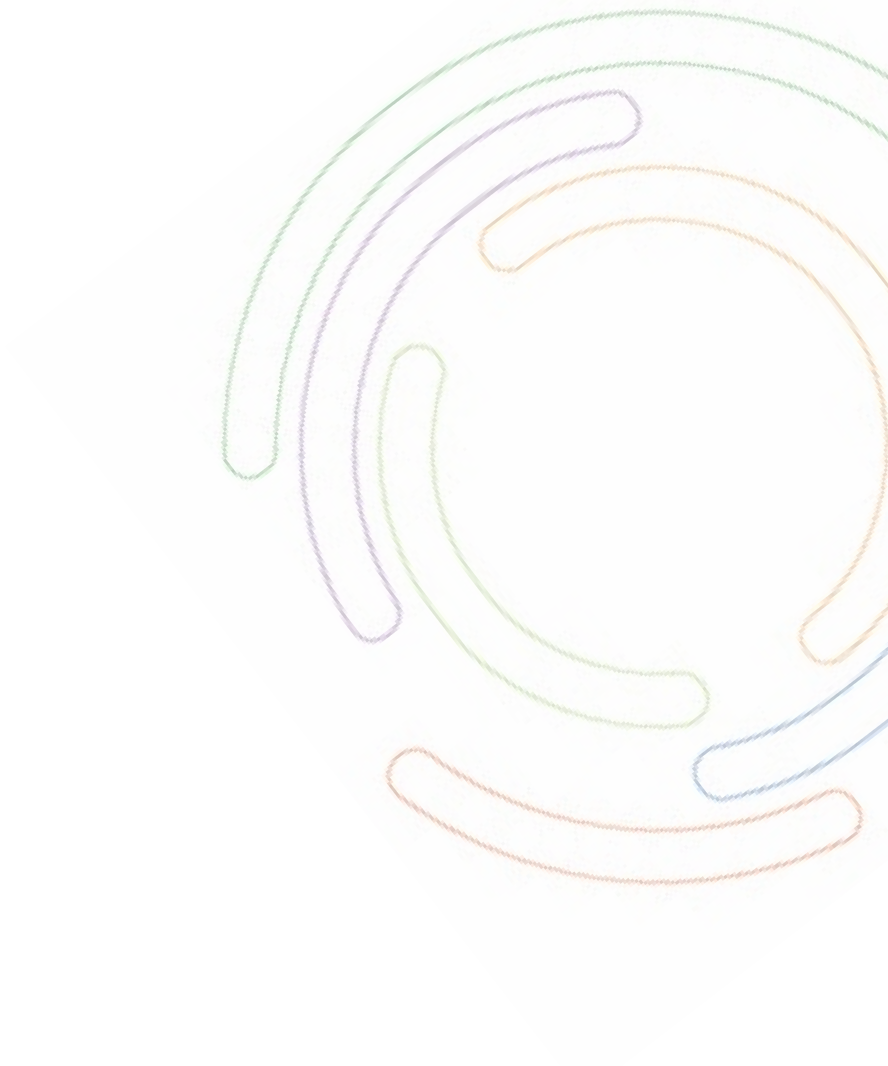
Ethics Processes for Clinical Research in WA

RESOURCE NOTES



CAHS Research Education Program Research Skills Seminar Series
✉ ResearchEducationProgram@health.wa.gov.au
cahs.health.wa.gov.au/ResearchEducationProgram

Table of Contents

2. General Guidelines / Information for Ethics in Health Research

The Australian Health Ethics Committee (AHEC) has statutory responsibility for developing guidelines regarding Ethical conduct of research. AHEC has also developed some other general guidelines with other committees. General guidelines relevant for researchers, Human Research Ethics Committees and institutions involved in research involving humans can be found at this website: https://www.nhmrc.gov.au/research-policy

Australian Code for Responsible Conduct of Research (updated online June 2018) https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

Resnik DB. "What is Ethics in Research & Why is it Important?" 2011. National institute of Environmental Health Sciences. https://www.researchgate.net/publication/242492652_What_is_Ethics_in_Research_Why_Is_It_Important

Research ethics, publication ethics and good practice guidelines. Equator Network: Enhancing the Quality and Transparency Of health Research. Excellent resources website https://www.equator-network.org/library/research-ethics-publication-ethics-and-good-practice-guidelines/

Guide to managing & investigating potential breaches of the Australian Code for the Responsible Conduct of Research, 2018 https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018#download

Disclosure of interests and management of conflicts of interest, 2018 https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018#download

3. HREC Composition

Composition in accordance with the National Statement S5.1.29.

