Investigating Human Research Ethics in Practice: Project Report

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Chief Investigators: Associate Professor Marilys Guillemin, Associate Professor Lynn Gillam, Professor Doreen Rosenthal

Project Officer: Dr Annie Bolitho
1. Executive Summary

Investigating Human Research Ethics in Practice aimed to investigate how health researchers and members of Human Research Ethics Committees (HRECs) understand research ethics, and how they make decisions about what constitutes ethical conduct in health research. A total of 83 participants were individually interviewed by the research team: 34 ethics committee members and 49 health researchers, from metropolitan and regional hospitals, universities, research institutes, government and non-government organisations across Victoria.

The data from these interviews showed that HREC members overwhelmingly believe that they do an important job and generally are doing it well. HREC members put in many hours of effort and are committed to the task. Almost without exception, researchers interviewed supported the need for a system of formal ethical review of research. Most felt that ethics review provided them with institutional backing and validation for their research studies. Many researchers also felt that the process of ethics review improved the quality of their projects. However, a large number of researchers reported frustrations with the time taken to put in ethics applications and delays before receiving approval. Some researchers described particularly poor experiences with ethics committees which had soured their view of the whole process.

Both researchers and HREC members described a number of different ways of thinking about ethics and making decisions about what counts as ethical practice in research. For each group, the different approaches were potentially complementary rather than competing. They ranged from use of the formal ethical principles set out in the National Statement on Ethical Conduct in Human Research (2007) to everyday folk strategies of intuition and ‘putting oneself in another’s shoes’ (which we have termed ‘imaginative identification’). There was considerable commonality between researchers and HREC members in the strategies they described, though not total overlap.

On the basis of the project findings, a number of recommendations are made relating to: mechanisms to improve communication and mutual understanding between researchers and HRECs; expanded training for both researchers and HREC members; and a working party to address the excessive length of Plain Language Statement and Consent Forms, which both researchers and HREC members saw as a major problem in the current system.
2. Background

Investigating Human Research Ethics in Practice

Conducting research that is ethical is indisputably important. Considerable time and effort is spent by Australian researchers and Human Research Ethics Committees (HRECs) in the process of ethical review to ensure high ethical standards in research practice. This work can be situated in the broader context of health research in developed countries where research proposals are reviewed by Institutional Review Boards (IRBs) in the US, Research Ethics Boards (REBs) in Canada, and Local and Multi-centre Research Ethics Committees in the UK (LRECs and MRECs).

Australian ethics committee members are expected to use the ethical guidelines in the *National Statement on the Ethical Conduct of Research Involving Humans*\(^1\) as the basis for their decisions. Researchers should design their research in accordance with the guidelines. However, little is known about how research ethics is put into practice, and Investigating Human Research Ethics in Practice set out to fill this gap.

Investigating Human Research Ethics in Practice was funded by the Australian Research Council from 2006–2008. It inquired into the ethical frameworks used by researchers and HREC members. Were they compatible with each other; and were they congruent with the *National Statement*? The focus of the study was on health research, as this type of research is rich in ethical issues and has the longest history of formal ethical review. Health research is also sufficiently broad to allow frameworks of different research areas—such as biomedical, clinical/medical, nursing and allied health, public health and social health—to be explored.

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Previous Research

Relationships between researchers and HRECs

Research has identified the potential for researchers and HRECs to misunderstand each others’ notions of ethical conduct, and points to emerging tension between ethics committees and researchers. Needless to say, misunderstandings waste time and resources, but they may also have more profound implications. Pettit has argued that a persistent sense of being misunderstood on the part of researchers may lead to ‘demoralisation’, such that researchers cease to care about ethics. In cases of demoralisation Pettit suggests that the process of ethics review may actually be having an adverse effect on the ethical conduct of research. Chalmers and Pettit have warned against the danger of the current system of research ethics review becoming adversarial, with HREC members and researchers adopting polarised positions.

