



# CAHS Research Education Program Research Skills Seminar

## Ethics Processes for Clinical Research in WA

12 November 2021

*Presented by*

**Associate Professor Sue Skull**

Head, Research Education Program

**CAHS Research Education Program  
Research Skills Seminar Series**

☎ (08) 6456 0514 ✉ [ResearchEducationProgram@health.wa.gov.au](mailto:ResearchEducationProgram@health.wa.gov.au)

🌐 <https://cahs.health.wa.gov.au/ResearchEducationProgram>



**Healthy kids, healthy communities**

Compassion

Excellence

Collaboration

Accountability

Equity

Respect

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



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Child and Adolescent Health Service, Department of Research

Department of Health, Government of Western Australia

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# Ethics Processes for Clinical Research in WA

## PRESENTATION SLIDES

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Government of Western Australia  
Child and Adolescent Health Service

# Ethics Processes for Clinical Research in WA

12 November 2021

Presented by **Associate Professor, Sue Skull**  
Head – Research Education Program, CAHS  
Deputy Director, Department of Research, CAHS

Research Education Program | Research Skills Seminar Series

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## Acknowledgement of country

I would like to acknowledge the  
traditional custodians of the land,  
the Noongar Whadjuk people,  
and pay my respects to their elders,  
past, present and future.

2

“It’s a sign of troubled times when the concept of pressure becomes an acceptable excuse for ethical shortcuts and moral shortcomings.....

Ethical people often do more than the law requires and less than it allows. The area of discretion between the legal must and the moral should tests our character. Noble talk and framed ethics statements are no substitute for principled conduct. The test is doing the right thing.”

*Michael Josephson*

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## Overview

1. General principles
2. Approval pathways
3. Practical requirements
4. General ethics processes
5. Participants: recruitment, information, consent
6. Data management
7. Monitoring and safety
8. Feedback



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# General Principles

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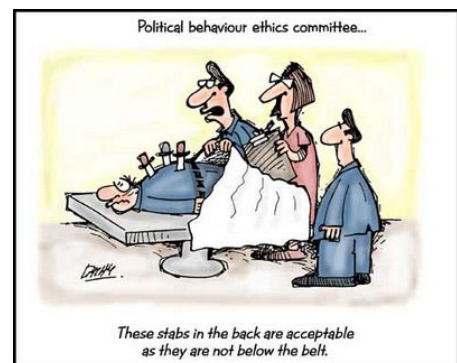
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## Ethics?

- 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*

**Revisit 5 April 2019 seminar:**  
“Ethical Principles for Research” by Dr Nik Zeps  
[@ResearchEducationProgram.org](mailto:@ResearchEducationProgram.org)



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## Why?

“Whoever is careless with the truth in small matters cannot be trusted with important matters”  
*Albert Einstein*

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



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## General Ethical Principles

### Justice

- Fair selection of participants

### Beneficence

- Consider welfare and interest of participants
- Risk vs Benefit, equipoise
- Awareness of social implications

### Respect

- Autonomy of individuals
- Protection of vulnerable groups



“In matters of truth and justice, there is no difference between large and small problems, for issues concerning the treatment of people are all the same” *Albert Einstein*

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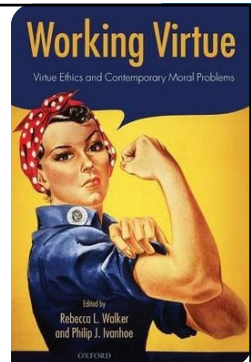
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# General Ethical Principles

## Research Merit

- Important question – priority, not done already
  - After appropriate literature review
  - Potential benefit
  - Useful contribution to knowledge and/or wellbeing
- Appropriate methods\*
- Appropriate skills
- Appropriate resources

“It seems to never occur to fools that merit and good fortune are closely united”  
*Johann Wolfgang von Goethe*



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# General Ethical Principles

## Researcher Integrity

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



<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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## Good Clinical Practice

- The international ethical, scientific and practical standard to which all clinical research involving human subjects is conducted
- Regular training essential to maintain awareness and compliance with relevant laws, policies and codes of conduct
- Onus is on the researcher to be up to date
- Overview Seminar: [ResearchEducationProgram.org](http://ResearchEducationProgram.org)
- Free on-line training: see handout

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## Important Guidelines

All in your handouts

### NHMRC

- National Statement 2007 on Ethical Conduct in Human Research (2018)
- Australian Code for the Responsible Conduct of Research (Jun 18)
- Competencies for Australian Academic Clinical Trialists (May 18)
- Guidelines approved under Section 95 & 95A of *Privacy Act 1988* (Oct 19)
- Challenging Ethical Issues in Contemporary Research on Human Beings (Dec 06)

### Universal Declaration on Bioethics and Human Rights UNESCO 2005

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# Approval Pathways

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## Approval Pathways

**Ethical review can be undertaken at various levels, according to the level of risk (NHMRC)**

- Human Research Ethics Committee
- Low and Negligible Risk Pathway
- Quality improvement activities



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## Role of Ethics Overview?

- To ensure best possible research practice
- To protect
  - research participants
  - researchers
  - organisations
- Stronger application!



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## Role of Researchers?