The minimum membership of an HREC is eight. As far as possible:

a. there should be equal numbers of men and women; and
b. at least one third of the members should be from outside the institution for which the HREC is reviewing research.

This minimum membership is:

a. a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement;
b. at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;

c. at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
d. at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
e. at least one lawyer, where possible one who is not engaged to advise the institution; and
f. at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

4. WA Department of Health

All procedures, policies and forms to cover the review and approval of research within WA Health are found within the RGS system.

Key Sites:

Standardised forms can be found at: https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx

Standardised Documentation Templates: https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx

Information on the new RGS IT system is found at: https://rgs.health.wa.gov.au/Pages/Home.aspx

WA Research Governance Policy and Procedures. Research Development Unit, Office of the Chief Medical Officer November 2021 Research Governance Policy (health.wa.gov.au)

5. Ethics Amendment and Monitoring Forms

NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

Serious Adverse Events within 24h to sponsor, 72h to HREC

Updated WA Health Forms reflect this new document and ensure research projects meet the requirements of research monitoring. They should be submitted to the HREC responsible for approving the project. Forms can be found at:

https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx

Include (with updates wherever appropriate):

- WA Health Amendment Form
- WA Health Annual Progress Report
- WA Health Final Progress Report
- WA Health Safety Report

***Please note the NEAF was replaced by the HREA in Dec 2016**
this website provides some information: https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-applications-hrea

6. NHMRC Safety Reporting Guidelines 2016/2017

NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods

https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

7. Audit/Quality Assurance Projects

SMHS Quality Improvement versus Research Guidelines

Policies, Procedures & Guidelines (health.wa.gov.au)

NHMRC: Ethical considerations in quality assurance and evaluation activities

https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities

CAHS Research Education Program, Clinical Audit Handbook

https://cahs.health.wa.gov.au/Research/For-researchers/Research-Education-Program/Clinical-Audit-Handbook

WA Health's Governance, Evidence, Knowledge, Outcomes (GEKO)

https://geko.hdwa.health.wa.gov.au/Login

Quality Improvement (QI) activities are to be registered in GEKO.

The below information hubs are all internal WA Department of Health (Healthpoint) pages.

CAHS	https://cahs-healthpoint.hdwa.health.wa.gov.au/directory/safetyandquality/continuousqualityimprovement/Pages/default.aspx
EMHS	https://emhs-healthpoint.hdwa.health.wa.gov.au/directory/SQaCE/Pages/Quality-Improvements.aspx
MHPHDS	https://mhphds-healthpoint.hdwa.health.wa.gov.au/directory/Corporate/SQP/Pages/Quality-Improvement.aspx
NMHS	https://nmhs-healthpoint.hdwa.health.wa.gov.au/directory/SQandG/Pages/Quality-Improvement-Projects-and-Initiatives.aspx
SCGOPHCG	https://scgophcg-healthpoint.hdwa.health.wa.gov.au/directory/Corporate/SQP/QI/Pages/default.aspx
SMHS	https://smhs-healthpoint.hdwa.health.wa.gov.au/directory/SQaCE/Quality-Improvement/Pages/default.aspx
WNHS	https://wnhs-healthpoint.hdwa.health.wa.gov.au/directory/CES/SQP/QualityImprovementAndAudit/Pages/default.aspx
HSS/ICT Support	https://wahealthdept.sharepoint.com/sites/hss-customer-ict-hosp-admin/SitePages/geko.aspx

8. Low and Negligible Risk Pathway

Premise:

The National Health and Medical Research Council (NHMRC) states that ethical review can be undertaken at various levels, according to the level of risk involved in the research.

The NHMRC define research as “low risk” where the only foreseeable risk to the participant is one of discomfort. Research is of “negligible risk” where the only foreseeable risk to the participant is one of inconvenience.

