Ethics Processes within WA Health Research

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Ethics Processes for Clinical Research in WA

CONTENTS:

Government of Western Australia
Child and Adolescent Health Service

CAHS Research Education Program

Community Health | Mental Health | Perth Children's Hospital

Compassion Collaboration Equity Respect Excellence Accountability

1

"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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Government of Western Australia
Child and Adolescent Health Service

RESEARCH SKILLS SEMINAR SERIES 2019
CAHS Research Education Program

Ethics Processes

Principles and Processes for Clinical Research in WA

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Research Skills Seminar Series | CAHS Research Education Program
Department of Child Health Research | Child and Adolescent Health Service

ResearchEducationProgram.org

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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Role of Ethics Committees?

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

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Role of Researchers?

- To ensure best possible research practice
- To protect
  - participants
  - researchers
  - organisations
  - **Approval is Prospective**

Exactly the same! But…..

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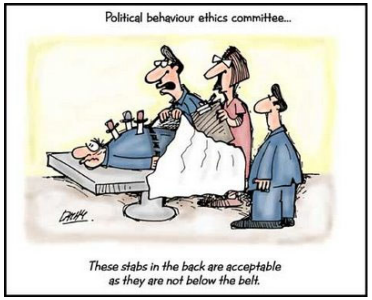
Ethics?

- 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*

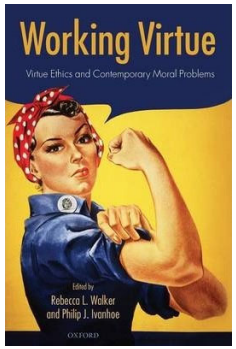
Revisit: "How to make Clinical Research Ethical by Design" Prof Nik Zeps
ResearchEducationProgram.org



General Ethical Principles

Research Merit

- Important question
  - 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

General Ethical Principles

Researcher Integrity

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

"Whoever is careless with the truth in small matters cannot be trusted with important matters"
Albert Einstein

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General Ethical Principles

Justice	Fair selection of participants
Beneficence	Consider welfare and interest of participants
	Risk versus benefit
	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

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
- Free on-line training: see handout

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Important Guidelines

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 the *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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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 and approval

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Quality Assurance or "Research" ? 1

- 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 "Research"? 2

- 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?*

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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)

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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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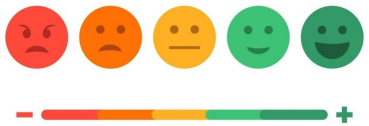
Suitable Projects - Low and Negligible Risk

- 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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Practical Requirements

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WA Health Research Governance Framework

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

Research Development Unit Website - info, forms agreements
https://ww2.health.wa.gov.au/Articles/N_R/Research-Development-Unit

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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** (clinical trial or non-clinical trial)* (templates can be found on RGS) **Participant/Parent information** and **consent form** (updated)*
    - + Any other required documents (e.g. clinical trial specific)

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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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Other Requirements – Clinical Trials

Clinical Trials

- Must be registered in order to be publishable
- International Committee of Medical Journal Editors
- E.g.: Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/Default.aspx
- Industry often requires registration details for participants
- + agreements, indemnities, insurances etc.

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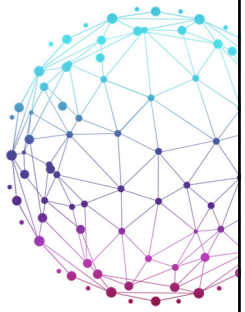
Multi-Site Research in Australia

- **National Mutual Acceptance**
- To improve quality & streamline review 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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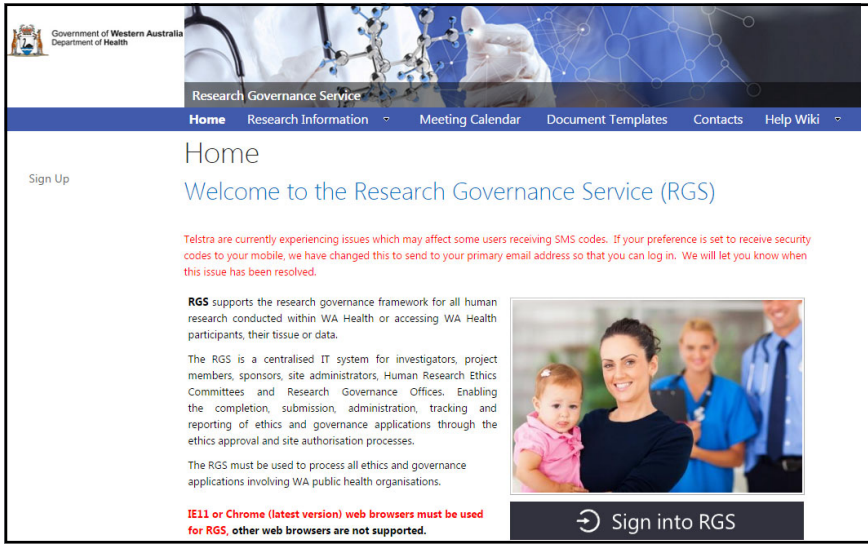