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

**Exactly the same! But.....**

**Remember Approval is Prospective**



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## Low and Negligible Risk Pathway

- Available at many WA Health sites
- Shorter turn around than full HREC review e.g. 3 weeks
- Defined as research projects of the highest possible scientific and ethical standard where the only foreseeable risk to the participants is
  - LOW RISK.... “no more than discomfort”
  - NEGLIGIBLE RISK.....”inconvenience”



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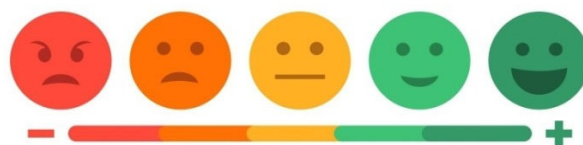
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## Suitable Projects - Low and Negligible Risk

- Most qualitative research protocols
- Studies where data is collected by questionnaire/via focus groups and the target population is allowed by NHMRC

### Example:

Experiences and needs of families with a Type 1 diabetic (voluntary questionnaire after obtaining consent)



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## NOT suitable for LNR Pathway - 1



- All interventions
- All “opt out” or “waiver of” consent (approval goes to HREC)
- Vulnerable individuals e.g.:
  - dependent relationship with medical personnel,
  - mental illness, cognitive or intellectual impairment
  - gender identity issues, involved in illegal activities

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## NOT suitable for LNR Pathway - 2



- 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
- **Have ethical issues been accounted for?** → +/- HREC
- MUST submit data collection forms
- Generate GEKO activity number +/- approval for publication



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## Quality Assurance or Higher Ethical Review?

- Participant data to be used for other purposes?
- Risks/burden for patients beyond routine care?
- Staff not those who usually access participant records?
- Risk of breaching confidentiality?
- Significant departure from routine clinical care?



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## Quality Assurance or Higher Ethical Review?

- Data collected beyond that of routine clinical care?
- Data provided to external organisations?
- Randomisation or control group or placebo?
- Potential infringement of rights, privacy or reputation of carers, health care providers or institutions?
- Results to be published?\*
- Multisite, sensitive information



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## Audit & Quality Assurance - Unsure?

- WA Health Research Governance Policy and Procedures: 3.1: p42
- Clinical Governance Unit/Safety and Quality staff
- Ethics and Research Governance Officers
- NHMRC: When does Quality Assurance in Health Care Require Independent Ethical Review?
- CAHS Clinical Audit Handbook (2019)
- Research Education Program: Additional Resources

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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
- Application for health data: DS001

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## WA Aboriginal Health Ethics Committee



### Within the Aboriginal Health Council of WA

Submit if research involves Aboriginal participants and:

- Aboriginal status is a key determinant
- Data collection directed at Aboriginal people
- Aboriginal people to be examined separately
- Data to impact on Aboriginal communities
- Aboriginal health funds are a source of funding
- Likely to be over-represented in the study

**WAAHEC:** <http://www.ahcwa.org.au/ethics>

“NHMRC values and ethics: guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research 2003” + NHMRC Keeping research on track 2006”

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## 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](http://www.anzctr.org.au)
- Industry often requires registration details for participants
- + agreements, indemnities, insurances etc.

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## Practical Requirements - HREC Submission

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## WA Health Research Governance Framework

Lots of positive change bringing WA in line with other states

- Approval by one WA Health HREC, standard forms - Sep 13
- National Mutual Acceptance - WA since July 2017
- WA Health online Research Governance Service (RGS) IT system
- NHMRC Safety Reporting Statement : new forms, requirements
- CAHS low and negligible risk approval pathway

Research Innovation Office Website - info, forms agreements  
[https://ww2.health.wa.gov.au/Articles/N\\_R/Research-and-Innovation-Office](https://ww2.health.wa.gov.au/Articles/N_R/Research-and-Innovation-Office)

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## Multi-Site Research in Australia

### National Mutual Acceptance

- To improve quality & streamline processes across Australia
- → Single ethical review by certified HRECs
- All multi-site research, not just clinical trials
- Implemented
  - in Eastern States July 2013
  - in WA July 2017
- WA = public hospital certified HRECs
- NHMRC Human Research Ethics Portal

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## Multi-Site Research

- Research Governance Service (RGS) IT system
  - Online application
  - Web-based portal and database
  - Approval, Reports, Monitoring, Amendments
  - Outcome assessment
- The coordinating principal investigator submits to a lead HREC:
  - WAHEA form OR HREA\* + WA Specific Module\*
- Principal investigators at each site submit to Governance

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The screenshot shows the homepage of the Research Governance Service (RGS). At the top, there is a header with the Government of Western Australia Department of Health logo on the left and a navigation bar with links: Home, Research Information, Meeting Calendar, Document Templates, Contacts, and Help Wiki. Below the header, the main content area has a large heading "Home" and a subheading "Welcome to the Research Governance Service (RGS)". A red text block states: "Telstra are currently experiencing issues which may affect some users receiving SMS codes. If your preference is set to receive security codes to your mobile, we have changed this to send to your primary email address so that you can log in. We will let you know when this issue has been resolved." Below this, a paragraph explains that RGS supports the research governance framework for all human research conducted within WA Health or accessing WA Health participants, their tissue or data. Another paragraph describes RGS as a centralised IT system for investigators, project members, sponsors, site administrators, Human Research Ethics Committees and Research Governance Offices, enabling the completion, submission, administration, tracking and reporting of ethics and governance applications through the ethics approval and site authorisation processes. A third paragraph states that the RGS must be used to process all ethics and governance applications involving WA public health organisations. To the right of the text, there is an image of a smiling woman holding a baby, with two healthcare professionals (a nurse and a doctor) standing behind her. At the bottom right, there is a dark blue button with a circular arrow icon and the text "Sign into RGS". A red text block at the bottom left states: "IE11 or Chrome (latest version) web browsers must be used for RGS, other web browsers are not supported."

Government of Western Australia  
Department of Health

Research Governance Service

Home Research Information Meeting Calendar Document Templates Contacts Help Wiki

Sign Up

# Home

## Welcome to the Research Governance Service (RGS)

Telstra are currently experiencing issues which may affect some users receiving SMS codes. If your preference is set to receive security codes to your mobile, we have changed this to send to your primary email address so that you can log in. We will let you know when this issue has been resolved.

