

Human research ethics in practice – preliminary findings

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Overview of presentation

Background – ethics review process in Australia

1. Questionnaire survey findings –brief summary

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

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

2. Qualitative 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

- 1966: NHMRC produced first *Statement on Human Experimentation* (biomedical)
- 1976: HRECs established ; NHMRC regulations extended to “investigations on human behaviour”
- 1999: *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

Compliance with National Statement not legislated – linked to research funding for institutions

1. Survey – Views of the ethics review process in Australia

- 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

1. Summary of survey findings

- Generally both HREC members and researchers satisfied with human ethics review in Australia
- However, number of areas of concern that require further attention:
 - timeliness and clarity of decisions,
 - expertise available, and
 - basis for decisions made by HRECs
- In many areas, researchers have more negative views of the ethics review process
 - Matter for concern in terms of confidence in the system and willingness to use it, whether or not views are justified

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

- **Aim to investigate these issues in more depth**
 - How do researchers and HREC members understand and think about research ethics?
 - What theoretical concepts and frameworks do they use?
 - What strategies do they use for thinking through ethical aspects of research?
- **Qualitative research- individual interviews**
 - 50 HREC members (clinical, lay, legal & religious)
 - 50 health researchers (clinical, lab biomedical, epidemiology & social health)

Interview study

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

Interview study

- Preliminary findings

- 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

- A. HREC ethical deliberation
- B. Researcher ethical deliberation
- Role of HRECs – perceived and actual
- Relations between the two groups – perceptions of each other

(A) HREC deliberation

- (1) Strategies for assessing an application
- (2) Individual deliberative strategies
- (3) Committee processes and strategies

(1) Strategies for assessing an application

■ Strategic reading

Focussing 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) Strategies for assessing an application

- “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

- Inner knowing
- Common sense
- Experience

- “Imaginative identification”
 - Putting oneself in the shoes of the participant
 - “if this were my wife/mother...”

- Not my own values

(2) HREC individual deliberations: Role of National Statement

- Most HREC members and researchers have ‘good’ to ‘some’ awareness of the *National Statement* guidelines
- Some HREC members directly use or refer to *National Statement* in process of decision-making in research ethics; some do not
 - “*Not a functionary of the National Statement*” (HREC member).

(3) Committee strategies and processes

- Consensus
 - Role of chair in achieving consensus
- “bouncing off” each other
 - Value of a variety of views

B. Ethical decision-making processes of health researchers

- (1) Ethical deliberation and reference points
- (2) Role of National Statement
- (3) Concerns about ethics review process

(1) Ethical deliberation & reference points of health researchers

- Consider research ethics at all stages of research design and implementation, not just the ethics application
- Ethics as implicit – would not even consider doing certain things

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
- colleagues
- unlikely to consult with HREC for advice

(2) Role of National Statement for health researchers

- Range of awareness of National Statement – did not know it exists to being very familiar with NS
- Some use NS explicitly; others not all

(3) Some issues for health researchers re ethics review process

- Importance of transparency of HREC membership and review process
 - Valued transparency, accessibility, openness if they experienced it
 - Frustrated / alienated when they don't get
- For some, it is an adversarial process – would not think to seek assistance from HREC

Conclusion

- Very little current research available on process of decision-making in research ethics
- Research in progress - but in summary to date:
 - Both groups serious about ethical responsibilities in research
 - Knowledge of the *National Statement* variable; ethical decision-making not usually linked to *National Statement*
 - Implicit / “inner knowing” and experience used by both groups in process of ethical decision-making