

# CAHS Research Education Program Research Skills Seminar

# Research Governance

19th April 2024



Presented by

**Dr Natalie Giles**Manager Ethics and Compliance,
CAHS





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Child and Adolescent Health Service, Department of Research

Department of Health, Government of Western Australia

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# Research Governance

# **PRESENTATION SLIDES**



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.

# Research Skills Seminar Series

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

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Use provided microphone

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# What is research governance and why is it necessary?

Research Governance is "a process used by an organisation for the oversight, assessment, authorisation and monitoring of research conducted at one or more of its sites or under its auspices."

NHMRC Good Practice Process for Site Assessment and Authorisation Phases of Clinical Trial Research Governance, 2016

# Research Governance = Ethics + Governance

### Relationship between research ethics and governance

Research governance consists of both ethical and governance components in the approval and monitoring of research. Previously research governance (both ethics and governance) was a responsibility of a Human Research Ethics Committee (HREC). With the introduction of the NHMRC's single ethical review scheme (SER), it is now an institutional responsibility, with a HREC responsible for ethics, and institutional Research Governance/Integrity Office (RG Office) responsible for governance.



Ethics & Governance can be separate (e.g. public/private health service) or combined (e.g. university).

Institutions must ensure both the ethical and governance elements of research governance are considered when undertaking a review of proposed research projects, or monitoring of authorised projects at their site(s).

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### Role of the HREC

### **Human Research Ethics Committee**

- Research Merit and Integrity
- Justice
- Beneficence
- Respect



# Good Clinical Practice (GCP) is a component of Research Governance

GCP is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials. Compliance with this standard provides public assurance that the data and reported results are credible and accurate, and that the rights, safety, well-being, integrity, and confidentiality of trial participants are protected. These are consistent with the principles that have their origin in the Declaration of Helsinki.

(International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice E6 R2, November 2016 [ICH GCP])



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### Research Governance

What risks are being considering?



- Risk to the Institution
- Risk to the Participants
- Risk to the Researchers at the Institution

# Legislation, Policies, Principles & Guidelines

- WA Health Research Governance Policy and Procedures 2021
- WA Health Research Governance and Single Ethical Review SOP 2013
- Health Services Act 2016
- · WA Health System Information Register
- WA Health Consent to Treatment Policy 2023
- · Information Access, Use and Disclosure Policy
- Information Security Policy
- · Information Breach Policy
- Patient Information Retention and Disposal Schedule (PIRDS)
- WA University Sector Disposal Authority (WAUSDA)
- Cloud Policy

- CAHS Research Policy Framework
- CAHS Research Policy Framework Investigator Responsibilities
- CAHS Standard Operating Procedures for the Approval of Research (2023)
- National Statement on the Ethical Conduct in Human Research (2023)
- Australian Code for the Responsible Conduct of Research, 2018
- · Section 95 and 95A of the Privacy Act 1988
- · Section 95A of the Privacy Act 1988
- · Privacy Act 1988

Note: The 1988 Privacy Act is a Commonwealth Act that WA did not ratify; so it is not applicable in WA. WA is guided by the Privacy act but follows Information Access, Use and Disclosure Policy

# Declaration of Confidentiality Conflicts of Interest

When is a Declaration of Confidentiality required?

Which "Hat" are you wearing when conducting this research project?

What is the difference between a WA Health Declaration of Confidentiality and a "Student Research and Confidentiality Declaration"

# What constitutes a Conflict of Interest?

A "**conflict of interest**" is a situation arising from a potential clash between the

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performance of a public duty and private personal interest. Conflicts of interest may be actual, perceived to exist, or potentially exist at some time in the future. Whilst it is not always possible to avoid a conflict of interest, appropriately identifying and dealing with the situation can mitigate any potential problems.

CAHS HealthPoint - Conflict of Interest (health.wa.gov.au)

# Understanding the roles of investigators

Coordinating
Principal
Investigator (CPI or CI)

- An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre project.
- Takes overall responsibility for liaising with the HREC, and conduct and monitoring of the project for all sites under the HREC approval.

Principal Investigator (PI)

- An investigator responsible for the conduct of the project at a site and for adequately supervising their research team
- Responsible for liaising with the site Research Governance Office.

Associate Investigators (AI)

 An investigator supervised by the PI, and provides some intellectual and/or practical input into the research and whose participation may warrant inclusion of their name on any publications.

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# Who is the Sponsor of the Project?

### Sponsor or Contract Research Organisation (CRO):

An individual (e.g. private clinician), company, institution (e.g. hospital), or organisation (e.g. university) which takes responsibility for the initiation, management, and/or financing of a clinical trial (ICH GCP Guideline, 2016) and carries the medico-legal responsibility associated with its conduct (TGA, 2018).



The type of Sponsor will vary for each project/trial, depending on who takes the overall responsibility for the conduct of the project/trial. The TGA requires an 'Australian' Sponsor.

In investigator-initiated or non-commercial projects, the investigator/institution takes on the responsibilities of the Sponsor (TGA 2016). As such, Investigators should ensure they are aware of their sponsor responsibilities in addition to their investigator responsibilities.

