



# Examining human research ethics: principles and practice

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# Research team

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# Overview of presentation

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- **Brief history** – ethics review process in Australia

- **Questionnaire survey findings**  
–**brief summary**

Views of human research ethics committee (HREC) members and researchers concerning the human research ethics review process in Australia

- **Interview study - Preliminary findings**

- process of ethical decision making of HREC members and health researchers
- how ethical issues are addressed by both in practice

# Brief history - ethics review in Australia

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- 1966: NHMRC produced first *Statement on Human Experimentation* (biomedical)
- 1976: HRECs est; NHMRC regulations extended to “investigations on human behaviour”
- 1999 & 2007: *National Statement on the Ethical Conduct of Research Involving Humans (NHMRC)*
  - *National Statement* guides the conduct of all research involving humans in Australia (all disciplines and research areas)
  - All research involving human participants requires approval by a properly constituted HREC
  - Primary role of HREC to protect welfare and rights of participants

# Questionnaire survey – Views of the ethics review process in Australia

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- Questionnaire survey of participants attending the NHMRC Ethics in Human Research Conference, Canberra, May 2005
- 252/407 registrants (62%) completed the questionnaire (with over half adding comments)
  - 219 were HREC members (11% Chairs, 19% lay persons, 9% researchers, 6% ministers of religion, 3% lawyers and 31% administrators)
  - 33 were researchers (50% allied health professionals, 25% clinicians; 25% psychologists)
  - Most participants were from universities and hospitals

# Summary of questionnaire survey findings

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- Generally both HREC members and researchers satisfied with human ethics review in Australia
- However, in many areas, researchers have more negative views of the ethics review process than HREC members
  - Identified areas of concern that require further attention:
    - timeliness and clarity of decisions,
    - expertise available, and
    - basis for decisions made by HRECs

Gillam, L., Guillemin, M., & Rosenthal, D. (2006). "Obstructive and power hungry"?: The Australian human research ethics process, *Monash Bioethics Review*, 25 (2).

# Interview study: Ethical decision making of HREC members & health researchers

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## ■ Aim to investigate:

- How do health researchers and HREC members understand and think about research ethics?
- What principles and frameworks do they use?
- How do health researchers and HREC members address ethical aspects of research in practice?

## ■ Qualitative research- individual interviews

- 50 HREC members (clinical, lay, legal & religious)
- 50 health researchers (clinical, lab biomedical, epidemiology & social health)

# Interview study

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- **Interview questions include:**
  - Perceived ethical responsibilities
  - Experience of contentious research issues and how these were dealt with
  - Knowledge of the *National Statement* and the relationship of the *National Statement* to their ethical decision-making
  - Ethical principles employed to address ethical issues in research
  - Views of current system of ethics review and regulation
  
- Research in progress- preliminary findings

# Interview study

## - Preliminary findings

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- Based on 73 interviews to date with:
  - 30 HREC members (1/3 clinical, 1/3 lay, 1/3 legal & religious)
  - 43 health researchers (1/4 clinical, 1/4 lab biomedical, 1/4 epidemiology & 1/4 social health)

### **Themes to date**

- Commitment of HRECs
- Ethical deliberation of HREC members
- Ethical decision-making processes of health researchers
- Role of HRECs
- Relationship between HRECs and health researchers

# Commitment of HREC members

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- Commitment and dedication of HREC members noteworthy; often long serving
- Time consuming: usu. monthly meetings ~ 3hrs duration, with at least 4 hrs preparation

Despite this, most HREC members found experience very satisfying:

*“Typically people used to be nominated for the faculty HREC and found the job very arduous and dumped it as quickly as they could. It was usually something they did as part of their push for promotion. It was very interesting to me that I found it to be one of the most interesting and rewarding things that I do, and the longer that I do it the more I get some satisfaction out of it and the more I see the purpose of it”.*

(HREC member)

# Ethical deliberation of HREC members

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- (1) Individual strategies for assessing HREC applications
- (2) Individual deliberative strategies of HREC members

# (1) Individual strategies for assessing HREC applications

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## ■ **Strategic reading**

Focus on specific sections of application:

- *PLS and consent form*
- *Lay summary*
- *Researchers' credentials*

## ■ **Thinking in terms of general principles**

- *Risk to participants*
- *Scientific merit and benefit– “worthwhileness”*
- *Justice*
- *Privacy*