National Statement on Ethical Conduct in Human Research 2023 | NHMRC

The following are examples provided by CAHS of projects suitable/ otherwise for the LNR Pathway

Studies eligible for the LNR Ethical Review at CAHS **do not** involve:

- any potential risk to the participant which will cause them anything more than discomfort
- an intervention

For example use of drugs or devices; taking specimens from children and public and mental health interventions that would cause the participant anything more than discomfort.

- vulnerable individuals

  For example people who have a dependant relationship with medical personnel, people with mental illness, cognitive or intellectual

impairment people with gender identity issues, people involved in illegal activities (illicit drug use)

- Aboriginal people or Torres Strait Islanders as the target study population
- genetic testing
- stem cells or their products
- the creation of a databank, biobank or registry
- the examination of sensitive personal or cultural issues
- women who are pregnant or their foetuses either *in utero* or *ex utero*
- a request for either a "Waiver of Consent" or permission to "Opt-out of Consent"

1. Types of Studies NOT Eligible for LNR Ethical Review at CAHS

- Any study that involves a drug or device
- Any data collection intended to create or add to a data bank, biobank or registry
- Any retrospective data collection where the participants have not already given consent for the data to be collected

Examples:

- A cohort study of otitis media in urban aboriginal children
  - study involves data collection by completion of a questionnaire; there is no intervention but study population targets aboriginal people; an exclusion criteria
- Palatable and chewable tramadol chocolate-based tablets for pain management in young paediatric patients
  - study involves an intervention – introducing a new drug formulation
- Australian Cystic Fibrosis Data Registry
  - study involves creation of a registry - an exclusion criteria

2. Types of Studies that would be Eligible for LNR Ethical Review at CAHS

- Most qualitative research protocols
- Any study where the data is collected by questionnaire and/or focus groups and the target population is not excluded by the criteria set out by the NHMRC (see above).

Examples:

- Development of a conflict management framework in hospital staff
  - data collection from hospital staff by voluntary completion of a questionnaire
- A grounded theory study: exploring the experiences of nurses who encounter young people with mental health problems
  - data collection *via* questionnaire from adult health care providers
- The roles of parental - and child-based self-determined motivation in family-oriented therapies for childhood obesity
  - data collection by voluntary completion of a questionnaire after obtaining consent
- A qualitative exploration of the experiences and needs of parents of a child diagnosed with Type 1 diabetes when one parent has Type 1 diabetes.
  - data collection by voluntary completion of a questionnaire after obtaining consent

9. How to write a good ethics application

Useful tips from UWA (UWA only): https://www.research.uwa.edu.au/staff/human-research/good-application

10. Ethics and Research Governance Structures

Example: CAHS, Perth Children's Hospital
https://cahs.health.wa.gov.au/Research/For-researchers/Ethics-and-governance-approval

The CAHS HREC operates under terms of reference based on the National Statement. The Chair and members of the HREC are appointed by the CAHS Executive for a 3 year term.

The Scientific Advisory Subcommittee (SASC) at CAHS assesses projects prior to HREC meetings, identifies and resolves remedial problems and makes recommendations to HREC.

The composition of the HREC and SASC shall be in accordance with the *National Statement S5.1.29*. *Note not all HRECs in WA utilise at SASC in addition to an HREC.

The Research Governance Office is required to ensure that researchers are aware of and compliant with relevant laws, policies and codes of conduct namely:

- Therapeutic Goods Administration (TGA) Note for Guidance on Good Clinical Practice
  https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
- 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 (2018)
  https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018
- WA Health and Institutional policies
  https://rgs.health.wa.gov.au/Pages/Research-Governance-Framework.aspx
- Medicines Australia - Clinical Trials
  https://www.medicinesaustralia.com.au/policy/clinical-trials/
- Australian Clinical Trials Handbook
  https://www.tga.gov.au/publication/australian-clinical-trial-handbook
- Government of Western Australia Intellectual Property Policy and Best Practice Guidelines:
  https://www.commerce.wa.gov.au/sites/default/files/atoms/files/wa_govt_ip_policy_and_best_practice_guidelines.pdf

- Working with Children Checks https://workingwithchildren.wa.gov.au/
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
- Guidelines under section 95 of the Privacy Act 1988: privacy and medical research (amended June 2015) https://www.comlaw.gov.au/Details/C2015C00279