# Types of Research Sponsors

Research Agreements, Insurance and Indemnity will be based on the type of Research Sponsor and type of research (e.g., clinical trial vs non-clinical trial)



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# Therapeutic Goods Administration

## **Clinical Trial Notification**



Clinical Trials Notification (CTN) vs Clinical Trials Approval (CTA) schemes

Clinical trials: the TGA online Clinical Trial Notification (CTN) for supply of TGA 'unapproved' therapeutic goods (e.g. placebo, unapproved use or dosage).

Sponsor responsible for application and paying CTN fee.

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# Governance resource and recruitment requirements

- Resources
  - o Appropriate facilities, infrastructure, staffing and training
  - o Departmental approvals e.g. clinical department, pharmacy, medical records, pathology, imaging etc
  - o Sufficient time to conduct the project
- · Participants Recruitment & Data/Biospecimens
  - o Appropriate suitable participants and the potential to recruit required numbers
    - o How are they recruited?
    - o Who will be making the initial contact?
    - o How do you have access to these participants?
  - Ability and approvals to access data collections or biospecimens
  - o PathWest Facilities and/or samples will PathWest be a site or a supporting department?

As these site requirements vary, assessment falls within the governance review (not ethics)

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# **Participants**



- How has the potential participant been identified?
- Who will make the initial approach, how and where?
- Where will the patient study assessment occur?



- Have all the participant facing documents been submitted?
  - PICFs
  - Email templates
  - SMS templates
  - Phone contact scripts
  - Flyers
  - Diaries
  - Questionnaires
  - Contact cards

# Master and Site Specific Participant Facing Documents

### Single site documents

- Approved by the HREC and already include:
  - · Correct branding
  - Site listed and referenced throughout the document
  - Site contacts listed including complaints contact in the PICFs

### Master documents for multi-sites

- · Approved by the Lead HREC
- Placeholders for site information
  - · Branding; Site name; Site contacts

# Site-specific documents based on a Master

- · Update all placeholders
- Add any site-specific requirements
- Include the contact for general information as well as a complaint at the site
- Tracked and clean copy

### **Version Control**

Example: PCH Parent/Guardian PICF v1 dated 29/2/2024 based on Master Parent/Guardian PICF v3 dated 15/12/2023

# **Data Management**

- How will participant research data be recorded?
- Is there a Data Custodian to be consulted?
  - In what format will the data be recorded and stored?
- If re-identifiable, where will the master patient contact list be kept and who will have access to it?

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- Where will data be stored and who will have access?
- How long do I store the data?

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# Research agreements

Understanding which agreement is required can be complex!



- Medicines Australia and Medical Technology Association of Australia have standard clinical trial research agreements (CTRA) for commercial and collaborative sponsors.
  - WA Health has pre-approved templates available on RGS which include WA Health special conditions

Data Transfer Agreement? Service Agreement? Material Transfer Agreement?

Contact the RG Office to see if an agreement is required, and which template to use

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# Indemnity

### Commercial sponsored projects (usually clinical trials):

- Sponsor provides indemnity for site staff conducting project, participants and the HREC review.
- Medicines Australia (MA) Form of Indemnity for Clinical Trials (drug)
  - > Participants covered by MA Compensation Guidelines
- Medical Technology Association of Australia (MTAA)
   Standard Indemnity Form for a Clinical Investigation (device)
  - ➤ Participants covered by MTAA Compensation Guidelines
- Institution covers liabilities of employees' negligence only (e.g. Private organisations insurer, Insurance Commission of WA)

### Non-commercial sponsored projects:

- Each party liable for its acts and omissions, sometimes bespoke terms.
- Each party maintains insurance necessary to provide indemnity to it in relation to any liability (e.g. Private organisation, Insurance Commission of WA)



### Insurance

- Agreements require the sponsor/CRO to provide an insurance Certificate of Currency (CoC) or full insurance policy to demonstrate their ability to meet their liability obligations.
- Insurance CoC can be project or organisation specific, often renewed annually.
- Clinical Trials require clinical trial, product and public liability cover, and claims made basis.
- Commercial insurance requirements in CTRA/CIRA Schedule 4:
  - o Public Liability AUD \$5Mill
  - o Clinical Trial/product Liability \$10Mill
- WA Health requires: insurer approved by Australian Prudential Regulation Authority (APRA) or overseas insurer with A- or better rating.
- Reviewed by RG to ensure the insurance will meet any liabilities.
   Annual updated insurance policies should be provided, reviewed and approved by RG.

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# Research budgets

The Detailed Budget should be:

- Accurate –best estimate of all research activity costs and funding, including those provided inkind (whose going to absorb these costs?)
- Transparent –line item representation of all protocol activity/procedural costs, against equivalent funding in agreements (e.g. grant, research agreement) or provided by an institution
- Justifiable –based on salaries/oncosts, departmental quotes, Medicare Benefits Schedule, ethics/governance review fees, and overhead charges.