RGS supports the research governance framework for all human research conducted within WA Health or accessing WA Health participants, their tissue or data.

The RGS is a centralised IT system for investigators, project members, sponsors, site administrators, Human Research Ethics Committees and Research Governance Offices. Enabling the completion, submission, administration, tracking and reporting of ethics and governance applications through the ethics approval and site authorisation processes.

The RGS must be used to process all ethics and governance applications involving WA public health organisations.

IE11 or Chrome (latest version) web browsers must be used for RGS, other web browsers are not supported.

Sign into RGS

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**IE11 or Google Chrome (latest version) web browsers must be used for RGS, other web browsers are not supported.**

**Need Help?**

- ✓ RGS Help
- ✓ RGS Quick Start Guide for New User
- ✓ RGS User Guides including Monitoring
- ✓ RGS Training - 4 module course on RGS
- ✓ About RGS
- ✓ FAQs / Glossary

**COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors** - Please refer to the joint statement published by the Australian Department of Health for up-to-date general information and advice on conducting and overseeing clinical trials within the COVID-19 context. This joint statement reflects the shared views of various state and territory stakeholders within the clinical trial environment, including the WA Department of Health.

**Announcements**

Guardianship Act Medical Research supporting documents available 6/10/2020

RGS On-line Course 27/05/2020

**Events**

There are no items to show in this view.

**Helpful Links:**

Glossary/Definitions

Help Wiki

**Technical Assistance:**

Hours: 9.00am to 5.00pm AWST (Mon - Fri)

WA Health employees: Contact your Service Desk for password issues only

Non WA Health employees: Email [RGS.Support@health.wa.gov.au](mailto:RGS.Support@health.wa.gov.au)

**Business Assistance:**

WA Health HRECs

Specialist HRECs External to WA Health

WA Health RGOs

Policy / Contractual

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## Application Forms – Standard Requirements

### Compulsory

- **WAHEAF or (HREA\* plus Western Australian-Specific Module)** (multi-centre studies) (\*replaces the NEAF)
- **WA Health Site-Specific Assessment (SSA) form, or WA Health Access Request form** (either → Governance)
- **WA Health Research Conflict of Interest form**
- **Declaration of Confidentiality**
- **Protocol** for all projects\* (templates on RGS – clinical trial, other)
- **Participant/Parent information and consent form** (updated)
- + Any other required documents (e.g. clinical trial specific)

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## Submission Process in WA

1. Scientific Advisory Safety Committee +
2. Human Research Ethics Committees:
  - » CAHS; Women and Newborn Health Service (KEMH)
  - » Other major hospitals e.g. RPH, South Metro; SCGH
  - » Other regional, specialist and Dept of Health HRECs
3. Research Governance AND if applicable
4. Western Australian Aboriginal Health Ethics Committee (WAAHEC)
5. Institutional Approval – Chief Executive/delegate

**Must have all approval letters before research can start**

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## Application Review Process

- Apply within Research Governance System
- Chief Investigator receives acknowledgement
- Ethics staff validate submission
- HREC considers
- Governance reviews simultaneously

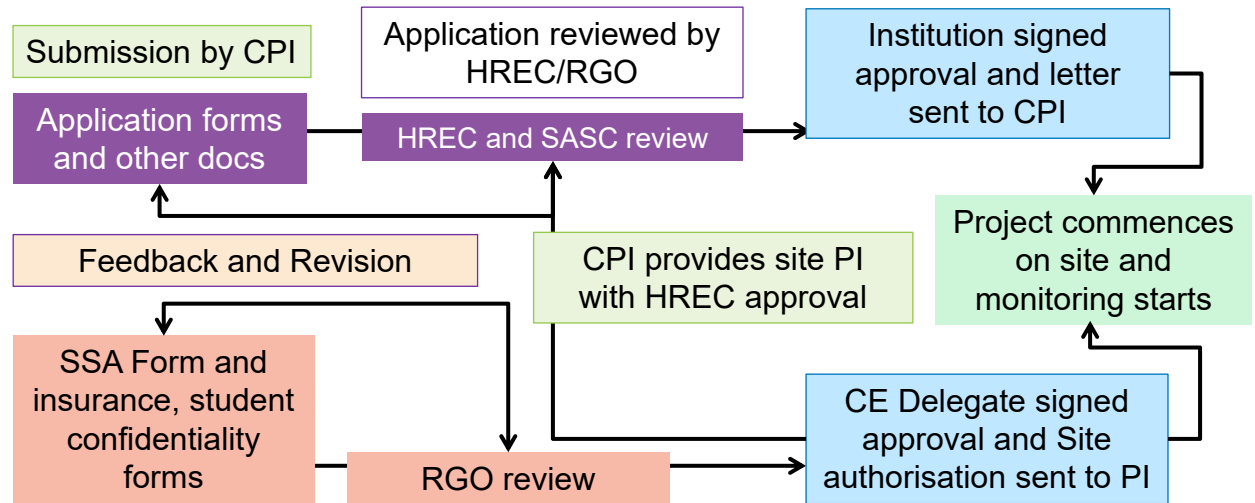
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# CAHS Research Application Review Process\*

\*complete process in handouts

## Ethics Review



## Governance Review

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## General Processes for HREC and Governance

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## HREC (+/- Scientific Advisory Safety Committee)

- May co-opt or access experts
  - Sign confidentiality agreement if attend meetings
- Publish meeting dates on HREC-specific sites
- RGS system has a “stop clock” to monitor process times
- Different HRECs have different time frames
- CAHS HREC meets 11 times per year, HREC submission approx. 2w before SASC
  - SASC review first, then HREC