11.Useful Guides

NHMRC: Aboriginal and Torres Strait Islander health https://www.nhmrc.gov.au/health-advice/aboriginal-and-torres-strait-islander-health

National Health and Medical Research Council "Ethical guidelines for research with Aboriginal and Torres Strait Islander peoples" (2018). https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-and-torres-strait-islander-peoples

https://www.nhmrc.gov.au/about-us/resources/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities

NHMRC Keeping Research on Track II: a guide for Aboriginal and Torres Strait Islander peoples about health research ethics https://www.nhmrc.gov.au/about-us/resources/keeping-research-track-ii

Challenging Ethical Issues in Contemporary Research on Humans (2009) https://www.nhmrc.gov.au/about-us/publications/challenging-ethical-issues-contemporary-research

Universal Declaration on Bioethics and Human Rights UNESCO 2005 https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights?hub=66535

NHMRC Competencies for Australian Academic Clinical Trialists (May 2018) https://www.nhmrc.gov.au/about-us/publications/competencies-australian-academic-clinical-trialists

12.Multi-site Research

On September 1 2013, WA Health implemented the WA Health Single Ethical Review process, whereby, all multi-centre research projects being conducted at sites under the control of WA Health or involving participants, their tissue or data accessed through WA Health must be ethically and scientifically reviewed only once, by a Lead WA Health Human Research Ethics Committee (HREC).

WA Health researchers should apply to their site's local HREC for ethical approval. For multi-centre research investigators should utilise the National Mutual Acceptance and National Approach processes in the RGS platform. For multi-centre studies (e.g. large national or international clinical trials) the coordinating principle investigator is responsible for organising submission of documents for scientific and ethical review by an appropriate lead HREC. Principle investigators at each site must submit applications for governance review and will be responsible for local approvals and compliance. Multi-centre studies submitted for ethics approval in WA, whether originating from WA or other states, must be submitted on the HREA form (replacing the NEAF in Dec 2016) and be accompanied by the WA-Specific Module together with the appropriate research governance forms.

The Research Governance Service (RGS) IT system is designed to facilitate on-line completion and submission of application forms, approvals, reports, monitoring and outcome assessment.

To gain access you must “sign up” and provide a WA Health employee as a referee before you can access the system to create your project
https://rgs.health.wa.gov.au/Pages/Home.aspx

- There is a Help Wiki available to guide you through the process

Remember to use Google Chrome to access the system, save your data entry regularly, and add RGS as a “safe sender” in your e-mail as all correspondence and feedback in relation to the review of your project will come via the RGS system

The National Mutual Acceptance of Ethical and Scientific Review for Multi-centre Clinical Trials Conducted in Public Health Organisations (**National Mutual Acceptance**) and the National Approach to Single Ethical Review of Multi-centre Research (**National Approach**) processes apply to all multi-centre research projects being conducted at sites within Australia for all categories of human research and streamline previous practise by ensuring review only once by a NHMRC Certified Lead HREC. The exception is those clinical trials that require additional specialist review.

Information in regards to **Multi-Centre Research, National Mutual Acceptance, and National Approach** can be found at: https://rgs.health.wa.gov.au/Pages/Multi-centre-Research.aspx

13. WA HREC Details

WAAHEC

For information about meeting dates, research application process and forms as well as useful links to other organisations that undertake Aboriginal health research: http://www.ahcwa.org.au/#!ethics/c6gq

WA Department of Health HREC

The Department of Health WA Human Research Ethics Committee (DOH HREC) is a Human Research Ethics Committee with special responsibility for oversight of the use and disclosure of personal health information held in the Department of Health data collections https://www.health.wa.gov.au/Articles/A_E/Department-of-Health-Human-Research-Ethics-Committee

13.1. **Office of Medical Research and Innovation**
https://www.health.wa.gov.au/Articles/N_R/Office-of-Medical-Research-and-Innovation
Email: DOH.OMRI@health.wa.gov.au

13.2. **CAHS Research Ethics and Governance Office**
(Human Research Ethics Office) Perth Children's Hospital, Level 5, Office 5E
Department of Child Health Research Tel: (08) 6456 0516
Email: CAHS.Ethics@health.wa.gov.au
Email: CAHS.RGO@health.wa.gov.au

The Ethics and Governance Office will generally be unattended over the two weeks encompassing Christmas and New Year.