Don't just accept sponsor's estimates of costs

### **HELP**

- RG or Finance provide assistance & research budget templates.
- Research Budget Templates available from:
  - WA Health RGS
  - Private organisation finance department

### **RGS Research Budget Template**

| Procedures                     | (bas | per item<br>ed on Time<br>Salary) | Screening | Со | st       | Week 0 | Cos | t      | Week 2 | Co: | st     |
|--------------------------------|------|-----------------------------------|-----------|----|----------|--------|-----|--------|--------|-----|--------|
| Informed consent               | \$   | 214.30                            | 1         | \$ | 214.30   |        | \$  | -      |        | \$  | -      |
| Vital signs                    | \$   | 57.71                             | 1         | \$ | 57.71    | 1      | \$  | 57.71  | 1      | \$  | 57.71  |
| Medical history                | \$   | 274.76                            | 1         | \$ | 274.76   | 1      | \$  | 274.76 |        | \$  | -      |
| Physical exam                  | \$   | 214.30                            | 1         | \$ | 214.30   | 1      | \$  | 214.30 |        | \$  | -      |
| ECG                            | \$   | 156.59                            | 1         | \$ | 156.59   | 1      | \$  | 156.59 |        | \$  |        |
| Adverse event monitoring       | \$   | 233.59                            |           | \$ |          |        | \$  |        |        | \$  |        |
| Blood draw                     | \$   | 214.30                            | 1         | \$ | 214.30   | 0      | \$  | -      | 1      | \$  | 214.30 |
| Questionnaire                  | \$   | 57.71                             |           | \$ | -        | 1      | \$  | 57.71  | 1      | \$  | 57.71  |
| Data entry                     | \$   | 57.71                             |           | \$ | -        | 1      | \$  | 57.71  |        | \$  | -      |
| Subtotal                       | \$   | 1,480.96                          |           | \$ | 1,131.95 |        | \$  | 818.77 |        | \$  | 329.72 |
| Unscheduled Procedures         |      |                                   |           |    |          |        |     |        |        |     |        |
| Unscheduled visit              | \$   | 332.47                            |           |    |          |        |     |        |        |     |        |
| Early withdrawal from treatmen | \$   | 662.18                            |           | П  |          |        |     |        |        |     |        |
| 12 Week Safety - week 6        | \$   | 118.17                            |           | П  |          |        |     |        |        |     |        |
| Week 12/ early termination     | \$   | 546.77                            |           | П  |          |        |     |        |        |     |        |
| Unscheduled visit              | \$   | 274.76                            |           | П  |          |        |     |        |        |     |        |
| Subtotal                       | \$   | 1,934.35                          |           |    |          |        |     |        |        |     |        |
| TOTAL                          | \$   | 3,415.31                          |           |    |          |        |     |        |        |     |        |

# Monitoring – Post Approval

**The purpose of monitoring** is to undertake an on-going routine assessment of the project to verify the:

- · rights and well-being of participants are protected
- · reported data is accurate, complete, and verifiable from source documents
- conduct of the research project complies with the currently approved protocol/amendments, GCP, and applicable regulatory requirements (e.g. HREC, TGA) (NS 5.5, ICH GCP 5.18.1)



- Submit to HREC, institution Progress Report annually, or more frequently
- Submit Site & Final Reports at project closure

**Amendments** 

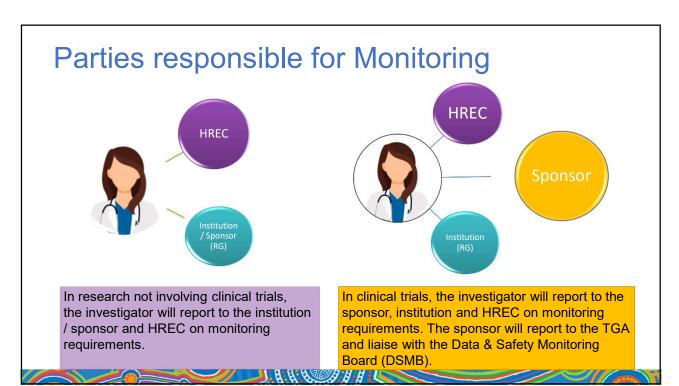
· Submit to HREC, institution any amendments to the protocol or documents

Deviation / Serious Breaches

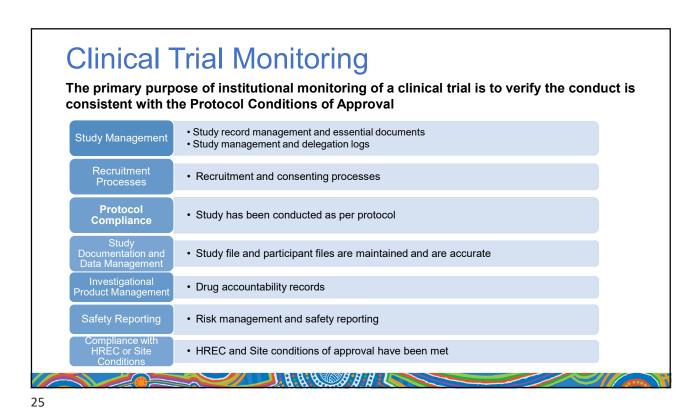
 Report all deviations to the sponsor. Report serious breaches to sponsor, HREC, institution within 72 hours (of event awareness)

