Research Ethics Matters

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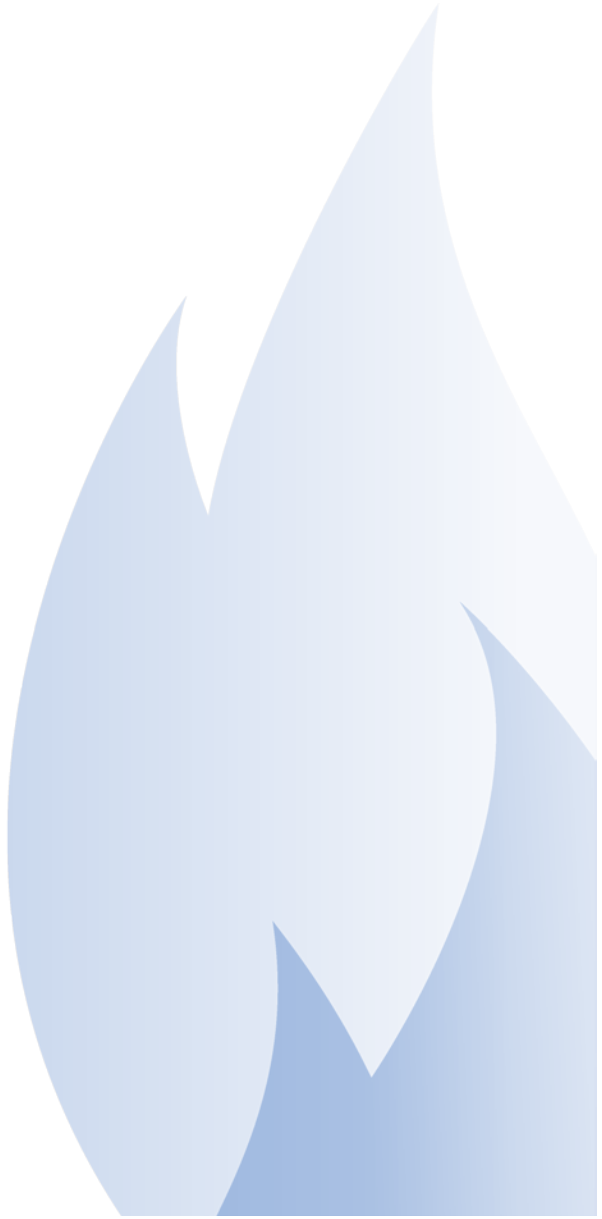
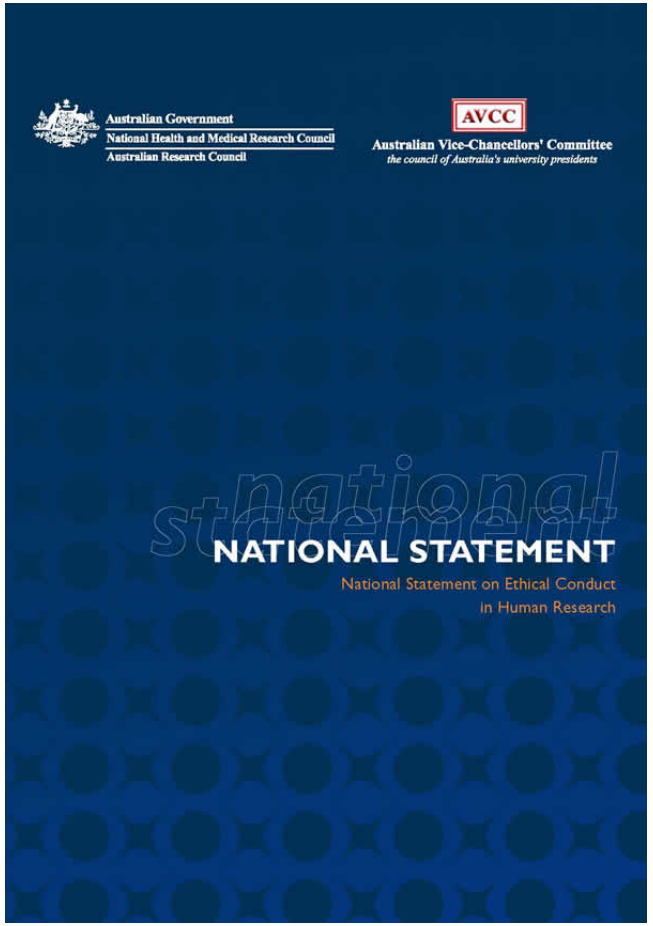


What is Human Research?