Ethical reasoning by researchers and HRECs

There are no published studies that systematically investigate the ethical reasoning processes of either researchers or HRECs in relation to research ethics. A 2004 study by Van Essen et al. touches on this area; it investigates whether HREC members are aware of and use the principles of natural justice, such as the right to a fair hearing. Natural justice issues are pertinent to discussions about the way HRECs operate and how this affects researchers and committee members. However, they are not relevant to substantive principles for making decisions about the ethical acceptability of projects, such as the approach to gaining informed consent.

There are a number of studies that investigate researchers’ views about ethics committees. In a landmark 1992 Australian study, McNeill investigated whether researchers accepted and complied with the required system of ethical review. He found that, on the whole, researchers did accept and support the need for ethical review although they found the process time consuming and demanding.

However, some did not always submit ethics applications for projects or seek approval for amendments. More recently, a New Zealand study found that health researchers held a range of positive and negative views about ethics committees.  

There is less published data on HREC members’ views of ethics committees. In 1994, McNeill et al. investigated HREC members’ perspectives of the ethics committee process. This study analysed group processes within the committee, specifically which types of members are most influential in the committee decision-making process. It did not investigate how HREC members actually think about research ethics. In their account of how open or closed ethics committees are, Fitzgerald and Yule provided interesting information about how committees operate as groups. However, they did not address the question of what ethical principles inform HRECs’ decisions.

A range of evidence for the ethical frameworks used by researchers is found in articles written by researchers on specific ethical issues in research. Some examples from this large and diverse literature include gaining consent from dying patients, and the implications of research on the users of illegal drugs. There are also discussions of a more general nature which provide insights into the way individual researchers think about ethics. These include reference to concepts such as integrity, responsibilities and researcher–participant relationships. While this literature provides valuable background information, it is too disparate to give a reliable answer to questions about how researchers conceptualise research ethics.

3. The Project

The Investigating Human Research Ethics in Practice project was funded by a Discovery Grant from the Australian Research Council (2006–2008). The research team was led by three Chief Investigators: Associate Professor Marilys Guillemin, Associate Professor Lynn Gillam and Professor Doreen Rosenthal, all from the School of Population Health at The University of Melbourne. The Project Officer was Dr Annie Bolitho.

Aims and Objectives

Investigating Human Research Ethics in Practice aimed to find out how HREC members and health researchers understand what constitutes ethical research, and to examine the process of ethical decision-making with respect to research ethics. The 1999 National Statement, since superseded by the 2007 version, provided guidelines regarding HREC procedures (2.13). Recognising that the context in which ethics review takes place varies from HREC to HREC, the project explored ways in which the procedures themselves might have a bearing on decision-making. The 1999 National Statement defined the primary role of a HREC as being ‘to protect the welfare and the rights of participants in research’ (2.5). With respect to this, a further project objective was to find out how HREC members and researchers understood the role of the HREC, since this too would make a difference regarding the scope of their decisions.

The main objectives of the project were to examine:

- HREC members’ and researchers’ understandings of the ethics review process;
- HREC members’ and researchers’ understandings of the role of the HREC;
- the ethical principles and conceptual frameworks used by health researchers and HREC members in their ethical decision-making in relation to health research, and how these compare; and
- how these ethical principles relate to the National Statement in the ethical decision-making process and practice of both groups.
## Study Methodology

An overview of the study methodology, including sampling methodology and interview questions, is set out in Figure 1 below.

<table>
<thead>
<tr>
<th>Victorian HRECs—members in these categories:</th>
<th>Victorian health researchers in these areas:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Researchers</td>
<td>- Biomedicine, pre-clinical</td>
</tr>
<tr>
<td>- Clinical care</td>
<td>- Clinical</td>
</tr>
<tr>
<td>- Legal</td>
<td>- Epidemiology</td>
</tr>
<tr>
<td>- Religious</td>
<td>- Social</td>
</tr>
<tr>
<td>- Laywomen</td>
<td>(who are primarily involved in health research with human participants, have at least five years’ experience, and have submitted at least one ethics application)</td>
</tr>
<tr>
<td>- Laymen</td>
<td></td>
</tr>
</tbody>
</table>