For emergencies, or any complaints regarding the study, you can contact the **Executive Director Medical Services** on **6456 2222**. Your concerns will be drawn to the attention of the Ethics Committee who are monitoring the study.

13.3. **East Metropolitan Health Service, Research Ethics and Governance**
https://emhs.health.wa.gov.au/Research/For-Researchers/REGS
Email: EMHS.REG@health.wa.gov.au

13.4. **Sir Charles Gairdner Hospital Research**
https://www.scgh.health.wa.gov.au/Research/Department-of-Research/My-Project/HREC
Email: scgh.hrec@health.wa.gov.au

13.5. **South Metropolitan Health Service/Fiona Stanley Hospital**
https://www.smhs.health.wa.gov.au/Our-research/For-researchers
Email: SMHS.HREC@health.wa.gov.au
Email: SMHS.RGO@health.wa.gov.au

WA Private HREC

13.6. **St John of God HREC**
Human Research Ethics Committee (sjog.org.au)

13.7. **Joondalup HREC**
https://www.ramsayhealth.com.au/Ramsay-Research/Reseach-Ethics-at-Ramsay

WA Universities HREC

13.8. **UWA HREC**
https://guides.library.uwa.edu.au/RDMtoolkit/ethics-compliance

13.9. **Notre Dame HREC**
https://www.notredame.edu.au/research/ethics-and-integrity/human-research-ethics

13.10. **Curtin University HREC**
https://www.curtin.edu.au/students/essentials/higher-degree-by-research/ethics-safety/human/

13.11. **Edith Cowan University HREC**
https://www.ecu.edu.au/centres/research-services/research-ethics-and-integrity

13.12. **Murdoch University HREC**
https://www.murdoch.edu.au/research/research-ethics-and-integrity/human-research-ethics

14. Good Clinical Practice Training

Global Health Trials
ICH Good Clinical Practice E6 (R2)

https://globalhealthtrials.tghn.org/elearning/

"This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by *TransCelerate BioPharma* as necessary to enable mutual recognition of GCP training among trial sponsors."

Research Education & Training Program (RETP) – WA Health Translation Network (WAHTN) **ICH Good Clinical Practice** - ICH E6 (R2) + TransCelerate Approved
https://retprogram.org/portfolio-item/ich-good-clinical-practice-gcp-e6-r2/

ARCS Australia

The Association of Regulatory and Clinical Scientists to the Australian Pharmaceutical Industry https://www.arcs.com.au/events/ethic-and-governance/

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

Perth Children's Hospital

CAHS Research Education Program

Research Skills Workshop Series

Navigating Research Ethics and Governance in WA

21st November 2023 • ***1.00 - 3.30pm*** • ***PCH, TKI Level 5 Seminar Room***

If you are undertaking a research project or are thinking about becoming involved in research, understanding the review and approval requirements for your research project may appear intimidating.

This workshop is to help you understand the process of ethical and governance review for research approvals at WA Health sites.

The Ethics and Governance team will provide an overview of the review processes in WA Health and explain the most common issues that cause delays or queries in relation to research submissions. We welcome your feedback and interaction throughout the workshop as we discuss issues that are relevant to you and your project.

The session allows you to meet the ethics and governance team at CAHS and ask questions in an open and supportive environment to help you understand and navigate the process.

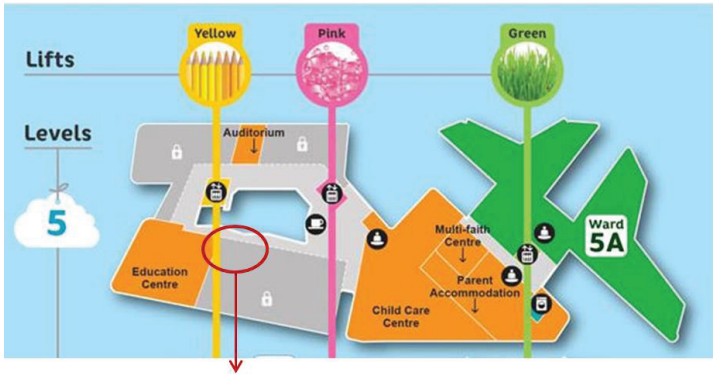
We invite experienced and inexperienced researchers and their support teams to attend if you would like to know more about the review and approval process within WA Health or refresh your knowledge.

