



Workshop A: Investigating human research ethics in practice

Cultures, roles and perceptions
of HRECs

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Aims and purpose of workshop

- To present and seek feedback from preliminary findings of Human Research Ethics in Practice (HREP) project
- Workshop potential suggestions & outcomes that arise from findings that will further inform research



Overview of workshop

- Aims of workshop
- Background to the project
- Preliminary findings:
 - Committee members' experience of HREC
 - Committee members' perceptions of the role of HREC
 - Researchers' perceptions of the role of HRECs
 - Relationship between HRECs and health researchers
 - Communication between HRECs and researchers
 - Discussion



Background to HREP project: a questionnaire survey

- What are the views of HREC members and researchers of the ethics review process in Australia?
 - Questionnaire survey of participants attending the NHMRC Ethics in Human Research Conference, Canberra, May 2005
- 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).



Human Research Ethics in Practice (HREP) project

○ **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 to date**

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



Experience of being a HREC member

- HREC members feel it is valuable, worthwhile, enjoyable
- High level of commitment; often long-serving
- Time consuming: usu. monthly meetings ~ 3hrs duration, with at least 4 hrs preparation

... you just get such an interesting perspective on it. I find that one of the most interesting things about being on an ethics committee, I really, really enjoy that. How people can pick up the same proposal and just have so many different questions about it. It's fantastic.

(HREC member)

- However, some HREC members report feeling powerless, constrained by regulation, and drug company trial protocols



Role of HREC as perceived by HREC members

- Protect participants
- Facilitate research
- Ensure research is beneficial – screen out ‘poor research’
 - Ensure researchers go about conducting research in an ethical way
 - Apply principles to applications
 - Pay close attention to the research process
- Ensure that researchers clarify and clearly articulate their research and make it understandable to a lay audience
- Meet institutional requirements



Role of HREC as perceived by health researchers

- Protect participants
- Check that benefits of research outweigh risks
- 'Gate-keeper' – both positive and negative senses
- Ensure that researchers are aware of their ethical responsibilities
- Provide guidance for researchers on ethical issues
- Offer protection for researchers (eg legally)
- Protect institution's interests



Paired discussion on HREC roles



Perceived role of HRECs from HREC members: On methodology and ethics

All HREC members claim that:

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

However, range of responses regarding the extent of this:

- from those who see it as the HREC's job to work out solutions to methodological problems, to those who see the HREC's role as to alert the researcher to the problem.

*Sometimes there's a little bit of nit picking. It happened in the last meeting. Because we didn't have enough information, the discussion started to go off into what we thought the research was wanting to do, and methodological suggestions and there were a couple of us who kept saying, we're second guessing the researcher, this discussion's going nowhere. We need to find out the answers to these questions and it's not our place to be telling them how to do it. There's a lot of reminding ourselves of what our role is.
(HREC member)*



Perceived role of HRECs from health researchers: methodology and ethics

- Most health researchers endorse the claim that sound methodology is necessary for ethical research and that HRECs should evaluate methodology
- However 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

- 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
- HREC responses likened to getting reviewers' comments back; although annoying, always end up with something better.



Valuing of HRECs by researchers

- HREC members felt their contributions not always acknowledged or valued by researchers
 - *"They think of ethics committees as this is the problem, this is the hurdle you've got to get over and it becomes so routinised and they hate it."* (HREC member)
 - *"They just want to get on with the job. I don't think they respect what we're doing at all which makes what we're doing all the more important."* (HREC member)



Communication between HRECs and health researchers (prior to HREC approval)

- a) HREC correspondence
- b) Researcher attendance at HREC meetings
- c) Informal interactions outside meetings



a) HREC correspondence

- Impact on researchers varies from serious – project delays and implications for funding – to annoying
- Some HRECs aware of potential negative impact and try to ameliorate
- Correspondence is ‘faceless’
- Committee comments may be perceived as interfering with methodology



b) Researcher attendance at HREC meetings – positive aspects

- Face-to-face interaction valued by HREC members and health researchers

- HRECs:

- Expeditious way of gaining understanding of researchers' reasons and views
- Valuable encounters with researchers

"Sometimes it's a question of re-presenting their ideas in a way that; oh now we understand what you're on about"
(HREC member)

- Researchers

- No longer 'the faceless committee'
- Can sort things out quickly



b) Researcher attendance at HREC meetings – difficult aspects

- HREC

- Adds additional time to the meeting

- Researchers

- Some researchers report unpleasant experiences

"I have to say that we were treated pretty shabbily by some ethics (committees) and I have a very vivid memory of fists being pounded on tables (about the research) we were going to do." (Researcher)

- Poor experiences leave a lasting legacy



c) Informal interactions outside meetings

- Access to committees
 - Membership of committees may or may not be public
 - Researchers describe access to committees as ranging from good to those where it's not possible to access them
- Some HRECs encourage discussion with administrator and HREC office before application is submitted
- Some HRECs provide feedback to researcher through informal meetings with committee members/shepherd or HREC administrator



Points for discussion

- Views on HREC approach to
 - Correspondence
 - Researcher attendance at meetings
 - Informal interactions between HREC and researchers
- How does your committee approach this?
- What do you consider good practice in these areas?



Points for discussion: Training

- Would it be useful to have training regarding interactions and relationships between HREC members and researchers?