Submission Process in WA

1. **Scientific Advisory Subcommittee +**
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

Application Review Process

- Apply within RGS
- CI receives acknowledgement
- Ethics staff validate submission
- HREC considers
- Governance reviews simultaneously

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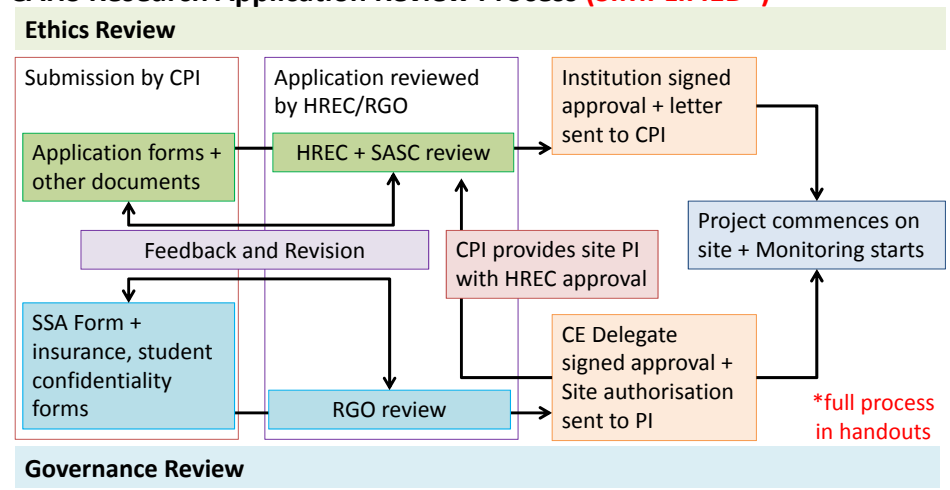
CAHS Research Application Review Process (SIMPLIFIED*)



WA Aboriginal Health Ethics Committee

- **Within the Aboriginal Health Council of WA**
  Submit if research involves Indigenous participants and:
  - Indigenous status is a key determinant
  - Data collection directed at Indigenous peoples
  - Indigenous people to be examined separately
  - Data to impact on Indigenous communities
  - Indigenous 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"

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
- Eg: CAHS HREC meets 11 times per year
  HREC submission approx. 2w before SASC
  - HREC review 2w after SASC

- **Meeting dates available online**

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HREC Composition

- Composition determined by the *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)

Scientific Advisory Safety Committee (SASC)

- Members appointed by the Institution
- Assesses projects prior to HREC meetings
- Reviews scientific integrity
  - Is the research justified – literature review
  - Is the design appropriate to answer the question
- 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 RGS
- Review, guidelines within the Site Specific Assessment form
- PI, 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!
- Contain:
  - Aims, objectives, methods
    - Participants, privacy, consent
    - Data management
    - Consultation, feedback
  - Names and titles of investigators - responsibilities
  - Conflict of interest, risks and benefit
  - Start date – <u>after</u> ethics approval

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 - <u>generally small</u> e.g. 2-3 FTE total

Duties covered may include:

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

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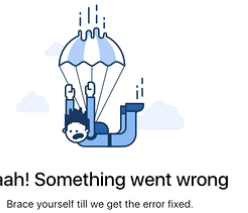
Key reasons for HREC issues

- 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



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How best to prepare?