Presented by

CAHS Ethics and Governance Team

If you have specific questions that you would like to have covered during the workshop please send them through to Natalie.Giles@health.wa.gov.au.

Scan to register



Location of the TKI Seminar Room
Accessible via yellow or pink lifts

Register via Eventbrite

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cahs.health.wa.gov.au/Research/For-researchers/Research-Education-Program

Perth Children's Hospital Foundation

Workshops are presented by the Research Education Program in partnership and with support from the PCH Foundation and Telethon Kids Institute as part of the Research Education Program Research Skills Workshop Series, presented by the WA Department of Health CAHS Department of Research and invited speakers.

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A free, open-access resource designed to upskill busy clinical staff and students and improve research quality and impact.

2023 Seminar Schedule

Scan to register

Interactive in pdf format
Last updated 17/11/23

	DATE	TOPIC	PRESENTER	ENROL	WATCH
1	3 Mar	**Research Fundamentals**	Dr Kenneth Lee, UWA	-	2023
2	17 Mar	**Introductory Biostatistics**	Michael Dymock, TKI	-	2023
3	28 Apr	**Scientific Writing**	A/Prof Tony Kemp, UWA	-	2023
4	5 May	**REDCap for Data Capture and Management**	Dr Jane Mugure Githae, CAHS	-	2023
5	12 May	**Using Social Media in Research**	Dr Kenneth Lee, UWA	-	2023
6	19 May	**Getting the Most out of Research Supervision**	A/Prof Sunalene Devadason, UWA/CAHS	-	2022
7	26 May	**Research Impact**	Dr Tamika Heiden, Vic	-	2023
8	2 Jun	**Survey Design & Techniques**	Dr Jane Mugure Githae, CAHS	-	2023
9	9 Jun	**Conducting Systematic Reviews**	Prof Sonya Girdler, Curtin Uni	-	2023
10	16 Jun	**Consumer & Community Involvement in Research**	Belinda Frank, TKI	-	2023
11	23 Jun	**Project Management**	Melanie Wright, SMHS	-	2023
12	30 Jun	**Sample Size Calculations**	Michael Dymock, TKI	-	2023
13	21 Jul	**Introduction to Good Clinical Practice**	Alexandra Robertson, CAHS	-	2023
14	28 Jul	**Data Collection and Management**	Dr Jane Mugure Githae, CAHS	-	2023
15	4 Aug	**Rapid Critical Appraisal of Scientific Literature**	Dr Natalie Strobel, ECU	-	2023
16	18 Aug	**Media and Communications in Research**	Keryn McKinnon, TKI	-	2023
17	25 Aug	**Oral Presentation of Research Results**	Dr Jane Mugure Githae, CAHS	-	2023
18	1 Sep	**Involving Aboriginal Communities in Research**	Cheryl Bridge - TKI Shakara Liddelow - Hunt – TKI A/Prof Bep Uink, Murdoch Uni	-	2023
19	8 Sep	**Knowledge Translation**	A/Prof Fenella Gill, Curtin Uni / CAHS	-	2023
20	13 Oct	**Research Governance**	Dr Natalie Giles, Tracy Chapman, CAHS	-	2023
21	20 Oct	**Grant Applications and Finding Funding**	Dr Tegan McNab, TKI	-	2023
22	27 Oct	**Statistical Tips for Interpreting Scientific Claims**	Michael Dymock, TKI	-	2023
23	17 Nov	**Ethics Processes for Clinical Research in WA**	Dr Natalie Giles, CAHS	-	2020
24	24 Nov	**Qualitative Research Methods**	Dr Lorna Davin, University of Notre Dame	REGISTER	2022
25	1 Dec	**Innovation and Commercialisation**	Dr Helga Mikkelsen, Brandon BioCatalyst + Ashley Schoof, TKI	REGISTER	2022

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✉ researcheducationprogram@health.wa.gov.au

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Seminars are held from 12:30-1:30pm at Perth Children's Hospital Auditorium and are broadcast live online through Teams and Avaya.
Seminars are recorded and uploaded to our website within a week of presentation. Topics are subject to change with appropriate email notice provided.
Handouts are revised and updated regularly. A light lunch is provided for attendees at our PCH auditorium. Attendance certificates are available on request.