# (1) Individual strategies for assessing HREC applications

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- **“Flags”** –specific issues/aspects that are of concern, eg

- *Placebo*
- *Discontinuing drug therapy after a trial*
- *Vulnerable participants*
- *Exclusion criteria*

## ■ **Assessment of researcher abilities**

- *Does researcher demonstrate understanding of ethical issues?*
- *Can researcher communicate and explain the research well?*

## (2) Individual deliberative strategies of HREC members

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- 'Inner knowing'
- Common sense
- Experience
  
- “Imaginative identification”
  - Putting oneself in the shoes of the participant
  - “if this were my wife/mother...”
  - “Folk strategies”
  
- Not own values

# Ethical decision-making processes of health researchers

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- (1) Ethical deliberation and reference points for health researchers
- (2) Awareness and use of National Statement by health researchers
- (3) Concerns of health researchers about ethics review process
- (4) Concerns about transparency from health researchers

# (1) Ethical deliberation & reference points of health researchers

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- Consider research ethics at all stages of research design and implementation, not just when completing the ethics application
- Ethics as implicit – difficult to articulate but researchers “know”
- When ethical issues arise in the field, researchers rely on:
  - individual integrity (conflation of personal and professional integrity)
  - previous experience, especially clinical training and experience
  - consultation with colleagues
  - some consult with HREC for advice

## (2) Role of National Statement

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- Awareness of National Statement (NS) by health researchers
  - Did not know it exists
  - Vague general idea
  - Very familiar with NS
  
- Use of NS by health researchers
  - Some use NS explicitly, especially where NS pertains directly to their research field eg vulnerable gps
  - Some 'internalise' basic principles of NS
  - Some do not use NS at all
  
- *National Statement used in a range of ways by both HREC members and health researchers*

### (3) Concerns of health researchers about ethics review process

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- Timeliness of ethics review process
- Problems with multi centre research applications
- Problems in completing application form, especially when perceived to be irrelevant to research field

## (4) Concerns about transparency from health researchers

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- Importance of transparency for health researchers:
  - HREC membership
    - HREC often perceived by researchers as a 'faceless' committee (akin to grant review committees)
  - HREC review process
  - Decision-making process of HRECs
- Access to HREC members
  - Value direct personal communication with HREC eg being able to attend meetings or consult with HREC members

# Role of HRECs for health researchers and HREC members

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Role of HREC from view of HREC members:

- Protect participants
- Promote/encourage research

Role of HREC from view of health researchers:

- Ethical role - ensure high ethical standards, protect participants
- Institutional role
  - Keep track of research being undertaken; make sure it accords with institutional policy
  - Compliance with legislation, codes, etc

# Perceived role of HRECs: On methodology and ethics

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All HREC members claim that:

- Sound methodology is necessary for ethical research
- HRECs should evaluate methodology

Most health researchers endorse this claim but some researchers question:

- the extent of this claim
- how prescriptive HRECs should be about methodological issues
- whether HRECs have the appropriate expertise to assess methodology of applications

# Relationship between HRECs and health researchers

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- Mixed responses regarding relationships between HRECs and researchers
- Some researchers consider HREC review to be adversarial process; some feel judged and mistrusted, while other researchers see it as collegial
- Researchers who had also been HREC member gained appreciation of the work of HREC

# Valuing of HRECs by researchers

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- HREC members felt their contributions not always acknowledged or valued by researchers
  - *“For them (researchers), the issue is really one of ticking the right boxes and ensuring that their practice is compliant with what they’ve said they’re going to do.”* (HREC member)
  - *“ I think most researchers feel very frustrated with the ethics committee; they just want to know: Why can’t I?”* (HREC member)

# Conclusion

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- Little systematic research available on beliefs and practices of HRECs and health researchers with regard to research ethics
- Preliminary findings from interview research highlight:
  - Both researchers and HREC members take research ethics very seriously
  - Existing sources of tension and misunderstanding between HRECs and health researchers
  - National Statement used in a range of ways by HREC members and health researchers
  - Process of decision-making in addressing ethical issues in research varied and often implicit (“folk strategies”)
  - Implications for improving confidence in HREC process and enhancing ethical research practice