Safety Reporting

· To Sponsor, HREC, Institution (RG) as per NHMRC guidelines



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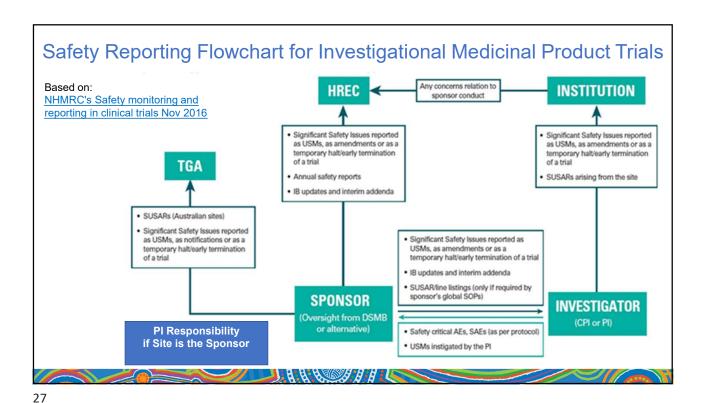
# Study Master File

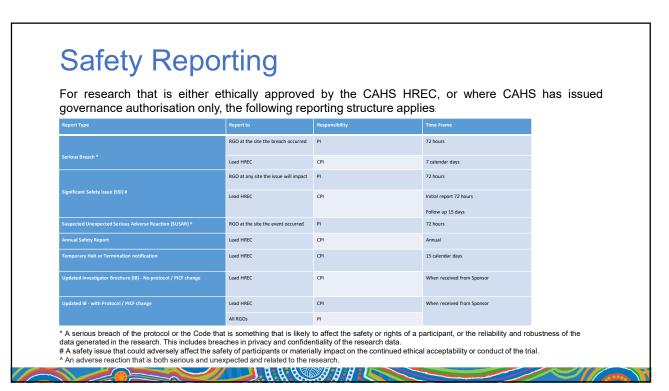
Guidance documents and templates and available on the CAHS
Research Intranet and Internet pages

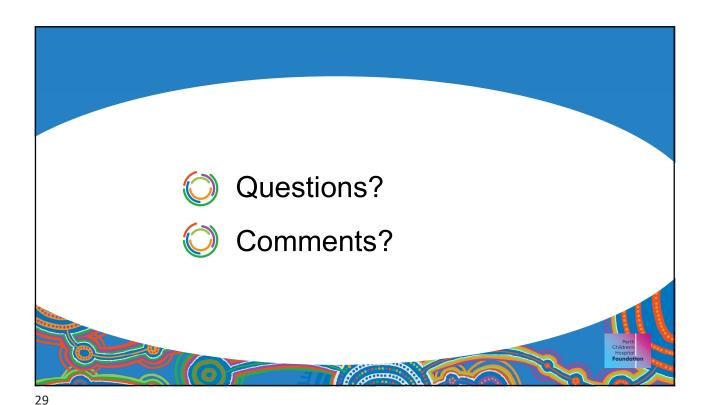
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- SMF table of contents guide
- Study Start Checklist
- · Signature and Delegation Log
- · Screening Log
- Enrolment Log
- · Eligibility Checklist
- Study Training Log

- Study Meeting Minutes Template
- HREC Self Audit Checklist
- · Note to File Guidance
- Central Non-Compliance Log
- Site Non-Compliance Log
- Data and Safety Monitoring Board (DSMB Charter Template











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# Research Governance



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# 1. Policy, Procedures and Guidelines

### 1.1. International and National

| Organisation  | Document Name and Link  |
|---|---|
| World Health<br>Organisation  | WHO and Council for International Organisations of Medical Sciences (CIOMS), International Ethical Guidelines for Health-related Research Involving Humans, November 2016   |
| International Council for<br>Harmonisation of<br>Technical Requirements<br>for Pharmaceuticals for<br>Human Use (ICH) | Integrated Addendum to ICH E6(R1): Guideline for Good Clinical     Practice ICH E6(R2), 2016 (ICH GCP)  |
| Australian Government   | <ul> <li>Australian Privacy Principles Guidelines, 1988 based on Privacy Act 1988 (Cth)</li> <li>Embryo Research Licensing Legislation</li> <li>Office of the Gene Technology Regulator</li> </ul>  |
| National Health and Medical Research Council (NHMRC)  | <ul> <li>National Statement on Ethical Conduct in Human Research, 2023 (National Statement)</li> <li>Australian Code for the Responsible Conduct of Research, 2018 (Code)</li> <li>Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders, 2018</li> <li>Keeping research on track II 2018</li> <li>Guidelines under Section 95 of the Privacy Act 1988, 2014</li> <li>Guidelines approved under Section 95A of the Privacy Act 1988, 2014</li> <li>Use and disclosure of genetic information to a patient's genetic relatives under Section 95AA of the Privacy Act 1988, 2014</li> <li>Research Governance Handbook, 2011</li> <li>Good Practice Process, 2016</li> <li>Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods, 2016</li> <li>Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods, 2018</li> </ul> |