Meeting dates available online

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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 lay people, one male, one female
    - no affiliation to the institution
    - not engaged in medical, scientific, legal or academic work
  - 1 person with experience in prof care/counselling/Rx
  - 1 pastoral carer + 1 lawyer
  - 2 with current relevant research experience (pool)

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## Scientific Advisory Safety Committee (SASC)

- Members appointed by the Institution – relevant expertise
- Assesses projects prior to HREC meetings
- Reviews scientific integrity
  - Is the research justified – literature review
  - Is the design appropriate to answer the question
  - Is it safe
- Makes recommendations to HREC
  - Approve
  - Conditional approval
  - Not approved

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## Research Governance

- Independent review of applications
- Focus on safety & risk
- Confidentiality agreements
- Budgets – adequacy, industry
- Insurance & indemnity, study agreements
- Use of approved equipment, procedures, drugs
- Conflict of interest
- Investigator/staff qualifications, experience
- Privacy/confidentiality, consent
- Data management
- Intellectual property, copyrights, patents
- Monitoring

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## Research Governance Office



- **Review**
  - Ethics application form
  - Protocol
  - Site forms – Site Specific Assessment or Access Request
  - Questionnaires, pamphlets, advertising material
  - Clinical Trial Research Agreement (CTRA)
  - Clinical Trial Notification (CTN) form – now online
  - Insurance Certificate
- **Correspond with Sponsors**

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## Budgets

- Form/template/signatures within the Research Governance System
- Review, guidelines within the Site Specific Assessment form
- Principal Investigator, Business manager, Divisional Director
- All costs above primary patient care
- For Industry sponsors SASC/HREC/Governance Fees:
  - \$3850 + \$600 per extra site + amendments



**SSA form budget table can NEVER be blank!**

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## 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 – after ethics approval



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## Ethics Amendments

- Go back to next HREC (and/or SASC) meeting
- Use RGS Ethics/Governance Amendments form
- Require
  - Amendment form
  - Amended documents (clean, and with tracked changes)
  - Explanatory notes

**Version control!**

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## HREC + Research Governance Offices

**Staffing - generally small**  
**e.g. 2-3 FTE total**

Duties covered may include:

- Ethics Officer
- Research Governance Officer
- Clinical trials pharmacist
- Compliance officer



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## Key reasons for HREC issues

- Inadequate document preparation
- Language difficult to understand
- Key information missing: information or consent forms
- Poor data protection or practices
- Inadequate statistical input
- Lack of supporting documentation
- Lack of community involvement



"Which brings us to my next point."

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## How best to prepare?

- Start early, allow sufficient time \*supervisors
- Community involvement
- Speak to in-house research support staff:  
Biostats, epi, data manager, ethics, governance, business manager
- Look at successful applications/ talk to successful researchers
- Peer review

***Resubmission means delay of final approvals***

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## Participants

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## Accounting for Recruitment Issues

- Healthy controls: harm vs benefit
- Adequate numbers
- Vulnerable populations
- Coercion of dependents
- Cultural sensitivities
- \*Community involvement



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## 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"

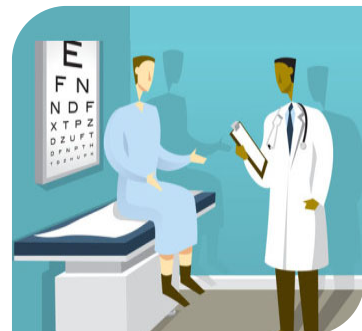
*National Statement on Ethical Conduct in Human Research (2007)*

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## Consent Forms

- WA Health form
- CAHS forms – pre-approved wording included
- NHMRC forms helpful: 3 categories of participants:
  - Individual / Child / unable to provide consent
- Within each category, 4 templates:
  - Genetic Studies
  - Interventional Studies
  - Non-Interventional Studies and
  - Health and Social Science Studies



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## Informed Consent: General Content

- Letter head, Title, Research team, Site, Version number, Date
- Consultation processes
- Use of interpreters
- Mandatory statement: This means you can say no
- Multi-segmental: list activities separately
  - Specific, extended, unspecified (National Statement 2.2.13 p21)
- Permission for recordings, images
- Names, signatures & dates: participant, interpreter, +/- witness

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## Consent Example – multiple options



### CONSENT FORM

#### Petrol Sniffing Recovery: Participant

This form means you can say "No" if you do not want to take part

If you are happy to be in this project, we ask that you agree to the following:

		Tick each box if you agree to:	
		Yes	No
1. Do some movement tests, thinking games on the computer and answer some questions about yourself?			
2. Answer some questions about using different substances like grog and gunga			
3. Allow us to ask some health workers in your community about how your health has been over the last 14 years and if you have been using substance			
4. Allow us to take some blood to look at how petrol sniffing changes your blood			
5. Allow us to access information about you from: (a) health files (b) prison files (c) employment history		a) Yes b) Yes c) Yes	No
6. Allow us to use information that we collect even if you decide to pull out of the study			
7. Allow us to contact you again in the future and see how you are going			

All the information you give us will be kept private. Your name will not appear next to any private information. A number will be used instead. I understand that I do not have to be in the study if I don't want to and I can stop at any stage.

I understand that the ownership of Aboriginal knowledge and cultural heritage is kept by the person telling us the information and this will be acknowledged in research findings and when the research is shown to other people.

Name (print): \_\_\_\_\_  
Signed (participant): \_\_\_\_\_  
Date: \_\_\_\_\_

#### WITNESS

I have described to ..... the nature of the procedures to be carried out. In my opinion she/he understood the explanation.

Status in Project: \_\_\_\_\_  
Name: \_\_\_\_\_  
(signature) (date)

#### INTERPRETER (IF USED):

I ..... have translated the above information explaining the nature of the procedures to be carried out. .... indicated that they understood the explanation.

