

Evidence in the research ethics application process

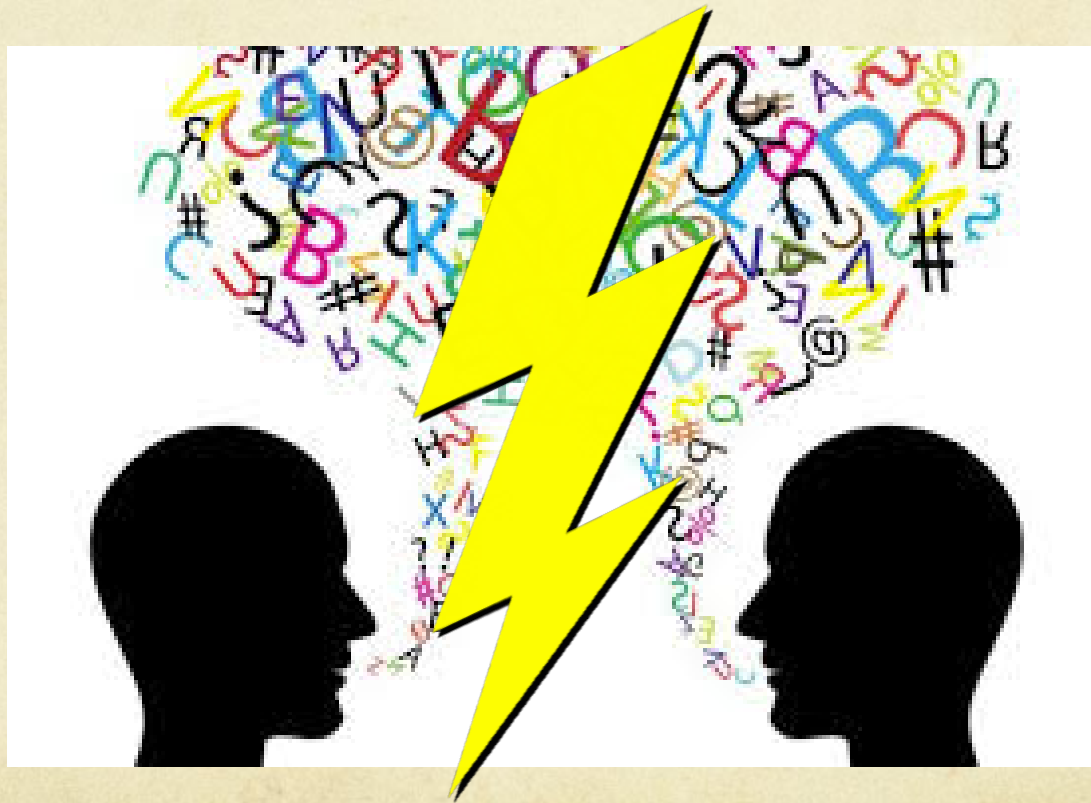
Prof. Bill Boyd

Chair

Southern Cross University Human Research Ethics Committee

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... stepping into a conversation



Principles of ethical research

The National Statement on the Ethical Conduct of Human Research

- ✓ Research merit & integrity
- ✓ Justice
- ✓ Beneficence
- ✓ Respect
- ✓ Risk

Research ethics principles provide the perfect framework for successful research

Australian Code of Practice for the Care and Use of Animals for Scientific Purposes ... the 3 Rs

“Reduce, Replace, Refine”

Origins of the National Statement principles

**It's always good
to know your
discipline's
history**

Emanuel, E. Wendler, D. & Grady, C. 2000. What Makes Clinical Research Ethical? *JAMA (Journal of the American Medical Association)*, 283(20), 2701-2711.

- 14 international & national research ethics statements of (1946-1999) → 7 common essentials

- social or scientific value
- scientific validity
- fair subject selection
- informed consent
- research risk/benefit ratio
- respect for potential and enrolled subjects
- independent review

... and in plain English ...

**When in doubt
... just talk it
out**

- **Its value:** Is the research worth doing?
- **Its validity:** Is the research design sensible?
- **Fair selection:** Have you chosen your participant groups well?
- **Informed consent:** Do your participants know what they are doing and why? Do they know what your responsibilities are?
- **Favourable risk-benefit ratio:** Are there any risks? Are they worth it? Are they managed well?
- **Respect for participants:** How do you show respect to your participants?
- **Independent review:** Has someone with expertise reviewed your proposed activity?

Translating to the National Statement

Principles – just fancy words for basic ideas

- **Social/scientific value**
- **Scientific validity**
- **Fair subject selection**
- **Favourable risk benefit ratio**
- **Informed consent**
- **Respect for potential & enrolled subjects**
- **Independent review**

- **Research merit and integrity**
- **Justice**
- **Beneficence**
- **Respect for human beings**
- **Risk**

Structure of the National Statement

So ... are there really six principles?

- **Research merit**
 - Integrity
 - Justice
 - Beneficence
- **Respect for human beings**
 - Risk

Integrity v Integrity

- Moral / virtue integrity

versus

- Process integrity



What are HRECs doing?



- *Cannot predict future integrity*
- **Best guess** on integrity outcome
- **Second guessing:**
 - Assuming merit ...
 - **Method** ... **reasonable chance** of generating credible & rigorous data?
 - **Data** ... **reasonable chance** of generating credible & rigorous analysis?
 - **Analysis** ... **reasonable chance** of generating an honest conclusion & outcome?
- **Basis of these second guesses** ... HREC needs **EVIDENCE**

Principles of ethical research ... evidence used by the committee

HREC application
= **evidence that**
you understand
the principles

- ✓ **Research merit Literature, context**
- ✓ **Integrity Methodology, design, method, data, alignment**
- ✓ **Justice Participant recruitment**
- ✓ **Beneficence “Do no harm”, participant benefit**
- ✓ **Respect Language, interactions with participants, arrangements, choice, place, behaviour**
- ✓ **Risk “What can go wrong”, “Is it actually a risk?” design, management**

Risk as principle not process

... the power of risk ...

○ Risk aversion

- ... avoid, limit, fear, damage, negativity, gut reaction ...
- ... “oh, but we can’t do this ...” ...

versus

○ Harnessing risk

- ... design, decision, principles, reality check, mitigation, thinking ...
- ... “what actually is the risk ...?” ...