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ResearchEducationProgram@health.wa.gov.au





|   | • | Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods, 2018  Data Safety Monitoring Boards (DSMBs), 2018  Competencies for Australian Academic Clinical Trialists, 2018   |
|---|---|--|
| Therapeutic Goods Administration (TGA)                              | • | Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice (ICH GCP E6 (R2) - Annotated with TGA comments, 2016  Australian clinical trial handbook: Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods, 2018  Clinical Evidence Guidelines, Medical Devices, 2017  Note for guidance on clinical safety data management: definitions and standards for expedited reporting (CPMP/ICH/377/95-Annotated with TGA comments), 2000  ISO 14155: Clinical investigation of medical devices for human subjects – Good clinical practice, 2020)  Australian Clinical Trials website |
| Australian Commission on Safety and Quality in Health Care (ACSQHC) | • | The National Clinical Trials Governance Framework, 2020  |
| Medicines Australia   | • | Clinical Trials – Clinical Trial Research Agreements and Indemnity Form and compensation guidelines templates  |

### 1.2. WA Health - (includes Department of Health & Health Service Providers - HSPs)

| Organisation | Document Name and Link   |
|--------------|--|
| Policies     | <ul> <li>WA Health Research Governance Policy</li> <li>WA Health Intellectual Property Policy</li> <li>WA Health Research Governance Framework</li> <li>WA Government Working with Children Check</li> </ul> |
| Procedure    | <ul> <li>WA Health Research Governance Procedure</li> <li>CAHS Standard Operating Procedures for the Approval of Research 2023</li> </ul>  |
| Guidelines   | <ul> <li>Research Governance Service (RGS) – Research Information, Templates,         Training Resources, Contacts     </li> <li>WA Specific Information on impaired consent in adults</li> </ul>            |

CAHS Research Education Program Research Skills Seminar Series

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



### 1.3 State/Territory Frameworks and Guidelines

Each Australian State and Territory government has Research Policy Frameworks and Good Clinical Practice related guidance specific to their jurisdictional legislation and policies. If investigators are conducting research in any of these jurisdictions, they are expected to understand and comply with all applicable local and national regulations. Click on the links for guidance or contact relevant jurisdictional Research Offices:

- **Australian Capital Territory**
- New South Wales
- Northern Territory
- Queensland
- South Australia
- Tasmania
- Victoria
- Western Australia

# 2. Contact for WA Ethics and Research Governance Offices

Each State/Territory will have specific research governance policies and legislation that must be complied with if conducting research at public health organisations, private organisations, universities, medical research institutes or not for profits within their jurisdiction. Researchers should contact the relevant ethics and/or RG Office for guidance prior to commencing the ethics and governance processes.

#### 2.1. WA Health

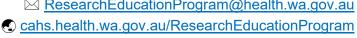
Links to Ethics/RG Offices are on RGS at https://rgs.health.wa.gov.au/Pages/Contacts.aspx

In addition, links are provided below to the Research related websites:

- Child and Adolescent Health Service
- Department of Health
- East Metropolitan Health Service
- North Metropolitan Health Service
- North Metropolitan Health Service, Mental Health
- South Metropolitan Health Service
- Women and Newborn Health Service
- WA Country Health Service



☑ ResearchEducationProgram@health.wa.gov.au





### 2.2. Private, University & Not for Profit

Links are provided below to the Research related websites:

| Private Health Organisation | St John of God Health Care             |
|-----------------------------|--|
| Private Health Organisation | Ramsay Health Care                     |
| University                  | <u>Curtin University</u>               |
| University                  | Edith Cowan University                 |
| University                  | Murdoch University                     |
| University                  | The University of Notre Dame Australia |
| University                  | The University of Western Australia    |
| Not for Profit              | Telethon Kids Institute                |
| Not for Profit              | Silver Chain Group                     |
| Not for Profit              | Aboriginal Health Council of WA        |
| Government                  | Office of the State Coroner            |

### 2.3. Research governance IT systems

Most Australian public health organisations have a web-portal research governance IT system which must be used to manage the ethics and governance processes for all human research projects within their jurisdictions. These IT systems allow for the online completion and submission of ethics and research governance application\* forms and documents to the relevant HREC and RG Offices. In addition, these systems allow researchers, sponsors, HRECs and RG Offices to manage, track and report on the governance of research though the review and approval processes.

\*Note: The RGS manages research governance through the whole project lifecycle, including monitoring, complaints, and publications. Researchers can upload GCP training certification to their profile to inform the research governance review process.

### These IT systems include:

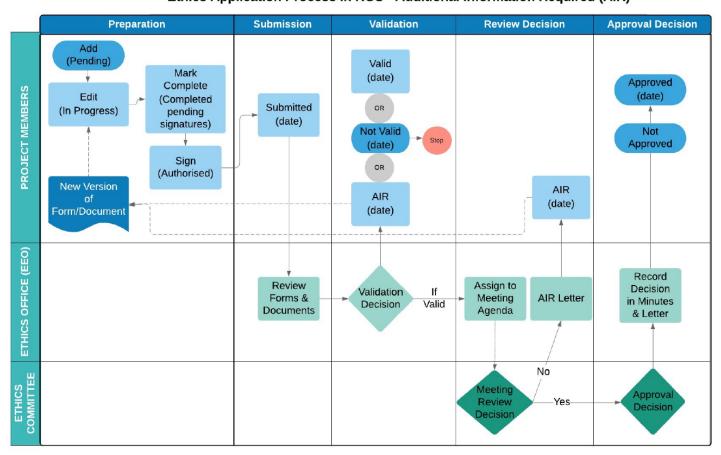
- Research Governance Service (RGS) WA.
- Research Ethics and Governance Information System (REGIS) ACT and NSW
- Ethics Review Manager (ERM) Queensland, Victoria and Mater
- Research GEMS- South Australia



# 3. Ethics and Governance Review Pathways

### WA Health Ethics submission and review process

Below is a flow chart to demonstrate how WA Health review an ethics application in RGS when additional information required (AIR) from the researcher before an application can be approved.