Interpreter's Name: \_\_\_\_\_  
(signature) (date)

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## Child-Specific Consent Issues



- Evaluate capacity to provide informed consent
- Assess coercion by parents, peers, staff
- Be aware of conflict of interest: parents vs children
- NHMRC guidelines do not provide age cut-offs
- Where appropriate, written consent to participate from when a “mature minor”
  - on the same form as the parent

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## Issues with Consent



- Who has the right to consent?
- Power imbalances? 2.2.9
- Interpreter services
- Time
- Renegotiate Consent 2.2.12
- Withdrawal of consent 2.2.19
- Future consent 2.2.14
- Recording of consent

**NHMRC National Statement provides guidance**

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## Participant Payments

- Must not be disproportionate or will be seen as inducement
- Timing can be important
- Must be documented in the Protocol
- Prior approval essential
- HREC very strict
- “Reimbursement for reasonable costs”  
e.g. travel, time, accommodation, small gift

**Always discuss**

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## Data Management

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## Authorisation to Access Data

- Reviewed at a governance level
- Ensure support from data custodians at each site/database, e.g. Chief Executive or delegate
- Site Specific Assessment Form or
- WA Health Access Request Form



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## Data De-Identification

- Choose an appropriate data capture program  
e.g. REDCap
- Use a unique identifier
- Separate out identifiable variables  
e.g. Name, DOB, Address, image, hospital record number
- For publication or presentation ensure no potentially identifiable individuals or groups

**Identifiable data cannot be stored on a USB/laptops**  
*- easily lost, misplaced, accessed*

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## Data Storage

- Locked facility for hard copies
- Password protected databases
- Limit access to research team
- Storage times – for audit, participants, peer review etc.
  - Adults: usually 5 years post publication
  - Children: at least 15y or until aged 25y
  - Historical data - oral histories – never expire
- Hard copies off site if accessible/infrequently used
- “Transfer to State Records Office” in WA\*



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## “Transfer to State Records Office” in WA

- Full for many years
  - → approved storage facility
- In practice: if in doubt, keep it indefinitely
  - Administrative/ functional records (approval, monitoring, publications) vs
  - Patient or subject research records (data, consent)
- Keep it safe



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# Monitoring and Safety

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## Compliance

**Because ethics approval is prospective...**

- Submit amendments
- Report adverse events
- Submit progress reports – annual, final
- NHMRC: “Safety monitoring & reporting in clinical trials involving therapeutic goods”
- And sometimes - Industry audit, Data safety monitoring boards (DSMBs), Other internal monitoring for high risk studies

**“Filling in a form well does not mean a study will be ethical unless ethical conduct follows”**

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## 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?



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## Adverse Event Reporting

### NHMRC Position Statement:

#### “Monitoring and Reporting of Safety for Clinical Trials”

- Serious Adverse Events
  - within 24h to sponsor,
  - 72h to HREC
- Recommendations made, recorded



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## Feedback

- Participants
- Broader general community
- Scientific community
- Ethics Committee
- Sponsors
- Don't forget in budget



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## 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
- Ethical conduct is prospective!



"Improvement begins with I." *Arnold H. Glasow*

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# Questions? Comments?

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## Upcoming Research Skills Seminars

**19 Nov** **Research Impact** with **Tara McLaren**

**26 Nov** **Qualitative Research Methods** with **Dr Shirley McGough**

**03 Dec** **Innovation and Commercialisation** with **CAHS & TKI**

Register → [researcheducationprogram.eventbrite.com.au](https://researcheducationprogram.eventbrite.com.au)

### We love feedback

A survey is included in the back of your handout or complete online  
via: <https://tinyurl.com/ethicsresearchprocesses>

✉ [ResearchEducationProgram@health.wa.gov.au](mailto:ResearchEducationProgram@health.wa.gov.au) 🌐 [cahs.health.wa.gov.au/ResearchEducationProgram](https://cahs.health.wa.gov.au/ResearchEducationProgram)

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Government of Western Australia  
Child and Adolescent Health Service

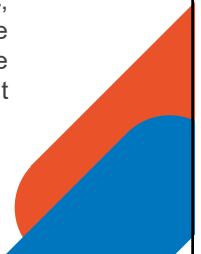


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[Department of Health, Government of Western Australia](#)

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# Ethics Processes for Clinical Research in WA

## RESOURCE NOTES

### CAHS Research Education Program Research Skills Seminar Series

☎ (08) 6456 0514 ✉ [ResearchEducationProgram@health.wa.gov.au](mailto:ResearchEducationProgram@health.wa.gov.au)

🌐 <https://cahs.health.wa.gov.au/ResearchEducationProgram>



Healthy kids, healthy communities

Compassion

Excellence

Collaboration

Accountability

Equity

Respect

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



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## 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](https://www.researchgate.net/publication/242492652)

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. <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research>

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 \(health.wa.gov.au\)](https://health.wa.gov.au/Research-Governance-Policy)

## 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

Refer to section 3.1 (page 42) of WA Health Research Governance Policy and Procedures to determine whether a project falls under the category of quality improvement or research.