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Qualitative Research Methods

24th November 2023

12.30 - 1.30pm

The use of qualitative research methods is becoming more popular in health either as the primary research method or as part of a mixed methods approach to investigating a health issue.

This seminar covers the benefits of using qualitative research; some of the myths associated with the use of qualitative research; the types of qualitative methods; how data is collected and analysed; and how the researcher uses qualitative research to improve health outcomes for individuals, families and communities.

Perth Children's Hospital Auditorium

Level 5, 15 Hospital Ave Nedlands
accessible via pink or yellow lifts
or access online via Teams or Avaya
or watch live
from a hosted video-conferencing site

- Bunbury Hospital
- Fiona Stanley Hospital
- Lions Eye Institute
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Meet the presenter

THE UNIVERSITY OF NOTRE DAME AUSTRALIA

Dr Lorna Davin

Senior Lecturer Medical Education, University of Notre Dame Australia

Lorna is an experienced educator, facilitator and researcher in the area of emotional well-being. She has worked in the health and education sectors for the last 30 years.

Lorna is a qualitative researcher who uses stories as the basis of her research. Her areas of interest are compassion and self-compassion, our values and beliefs, the stories we tell ourselves, and the way they shape our lives. She is a regular presenter at state and national conferences, has contributed a range of publications to the field and supervises and mentors students undertaking research in health professional education.

researcheducationprogram@health.wa.gov.au (08) 6456 0514

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Research Skills Seminar Series 2023

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Innovation and Commercialisation

1st December 2023

12.30-1.30pm

Innovation drives improvement in both research and processes. Commercialisation takes the next step to translate those ideas into a saleable product.

Learn about how to get involved in innovation and commercialisation activities in child and adolescent health in WA.

This session will cover: what you need to know and what support is available to help you achieve real-world impact from your research.

Perth Children's Hospital Auditorium

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Access online via Teams or Avaya or

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Meet the presenters

TELETHON KIDS INSTITUTE
Discover. Prevent. Cure.

Ashley Schoof
Commercialisation Officer

Ashley is responsible for the identification, protection and commercialisation of Intellectual Property at Telethon Kids to support the development of new discoveries, preventions and cures.

Dr Helga Mikkelsen
Investment Analyst

Following degrees in Chemical Engineering and Biotechnology, Helga completed her PhD in microbiology at the University of Cambridge and postdoctoral research in bacterial genetics at Imperial College London.

She has since worked with medical innovation and has managed the development of devices and drug treatments in the UK and Australia in her work with Brandon Biocatalyst.

Brandon Capital manages Australia and New Zealand's largest life science investment fund, Brandon BioCatalyst.

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Ethics Processes for Clinical Research in WA

Thank you for your interest in this seminar

Please complete this 1-minute evaluation.
Your feedback will help guide future presentations and educational activities.

How did you attend the seminar?

- ○ Live seminar at Perth Children's Hospital
- ○ Hosted video-conference on-site (e.g. Bunbury Hospital, FSH, Lions Eye, RPH etc.)
- ○ Online via Avaya or Teams
- ○ Viewed online recording

Please rate your agreement with the following statements:

	N/A	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
The aims and objectives were clear	○	○	○	○	○	○
The session was well structured	○	○	○	○	○	○
Presentation style retained my interest	○	○	○	○	○	○
The speaker communicated clearly	○	○	○	○	○	○
The material extended my knowledge	○	○	○	○	○	○
The additional resources were helpful	○	○	○	○	○	○

What were the best aspects of the seminar?

What changes or improvements would you suggest?

How did you hear about the seminar?
(you can select multiple answer)

- ☐ Email invitation from Research Education Program
- ☐ CAHS Newsletters e.g. The Headlines, The View, CAHS Research Newsletter
- ☐ "Health Happenings" E-News
- ☐ Healthpoint Intranet Upcoming Events
- ☐ Collegiate lounge screen or other posted promotional material
- ☐ Telethon Kids Institute screen or other posted promotional material
- ☐ Telethon Kids Institute Newsletter
- ☐ Other

Thank you!

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

Perth Children's Hospital

cahs.health.wa.gov.au/ResearchEducationProgram

CAHS Research Education Program Research Skills Seminar Series

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