- Human research is conducted with or about people, or their data or their tissue.
- Examples of human research
  - Trials of clinical interventions – drugs/devices
  - Interviews
  - Surveys
  - Focus Groups
  - Observations
  - Medical records
  - Clinical Audits

- National Statement on Ethical Conduct in Human Research (2007)
- Australian Code for the Responsible Conduct of Research (2007)



PRINCIPLES OF ETHICAL CONDUCT

MERIT AND INTEGRITY

Genuine search for knowledge

Based on literature, prior research and / or established problem

Sufficient expertise and resources

Any conflicts of interest addressed

RESPECT FOR PERSONS

Intrinsic value of humans, rather than resources

Welfare, beliefs, perceptions, customs and cultural heritage

Privacy, confidentiality & cultural sensitivities

Honour assurances provided

Respect the capacity for self determination

BENEFICENCE

Responsibility to minimise harms

Not non-maleficence

Not overstating the benefits

Benefits must justify the risks

Fair flow of benefits versus burdens

Genuinely informed consent

JUSTICE

Fair selection and inclusion

Distributive justice

No unfair burden

Fair flow of / access to benefits

No exploitation

Impact on prejudice and discrimination

What makes Clinical Research Ethical?

Table 2. Seven Requirements for Determining Whether a Research Trial Is Ethical*

Requirement	Explanation	Justifying Ethical Values	Expertise for Evaluation
Social or scientific value	Evaluation of a treatment, intervention, or theory that will improve health and well-being or increase knowledge	Scarce resources and nonexploitation	Scientific knowledge; citizen's understanding of social priorities
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Independent review	Review of the design of the research trial, its proposed subject population, and risk-benefit ratio by individuals unaffiliated with the research	Public accountability; minimizing influence of potential conflicts of interest	Intellectual, financial, and otherwise independent researchers; scientific and ethical knowledge
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JAMA 2000: v.283(20) pg 2701-2711

Social or Scientific validity –
result is important, adds to potential well-being

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Scientific validity – methodology appropriate, can give an answer

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Equity of access–
does not target the vulnerable
OR exclude the marginalised

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Risk/benefit ratio–
minimise risks but do not ignore them

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Study design to minimise risk

- Phase 1 FIM studies require pre-clinical 2 animal species models

- Additive studies acceptable
  Current standard of care PLUS investigational agent OR placebo
- Negative studies not acceptable
  ie. Standard of Care PLUS investigational agent
  ie. Standard of Care MINUS investigational agent

- Current studies with biosimilars controversial

Independent review - HREC

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Informed Consent –
clear simple language, voluntary, no coercion

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Respect– maintaining the welfare of participants privacy, capacity to withdraw, informed of changes

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Why Research Ethics Matters

- Responsibility to participants
- Professional obligations and reputations
- Use of public funds carries with it obligations to the community
- Requirements of research funding bodies, state, federal and international
- Requirements of the Hospital insurer – indemnification of researchers
- Requirements of many journals
- Reputation of the Hospital

Risks in human research

A common mistake researchers make is to describe a project as involving no risks

When what they actually mean is that there are strategies in place to negate or minimise the risks

Risks in human research

"Another common mistake is to assume that risks only refers to physical or perhaps also significant psychological harms."

- **Physical** (Injury, illness, harm)
- **Psychological** (significant distress)
- **Social** (impact on social networks, access to services and support)
- **Economic** (loss of income, earnings and cost to participants)
- **Legal** (exposure to civil or criminal proceedings)
- **Humiliation** (devaluation of worth)

Assessing risks in human research: Recognition of burden on participants

- To whom do the risks apply?
  - Participants, potential participants, third parties, environment, and / or researchers.
- Addressing risks
  - Are there alternatives?
  - Can risks be negated or minimised?
  - Can risks be managed?
- Can the risks be justified?
- Disclosure to potential participants

Research Integrity

- **the trustworthiness of research due to the soundness of its methods and the honesty and accuracy of its presentation**
- Singapore Statement on Research Integrity (2010)

Research Integrity: Individual

- Intellectual honesty in proposing, performing, and reporting research.
- Accuracy in representing contributions to research proposals and reports.
- Fairness in peer review.
- Collegiality in scientific interactions, including communications and sharing of resources.
- Transparency in conflicts of interest or potential conflicts of interest.
- Protection of human subjects in the conduct of research.
- Humane care of animals in the conduct of research.
- Adherence to the mutual responsibilities between investigators and their research participants.

Research Integrity: Institution

- Integrity is a commitment to creating an environment that promotes responsible conduct by embracing standards of excellence, trustworthiness, and lawfulness.
- 'Responsible Conduct of Research' refers to a wide range of areas of research compliance, professional conduct, and personal responsibility which include:
  - Data management
  - Research misconduct
  - Peer review
  - Publication & authorship
  - Care of human participants in research
  - Conflict of Interest declaration
  - Collaboration in research
  - Health and safety

Research Misconduct

- Failure to comply with the Code of Conduct for Research
- includes conduct in, or in connection with, research that is:

(a) dishonest, reckless or negligent and

(b) seriously deviates from accepted standards within the scientific and scholarly community for proposing, conducting or reporting research:

- the fabrication or falsification of data or results,
- the use of another person's ideas, work or data without appropriate acknowledgement (plagiarism),
- misleading ascription of authorship to a publication
- failure to disclose conflicts of interest
- failure to obtain the required prior ethical or regulatory approval for the research project to proceed;
- or failure to conduct the research project in accord with the approved ethical or regulatory protocol.

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