Ethics Application Process in RGS - Additional Information Required (AIR)

CAHS Review process flowchart is also available here:

https://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/CAHS/Human %20research%20ethics/CAHSRevie%20processflowchart18.pdf



### WA Health Governance submission and review process

Below is a flow chart to demonstrate how WA Health review a governance application in RGS when additional information required (AIR) from the researcher before site authorisation is given.

#### Submission Validation **Review Decision Approval Decision** Preparation Recommended New Version Valid (Pending) (date) (date) Form/Document Authorised OR PROJECT MEMBERS (date) Edit OR Under review Form (In Progress) (date) Not Valid Not Doc (date) Authorised Mark (date) Complete Noted (Completed (date) pending Submitted AIR Sign OR signatures) (date) (Authorised) (date) **AIR** (date) HOSPITAL ADMINISTRATOR Sign (Completed) AIR Letter GOVERNANCE (if applicable) Record Decision in Review Validation Valid Review Forms & Letter Decision Decision Documents SITE EXECUTIVE Review RGO Authorisation Decision Recommnedation

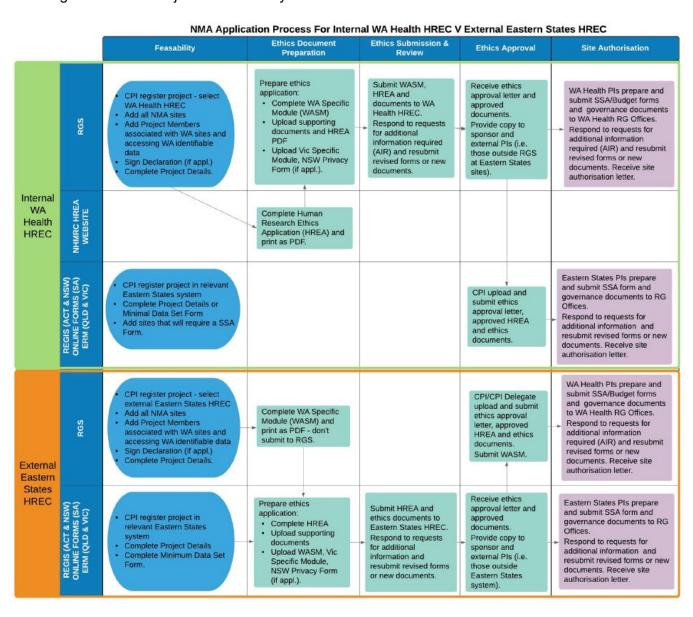
Governance Application Process in RGS - Additional Information Required (AIR)



### 4. Multi-centre Research

Information on how single ethical review in multicentre research is applied both at a WA Health and National level is available from <a href="https://rgs.health.wa.gov.au/Pages/Multi-centre-Research.aspx">https://rgs.health.wa.gov.au/Pages/Multi-centre-Research.aspx</a>

Below is a flow chart to assist with navigating the National Mutual Acceptance (NMA) when using RGS and other jurisdictions IT systems.





# 2024 Research Skills Workshop Series

# Navigating Research Ethics and Governance in WA



Wednesday 1st May 2024

1.30 - 3.30pm

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.



Meet the presenters Medya Ahmadian **Research Governance** Coordinator CAHS

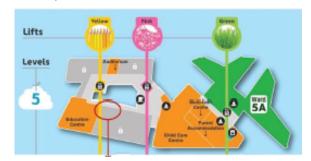
Samantha Crawford **Research Governance** Coordinator **CAHS** 



With a background in public health, Medya has been a Research Governance Coordinator at the Child and Adolescent Health Service since 2022. In addition to assisting researchers making quality governance applications, Medya is responsible for reviewing and monitoring research projects across Child and Adolescent Health Service sites.

As the Research Governance Coordinator at the Child and Adolescent Health Service, Samantha is part of the team responsible for reviewing, approving and monitoring Research projects that happen at a CAHS site which include Perth Childrens Hospital, Community Health, Mental Health & Neonatology. Samantha offers researchers specialised support services to assist in the development, governance and implementation of effective research across the health service.

### PCH, TKI Level 5 Seminar Room



Accessible via the yellow or pink lifts

**Register** via Trybooking.com

**liew** recorded seminars online

Subscribe to our mailing list

Places are capped at 40.