<https://ww2.health.wa.gov.au/About-us/Policy-frameworks/Research/Mandatory-requirements/WA-Health-Research-Governance-Policy-and-Procedures>

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	<a href="https://cahs-healthpoint.hdwa.health.wa.gov.au/directory/safetyandquality/geko/Pages/default.aspx">https://cahs-healthpoint.hdwa.health.wa.gov.au/directory/safetyandquality/geko/Pages/default.aspx</a>
EMHS	<a href="https://emhs-healthpoint.hdwa.health.wa.gov.au/directory/SQaCE/innovation-improvement/Pages/GEKO.aspx">https://emhs-healthpoint.hdwa.health.wa.gov.au/directory/SQaCE/innovation-improvement/Pages/GEKO.aspx</a>
NMHS	<a href="https://nmhs-healthpoint.hdwa.health.wa.gov.au/directory/SQandG/Pages/Quality-Improvement-Projects-and-Initiatives.aspx">https://nmhs-healthpoint.hdwa.health.wa.gov.au/directory/SQandG/Pages/Quality-Improvement-Projects-and-Initiatives.aspx</a>
SMHS	<a href="https://smhs-healthpoint.hdwa.health.wa.gov.au/directory/SQaCE/IPCPI/Pages/default.aspx">https://smhs-healthpoint.hdwa.health.wa.gov.au/directory/SQaCE/IPCPI/Pages/default.aspx</a>
WNHS	<a href="https://wnhs-healthpoint.hdwa.health.wa.gov.au/directory/CES/SQP/QualityImprovementAndAudit/Pages/GEKO-Database.aspx">https://wnhs-healthpoint.hdwa.health.wa.gov.au/directory/CES/SQP/QualityImprovementAndAudit/Pages/GEKO-Database.aspx</a>
HSS/ICT Support	<a href="https://hss-healthpoint.hdwa.health.wa.gov.au/business-at-health/ICT-servicedelivery-and-operations/geko/Pages/default.aspx">https://hss-healthpoint.hdwa.health.wa.gov.au/business-at-health/ICT-servicedelivery-and-operations/geko/Pages/default.aspx</a>

## 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.

NHMRC Statement on Ethical Conduct in Human Research, 2007 (Updated May 2015)

### 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: <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 three 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 – updated May 2015  
<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>
- 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://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](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 15) <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 “Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research” 2003; <https://www.nhmrc.gov.au/about-us/publications/values-and-ethics-guidelines-ethical-conduct-aboriginal-and-torres-strait-islander-health-research>

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 <https://www.nhmrc.gov.au/about-us/publications/challenging-ethical-issues-contemporary-research>

Universal Declaration on Bioethics and Human Rights UNESCO 2005  
<http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/>

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 1st 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/c6gg>

### 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://ww2.health.wa.gov.au/Articles/A\\_E/Department-of-Health-Human-Research-Ethics-Committee](https://ww2.health.wa.gov.au/Articles/A_E/Department-of-Health-Human-Research-Ethics-Committee)

#### 13.1. Research Development Unit

[https://ww2.health.wa.gov.au/Articles/N\\_R/Research-Development-Unit](https://ww2.health.wa.gov.au/Articles/N_R/Research-Development-Unit) Email:  
CMOResearchDevelopment@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](mailto:CAHS.Ethics@health.wa.gov.au)



The Ethics 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>

13.4. **Sir Charles Gairdner Hospital Research**

<https://www.scgh.health.wa.gov.au/Research/Department-of-Research>

13.5. **South Metropolitan Health Service/Fiona Stanley Hospital**

- <https://ww2.health.wa.gov.au/About-us/South-Metropolitan-Health-Service/Involving-our-community/Human-Research-Ethics-and-Governance>
- <https://www.fsh.health.wa.gov.au/Research/Research-contacts>
- <https://www.fsh.health.wa.gov.au/Research/Research-governance>

## **WA Private HREC**

13.6. **St John of God HREC**

<https://www.sjog.org.au/research/human-research-ethics-committee>

13.7. **Joondalup HREC**

<https://www.joondalupprivate.com.au/About-Us/Research>

## **WA Universities HREC**

13.8. **UWA HREC**

<http://www.governance.uwa.edu.au/committees/other/human-research-ethics>

13.9. **Notre Dame HREC**

<https://www.notredame.edu.au/research/research-at-notre-dame/ethics-and-integrity/hre/hrec>

13.10. **Curtin University HREC**

<https://research.curtin.edu.au/standards/human/>

13.11. **Edith Cowan University HREC**

<https://www.ecu.edu.au/centres/research-services/our-services/ethics-and-research>



### 13.12. Murdoch University HREC

<http://our.murdoch.edu.au/Research-Ethics-and-Integrity/Human-research-ethics/> <http://our.murdoch.edu.au/Research-Ethics-and-Integrity/Human-research-ethics/Committee/>

## 14. GOOD CLINICAL PRACTICE TRAINING

### Global Health Trials

#### ICH Good Clinical Practice E6 (R2)

<https://globalhealthtrials.tghn.org/elearning/>  
<https://globalhealthtrainingcentre.tghn.org/elearning/short-courses/>