- Start early
- Speak to in-house research support staff
  - Biostats, epi, data management, ethics, governance, business managers
- Community involvement
- 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
- 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 Information

- Voluntary
- ***Ongoing*** process
- Plain language:

Aim 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)

Informed Consent: Forms

- WA Health form
- 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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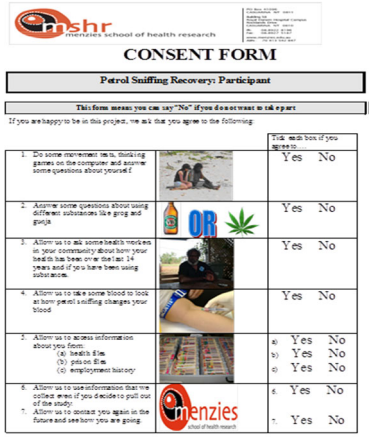
Consent Example – multiple options



mshr menzies school of health research

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...
1. Do some movement tests, thinking games on the computer and answer some questions about yourself		Yes No
2. Answer some questions about using different substances like grog and ganja	OR	Yes No
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 substances.		Yes No
4. Allow us to take some blood to look at how petrol sniffing changes your blood		Yes No
5. Allow us to access information about you from: (a) health files (b) jails or files (c) employment history		a) Yes No b) Yes No c) Yes No
6. Allow us to use information that we collect even if you decide to pull out of the study	menzies	6. Yes No
7. Allow us to contact you again in the future and see how you are going.		7. Yes No

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)*

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

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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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Data

- Numbers
- Conversations – what people say
- Images/ songs/ paintings/ sculptures
- Stories/personal histories/ biographies
- Analysis of existing information
- Personal information
- Information derived from human tissue e.g.
  measurements, blood, urine, skin bone, exhaled air, hair, tumour or biopsy

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Authorisation to Access Data

- Reviewed at a governance level (e.g. RGS online)
- 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

- **Data can be:**
  - Individually identifiable
  - Re-identifiable: identifiers replaced by a code, potentially re-identifiable eg by DOB, Address, image
  - Non-identifiable: never labelled with individual identifiers, or identifiers permanently removed
- **For publication:**
  - Delete names, other personal information from data
  - Use unique identifier not linked to names or personal details

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

Data Storage

- Locked facility for hard copies
- Password protected
- 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 (IDSMBs), 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
- New standardised processes for development
- Recommendations made, recorded

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Feedback

- Participants
- Communities
- Scientific community
- Ethics Committee
- 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 - supervisors*
- Get help, Look at successful examples
- Use the National Statement (2007)
- Plain language
- Be fussy about detail
- Ethical conduct is prospective!

"Improvement begins with I."
Arnold H. Glasow

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2 ETHICS – ADDITIONAL NOTES AND RESOURCES

2.1 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 the website below.

https://www.nhmrc.gov.au/research-policy

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

Resnik DB. "What is Ethics in Research & Why is it Important?" 2011. National institute of Environmental Health Sciences.

https://www.researchgate.net/publication/242492652_What_is_Ethics_in_Research_Why_Is_It_Important

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

2.2 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-2007-updated-2018#toc__1642

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.

2.3 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 2012

http://www.health.wa.gov.au/CircularsNew/attachments/724.pdf

2.4 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

2.5 New 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

2.6 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.

http://www.health.wa.gov.au/CircularsNew/attachments/724.pdf

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://pch.health.wa.gov.au/Research/For-researchers/ResearchEducationProgram/Clinical-Audit-Handbook

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

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

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

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

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

2.7 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"

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

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

2.8 How to write a good ethics application

Useful tips from UWA:
http://www.research.uwa.edu.au/staff/human-research/good-application/good-application

2.9 Ethics and Research Governance Structures

Example: CAHS, Perth Children's Hospital https://ww2.health.wa.gov.au/About-us/Child-and-Adolescent-Health-Service/Our-Community/Research/Human-Research-Ethics-and-Governance

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
  http://medicinesaustralia.com.au/issues-information/clinical-trials/

- Australian Clinical Trials Handbook
  https://www.tga.gov.au/publication/australian-clinical-trial-handbook

- Government of Western Australia Intellectual Property Policy and Best Practice Guidelines:
  https://www.commerce.wa.gov.au/sites/default/files/atoms/files/wa_govt_ip_policy_and_best_practice_guidelines.pdf

- Working with Children Checks
  http://www.checkwwc.wa.gov.au/checkwwc

- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
  http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm

- Guidelines under section 95 of the Privacy Act 1988: privacy and medical research (amended June 15)
  https://www.comlaw.gov.au/Details/C2015C00279

2.10 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

2.11 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

3 WA HREC DETAILS

3.1 WAAHEC

For information about meeting dates, research application process and forms as well as useful links to other organisations that undertake Aboriginal health research:

http://www.ahcwa.org.au/#!ethics/c6gq

3.2 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

3.2.1 Research Development Unit

https://ww2.health.wa.gov.au/Articles/N_R/Research-Development-Unit

Email: CMOResearchDevelopment@health.wa.gov.au

3.2.2 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

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.