(08) 6456 0514



researcheducationprogram@health.wa.gov.au



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















The Research Education Program - supported by the Perth Children's Hospital Foundation and the Telethon Kids Institute - offers a series of hands-on workshops that focus on the most integral features of REDCap and its application to your research project data. Workshops aim to directly build user skills in a guided environment, with time to ask questions and work on your own project.

Dates below are still being finalised so check back again for latest version.

Presented by: Research Education Program Research Fellow Dr Giulia Peacock

Location: PCH, TKI Seminar Room, Level 5 (West).



| Topic  | Day     | Date     | Time                | Max No (in person)    |
|--|---------|----------|---------------------|-----------------------|
| Workshop 1 – Basic Walkthrough                     | Tuesday | 27 Feb   | 2:30pm to<br>4:30pm | <u>Watch</u>          |
| Workshop 2 – Intermediate Walkthrough              | Tuesday | 12 March | 1:00pm to<br>3:30pm | Watch                 |
| Workshop 3 – Advanced REDCap<br>- Creating Surveys | Tuesday | 30 April | 1:00pm to<br>3:30pm | 40<br>Register        |
| Workshop 4 – REDCap Troubleshooting<br>Workshop    | Tuesday | 28 May   | 2:00pm to<br>4:00pm | 40<br>Register        |
| Workshop 5 – Basic Walkthrough                     | Tuesday | 16 July  | 1:00pm to<br>3:30pm | <b>40</b><br>Register |
| Workshop 6 – Intermediate Walkthrough              | Tuesday | 20 Aug   | 1:00pm to<br>3:30pm | <b>40</b><br>Register |
| Workshop 7 – Advanced REDCap<br>- Creating Surveys | Tuesday | 10 Sep   | 2:00pm to<br>4:30pm | <b>40</b><br>Register |
| Workshop 8 – REDCap Troubleshooting<br>Workshop    | Tuesday | 15 Oct   | 1:00pm to<br>3:30pm | <b>40</b><br>Register |

### **IMPORTANT**

Attendance is open to all Department of Health and Telethon Kids Institute staff.

Places are strictly limited and offered on a first-come, first-serve, basis. If you are not able to attend a workshop for which you have registered, please contact Research Education Program support via phone or email to cancel your reservation and/or be placed in another workshop or on the waitlist.

Register via Trybooking.com

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| Contact Us | or Register here |
|------------|------------------|
|            |                  |

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# Advanced REDCap and Creating Surveys

30th April 2024

1.00 - 3.30pm

### Level UP!

- This workshop explores a more in-depth look at advanced features in REDCap and how to design and distribute a survey through REDCap.
- Enrolment in this workshop requires previous attendance at one of our preliminary sessions (Basic OR Intermediate) or be able to demonstrate that you are already administering projects within REDCap.
- Do you know how to create a project from scratch AND are you comfortable with applying branching logic? If no please register for an Intermediate Workshop. This workshop is for users who are already comfortable using the REDCap interface.



Meet the presenter

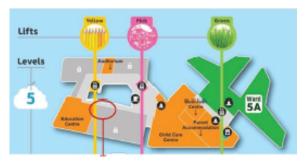
Open to all WA Health and TKI staff only.

Dr Giulia Peacock
CAHS Research Education Program Research Fellow

Giulia graduated medical school from the University of Notre Dame Fremantle in 2014. She supplements her clinical work as an Advanced Paediatric Trainee by conducting and publishing research in paediatric cardiology and through active involvement in medical education.

She is currently completing her Masters in Clinical Science, Child Health Research at the University of Western Australia. She hopes to ensure easy accessibility to research education and support, to create best outcomes for all patients.

### PCH, TKI Level 5 Seminar Room



Accessible via the yellow or pink lifts

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Places are capped at 40. Laptops are available if required

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# Research Skills Seminar Series