“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

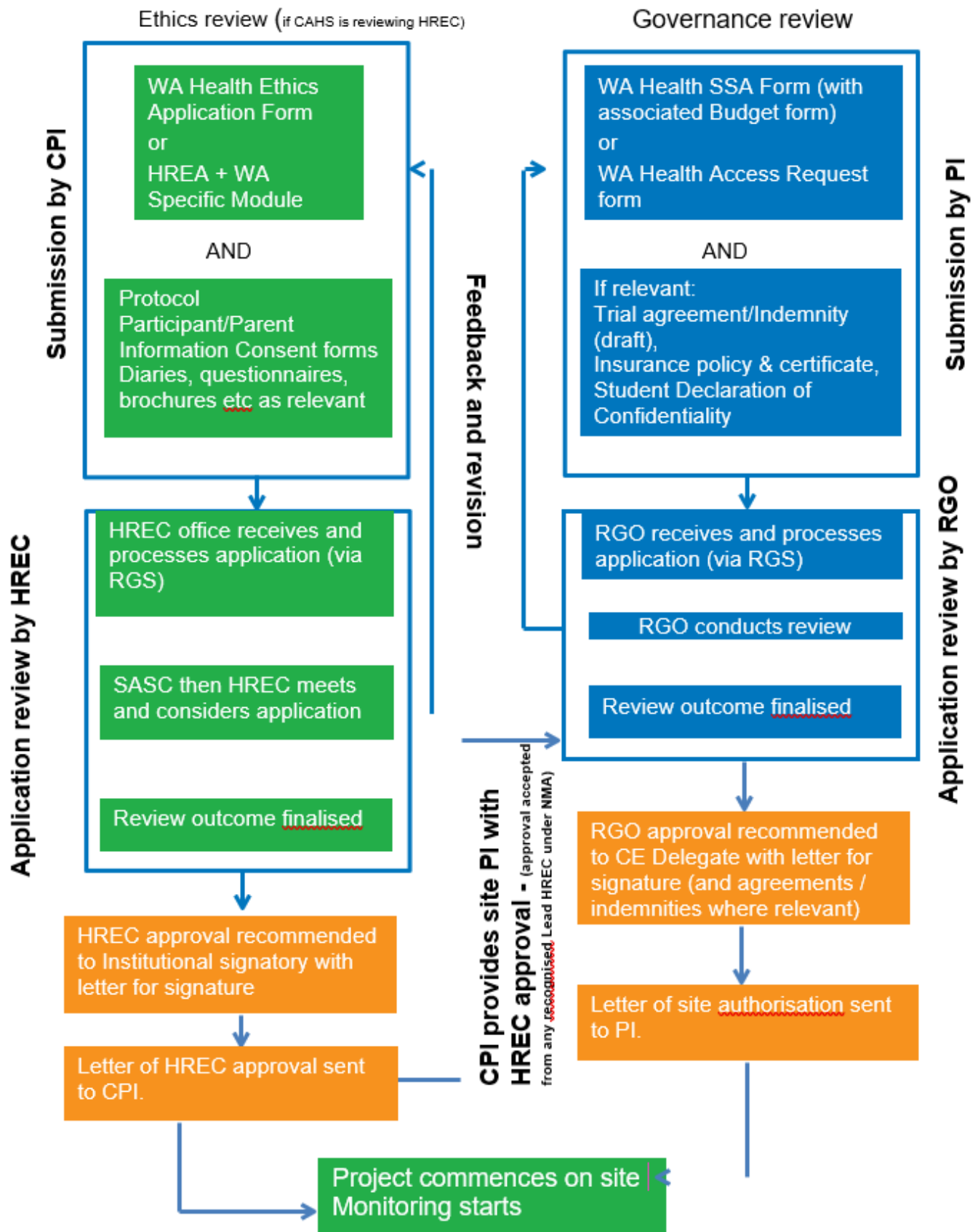
<https://retprogram.org/portfolio-item/ich-good-clinical-practice-gcp-e6-r2/>

### ARCS Australia

“The Association of Regulatory and Clinical Scientists to the Australian Pharmaceutical Industry”

<https://www.arcs.com.au/events/category/online-learning>

## 15.CAHS Research Application Review Process





# CAHS Research Education Program

## Research Skills Seminars Series 2021

# RESEARCH IMPACT

Friday 19th November 2021 | 12:30pm – 1:30pm | Perth Children's Hospital

There is an increasing requirement for researchers to demonstrate the impacts of their research to funders, stakeholders and to the community.

This seminar will provide an overview of research impact, showcasing recently published AAMRI Research Impact Framework. The session will also provide an overview of the requirements of impact statement for an NHMRC Investigator or Synergy grant.

### About the Presenter

#### Tara McLaren

After completing a Bachelor of Psychology at UWA, Tara lived in the UK for nine years where she re-trained as a Primary Teacher, working in both the government and private school systems. Since her return to Australia in 2005, Tara has worked in the Higher Education sector across a number of roles including: Research Development Advisor, Communications Manager, General Manager, Marketing Manager, and most recently as Manager of Impact and Engagement at TKI. Tara has a particular interest in supporting researchers secure research funding and to translate their research into outcomes that benefit the community.



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**Level 5, 15 Hospital Ave Nedlands**  
Accessible via **pink** or **yellow** lifts

- OR -

Access online via  
[Avaya Workplace](#)

- OR -

Watch live from a hosted  
video-conferencing site at

- Fiona Stanley Hospital
- Lions Eye Institute
- Royal Perth Hospital

[Click here to register online](#)

or visit

[https://20211119nd.  
eventbrite.com.au](https://20211119nd.eventbrite.com.au)

### Discover

To watch past seminar recordings, download presentation material or subscribe to our event notification newsletter, visit:

[cahs.health.wa.gov.au/ResearchEducationProgram](https://cahs.health.wa.gov.au/ResearchEducationProgram)

### Contact

Phone (08) 6456 0514

Email [researcheducationprogram@health.wa.gov.au](mailto:researcheducationprogram@health.wa.gov.au)

Intranet [cahs-healthpoint.hdwa.health.wa.gov.au](https://cahs-healthpoint.hdwa.health.wa.gov.au)





# CAHS Research Education Program

## Research Skills Seminars Series 2021

# QUALITATIVE RESEARCH METHODS

**26th November 2021 | 12:30pm – 1:30pm | Perth Children's Hospital**

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 research prepares to use qualitative research to improve health outcomes for individuals, families and communities.

### About the Presenter

#### Dr Shirley McGough

Shirley is a Lecturer at the School of Nursing, Midwifery and Paramedicine, Curtin University. She has a wide range of experience conducting health research in the area of mental health using a mix of research designs. She is a registered nurse and a credentialed mental health nurse.



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**Level 5, 15 Hospital Ave Nedlands**

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- OR -

**Access online via**  
[Avaya Workplace](#)

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# CAHS Research Education Program

## Research Skills Seminars Series 2021

# INNOVATION & COMMERCIALISATION

**3rd December 2021 | 12:30pm – 1:30pm | Perth Children's Hospital**

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.