3.2.3 East Metropolitan Health Service, Research Ethics and Governance

https://emhs.health.wa.gov.au/Research/For-Researchers/REGS

3.2.4 Sir Charles Gairdner Hospital Research

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

3.2.5 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

3.3 WA Private HREC

St John of God HREC

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

Joondalup HREC

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

3.4 WA Universities HREC

UWA HREC

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

Notre Dame HREC

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

Curtin University HREC

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

Edith Cowan University HREC

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

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/

4 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

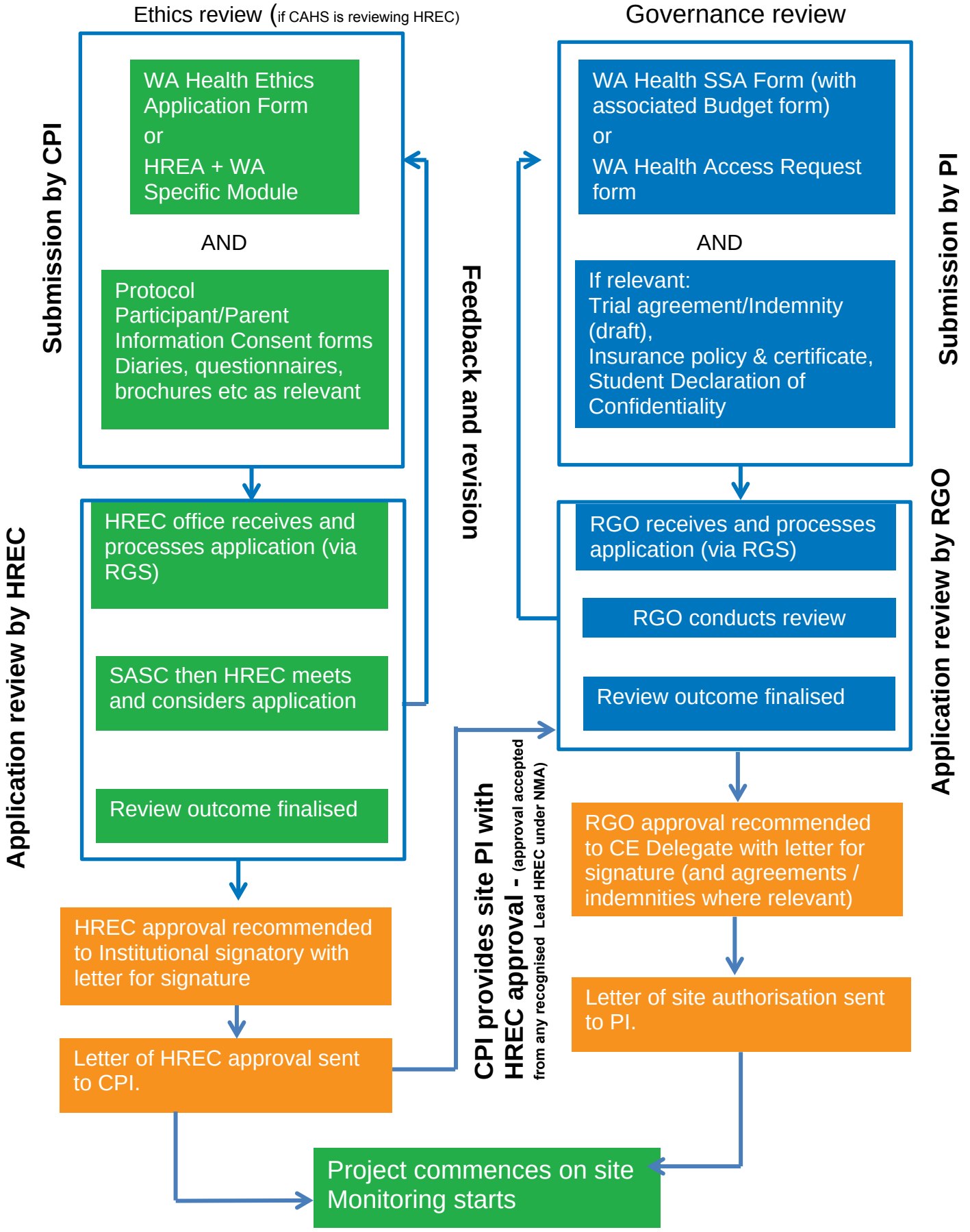
https://retprogram.org/portfolio-item/ich-good-clinical-practice-gcp-e6-r2/

ARCS Australia

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

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

CAHS Research Application Review Process



ResearchEducationProgram.org

ReserachEducationProgram@health.wa.gov.au