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

# 2024 Seminar Schedule

Interactive in pdf format Last updated 5/4/24

| #  | DATE   | TOPIC   | PRESENTER   | ENROL    | WATCH       |
|----|--------|---|---|----------|-------------|
| 1  | 9 Feb  | Research Fundamentals                               | Dr Kenneth Lee, UWA   | -        | 2024        |
| 2  | 16 Feb | Introductory Biostatistics                          | Michael Dymock, TKI   | -        | 2024        |
| 3  | 8 Mar  | Social Media in Research                            | Dr Amy Page, UWA  | -        | <u>2024</u> |
| 4  | 22 Mar | Introduction to Good Clinical Practice              | Alexandra Robertson, CAHS   | -        | <u>2024</u> |
| 5  | 19 Apr | Research Governance                                 | Dr Natalie Giles, CAHS  | REGISTER | 2023        |
| 6  | 3 May  | Scientific Writing                                  | A/Prof Tony Kemp, UWA   | REGISTER | 2023        |
| 7  | 17 May | Project Management                                  | Melanie Wright, SMHS  | REGISTER | 2023        |
| 8  | 7 Jun  | Research Impact                                     | Dr Tamika Heiden, Vic   | REGISTER | 2023        |
| 9  | 14 Jun | Consent and Participant Recruitment                 | Prof Daniel Fatovich and<br>Mark Woodman, EMHS                    | REGISTER | 2024        |
| 10 | 21 Jun | Consumer & Community Involvement in Research        | Belinda Frank, TKI  | REGISTER | 2023        |
| 11 | 19 Jul | Getting the Most out of Research Supervision        | A/Prof Sunalene Devadason,<br>UWA/CAHS                            | REGISTER | 2022        |
| 12 | 26 Jul | Oral Presentation of Research Results               | Dr Giulia Peacock, CAHS   | REGISTER | 2023        |
| 13 | 2 Aug  | Sample Size Calculations                            | Michael Dymock, TKI   | REGISTER | 2023        |
| 14 | 9 Aug  | Rapid Critical Appraisal of Scientific Literature   | Dr Natalie Strobel, ECU   | REGISTER | 2023        |
| 15 | 16 Aug | Media and Communications in Research                | Peta O'Sullivan, CAHS   | REGISTER | 2023        |
| 16 | 23 Aug | Knowledge Translation                               | Prof Fenella Gill, Curtin/CAHS                                    | REGISTER | 2023        |
| 17 | 30 Aug | Conducting Systematic Reviews                       | Prof Sonya Girdler, Curtin Uni                                    | REGISTER | <u>2023</u> |
| 18 | 6 Sep  | Involving Aboriginal Communities in Research        | Cheryl Bridge, TKI and co.  | REGISTER | 2023        |
| 19 | 11 Oct | Grant Applications and Finding Funding              | Dr Tegan McNab, TKI   | REGISTER | <u>2023</u> |
| 20 | 18 Oct | Data Collection & Management (REDCap)               | Dr Giulia Peacock, CAHS   | REGISTER | 2023        |
| 21 | 25 Oct | Statistical Tips for Interpreting Scientific Claims | Michael Dymock, TKI   | REGISTER | 2023        |
| 22 | 1 Nov  | Survey Design and Techniques                        | Dr Giulia Peacock. CAHS   | REGISTER | 2023        |
| 23 | 15 Nov | Ethics Processes for Clinical Research in WA        | Dr Natalie Giles, CAHS  | REGISTER | <u>2023</u> |
| 24 | 22 Nov | Qualitative Research Methods                        | Dr Lorna Davin, Uni Notre Dame                                    | REGISTER | <u>2023</u> |
| 25 | 29 Nov | Innovation and Commercialisation                    | Dr Helga Mikkelsen (Brandon<br>BioCatalyst) & Ashley Schoof (TKI) | REGISTER | 2022        |

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# Scientific Writing

3rd May 2024

12.30 -1.30pm



### Academic writing tips to improve publication success

Writing is the most used channel for communication of ideas, research, and findings. Being able to have quality and effective scientific writing is a fundamental part of successful research translation.

This seminar provides a practical overview of scientific writing; including principles of good writing, how to get started, article structure and organisation, how to negotiate authorship, and the publication process.



### Meet the presenter

A/Prof Tony Kemp Senior Lecturer - School of Earth Sciences, UWA



Tony completed his PhD at the ANU in Canberra, and held research positions in the UK, Japan and the USA, before relocating to UWA in 2011 as an ARC Future Fellow. He has > 120 peer reviewed publications, including first authored papers in Nature and Science, is an expert assessor for a number of national research funding bodies (including ARC, NERC, NSF) and serves as Associate Editor for two international journals.

### Perth Children's Hospital Auditorium

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

Access online via Teams or Watch from a hosted video-conferencing site

- Fiona Stanley Hospital
- Lions Eye Institute
- Pathways in Shenton Park
- Royal Perth Hospital









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A light lunch is provided for our in-person attendees. Bookings are essential.





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| Thank you for your interest in this seminar  |          |              |            |            |       |          |  |
|--|----------|--------------|------------|------------|-------|----------|--|
| Please complete this 1-minute evaluation.<br>Your feedback will help guide future presentations and educational activities.  |          |              |            |            |       |          |  |
| How did you attend the seminar?  Live seminar at Perth Children's How Hosted video-conference on-site (conference on the conference on the |          | Lions Eye, F | RPH etc.)  |            |       |          |  |
| Please rate your agreement with the fol  | lowing s | tatements:   |            |            |       | Strongly |  |
| The aims and objectives were clear   | N/A      | Disagree     | Disagree   | Neither    | Agree | Agree    |  |
| The session was well structured  |          | 0            | 0          | 0          |       |          |  |
| Presentation style retained my interest  | 0        | $\circ$      |            |            |       | $\circ$  |  |
| The speaker communicated clearly   | 0        | 0            | $\circ$    |            | 0     | 0        |  |
| The material extended my knowledge   | $\circ$  | 0            | 0          | 0          |       | 0        |  |
| The additional resources were helpful  |          | $\circ$      | 0          |            |       | 0        |  |
| What were the best aspects of the semi   |          |              |            |            |       |          |  |
| What changes or improvements would y   | ou sugg  | est?         |            |            |       |          |  |
| How did you hear about the seminar?  Yyou can select multiple answer)  Email invitation from Research Ed   | ducation | Program      |            |            |       |          |  |
| CAHS Newsletters e.g. The Headli "Health Happenings" E-News Healthpoint Intranet Upcoming E Collegiate lounge screen or other  | vents    |              | Research N | Newsletter |       |          |  |

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