### About the Presenters

#### Richard Macliver

Richard is the Innovation lead at CAHS. He utilises his skills in human-centered design, communication, and health technology development to understand complex problems and design solutions that improve the experience and outcomes of clinicians and patients.

#### Ashley Schoof

As the Commercialisation Officer at the Telethon Kids Institute, 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.

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**Perth Children's Hospital**  
**Level 5, 15 Hospital Ave Nedlands**  
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# 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.

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INTERACTIVE IN PDF MODE

## 2021 Seminar Schedule

Updated 9 November 2021

Date	Topic	Presenter	Attend in person or online	Watch most recent recording
Feb 5	<b>Research Fundamentals</b>	A/Prof Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Feb 19	<b>Scientific Writing</b>	A/Prof Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Mar 12	<b>Introduction to Good Clinical Practice</b>	Natalie Barber	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Mar 19	<b>Research Governance</b>	A/Prof Sunalene Devadason	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Apr 30	<b>Using Social Media in Research</b>	Dr Kenneth Lee	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
May 7	<b>Using REDCap</b>	TKI Biometrics Team	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
May 14	<b>Survey Design and Techniques</b>	A/Prof Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
May 28	<b>Getting the most out of Research Supervision</b>	Prof Jonathan Carapetis AM	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Jun 18	<b>Introductory Biostatistics</b>	Dr Julie Marsh	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Jun 25	<b>Sample Size Calculations</b>	Dr Julie Marsh	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Jul 23	<b>Data Collection and Management</b>	A/Prof Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Jul 30	<b>Consumer and Community Involvement</b>	Anne McKenzie AM	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Aug 6	<b>Knowledge Translation</b>	Dr Fenella Gill	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Aug 13	<b>Media and Communications in Research</b>	Elizabeth Chester	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Aug 27	<b>Oral Presentation of Research Results</b>	A/Prof Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Sep 10	<b>Conducting Systematic Reviews</b>	Prof Sonya Girdler	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Sep 17	<b>Involving the Aboriginal Community in Research</b>	Glenn Pearson & Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Oct 22	<b>Statistical Tips for Interpreting Scientific Claims</b>	Dr Julie Marsh	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Oct 29	<b>Rapid Critical Appraisal of Scientific Literature</b>	A/Prof Sue Skull	CANCELLED	<a href="#">WATCH</a>
Nov 5	<b>Grant Applications and Finding Funding</b>	Tegan McNab	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Nov 12	<b>Ethics Processes for Clinical Research in WA</b>	A/Prof Sue Skull	CANCELLED	<a href="#">WATCH</a>
Nov 19	<b>Research Impact</b> <i>*New date (formerly 12Nov)</i>	Tara McLaren	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Nov 26	<b>Qualitative Research Methods</b>	Dr Shirley McGough	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
Dec 3	<b>Innovation and Commercialisation</b> <i>*New in 2021</i>	REP & Telethon Kids Institute	<a href="#">REGISTER</a>	

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Interactive in pdf format  
Last updated 26Oct21

### 2022 Seminar Schedule

	Date	Topic	Presenter	Enrol	2021 recording
1	04 Feb	Research Fundamentals	A/Prof Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
2	18 Feb	Scientific Writing	A/Prof Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
3	11 Mar	Introduction to Good Clinical Practice	Natalie Barber	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
4	18 Mar	Research Governance	Katherine Coltrona	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
5	25 Mar	Project Management	Tara McLaren	<a href="#">REGISTER</a>	<i>*New in 2022</i>
6	08 Apr	Rapid Critical Appraisal of Scientific Literature	A/Prof Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
7	29 Apr	Social Media in Research	Dr Kenneth Lee	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
8	06 May	REDCap for Data Capture & Management	Ali Hollingsworth & Raskshya Khadka	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
9	13 May	Survey Design & Techniques	A/Prof Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
10	27 May	Getting the most out of Research Supervision	Prof Jonathan Carapetis AM	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
11	17 Jun	Introductory Biostatistics	Michael Dymock	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
12	24 Jun	Sample Size Calculations	Michael Dymock	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
13	22 Jul	Knowledge Translation	A/Prof Fenella Gill	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
14	29 Jul	Consumer & Community Involvement in Research	Belinda Frank	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
15	05 Aug	Data Collection and Management	A/Prof Sue Skull & Rad Aniba	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
16	12 Aug	Media & Communications in Research	Elizabeth Chester	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
17	26 Aug	Oral Presentation of Research Results	A/Prof Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
18	09 Sep	Conducting Systematic Reviews	Prof Sonya Girdler	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
19	16 Sep	Involving Aboriginal Communities in Research	Glenn Pearson & Dr Brad Farrant	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
20	21 Oct	Grant Applications and Finding Funding	Tegan McNab	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
21	28 Oct	Statistical Tips for Interpreting Scientific Claims	Michael Dymock	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
22	04 Nov	Innovation & Commercialisation	Richard MacIver & Ashley Schoof	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
23	11 Nov	Research Impact	Tara McLaren	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
24	18 Nov	Ethics Processes for Clinical Research in WA	A/Prof Sue Skull	<a href="#">REGISTER</a>	<a href="#">WATCH</a>
25	25 Nov	Qualitative Research Methods	Dr Shirley McGough	<a href="#">REGISTER</a>	<a href="#">WATCH</a>

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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. FSH, Lions Eye, RPH etc.)
- ☐ Online via Scopia
- ☐ 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		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The session was well structured		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Presentation style retained my interest		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The speaker communicated clearly		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The material extended my knowledge		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The additional resources were helpful		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

### 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!



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**Healthy kids, healthy communities**

Compassion

Excellence

Collaboration

Accountability

Equity

Respect

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