**Australian Health Ethics Committee constituted committees, with at least two years’ experience**

### Our sample

<table>
<thead>
<tr>
<th>34 members of 17 HRECs</th>
<th>49 Health researchers at 16 institutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>27 metro</td>
<td>44 metro</td>
</tr>
<tr>
<td>7 regional</td>
<td>5 regional</td>
</tr>
</tbody>
</table>

### We asked:

- What kind of projects does your committee usually see and is membership of your committee public?
- What are important ethical issues you think your committee is looking for?
- How do you undertake the process of reviewing an application before the meeting?
- How do you review an application as a committee?
- What reference do you make to the National Statement?
- What do you think is the role of a HREC?
- How do you know what is ethical in research practice?
- As a supervisor how do you assist students to look out for the ethical implications in their research?
- What resources do you use as guidelines or guiding ideas about ethical conduct of research, including the *National Statement*?
- When you plan a project, how are you thinking about ethics?
- What kinds of responses to your proposals have you received from HRECs?
- How do you deal with ethical dilemmas in your research?
- What do you think is the role of a HREC?

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**Figure 1:** Study methodology
Sample

The study sample was drawn from metropolitan and regional centres in Victoria, and comprised HREC members and health researchers. It did not include administrators of HRECs. While a number of Chairs of HRECs are included in the sample, they were not recruited specifically. In total, there were eighty-three participants. Thirty-four ethics committee members took part in the study. They had at least two years’ experience serving on an Australian Health Ethics Committee (AHEC) constituted committee and came from all categories of membership: researchers, those involved in clinical care, and legal, religious and lay members (see Figure 2). However it is worth noting that a number of members were not able to specify to which category of membership they belonged. This was particularly the case when it came to distinguishing between the categories relating to ‘experience in professional care’ and ‘research experience’. Only two HREC members identified in the former category.

Forty-nine health researchers in the fields of biomedicine, epidemiology, clinical and social health research were recruited (see Figure 3). Health researcher participants were primarily involved in health research with human participants, had at least five years’ research experience, and had submitted at least one ethics application in this period (see Figure 4). While the disciplinary categories we used are distinct and broadly recognised, many of the studies described by participants cut across categories, and this often reflected the growing importance of large, mixed-methods public health studies in this research field.

![Categories of HREC membership in project sample](image1)

Figure 2: Categories of HREC membership in project sample

![Categories of health researchers in project sample](image2)

Figure 3: Categories of health researchers in project sample

![Researchers’ experience in submitting projects for ethics review](image3)

Figure 4: Researchers’ experience in submitting projects for ethics review
Recruitment

HREC member participants were recruited through HREC administrators, who circulated the project's Plain Language Statement to their membership and advertised the project at their meetings. Those interested made contact with the research team. Health researcher recruitment was carried out through 'node contacts'. Twenty-seven researcher 'node contacts' across the health research disciplines of biomedicine, epidemiology, clinical, and social and behavioural sciences research were identified by the research team as leaders in their fields. These 'node contacts' did not participate in the research but were asked either to contact, on behalf of the research team, researchers in their field who they believed met the selection criteria, or to supply the research team with contact details that would otherwise be available in the public domain. Contact was then made with these prospective participants. Additionally, two HREC administrators circulated the project's Plain Language Statement to researchers at their institutions, and some health researchers were recruited through this avenue.

To maximise heterogeneity, recruitment for HREC members and health researchers was undertaken in both urban and regional locations of Victoria, and across hospital, university, and non-government and government sectors.

Method

The participants took part in in-depth individual interviews. They were also surveyed for demographic information, such as length of experience, amount of time spent on ethics review, and overall experience of the system. The interview questions focused on participants’:

- knowledge of the National Statement and the relationship of the National Statement to their ethical decision-making;
- perceived ethical responsibilities as a health researcher or HREC member;
- experience of ethically contentious health research issues encountered and how these were addressed;
- ethical principles that influenced their decision-making in relation to health research ethics;
- views of the current system of ethics review and regulation;
- experience of ethics committees; and
- experience of research ethics training.

For researchers, views were sought about the role of ethics in the design and conduct of their research practice.

Interviews were conducted with five health researchers to pilot both the interview questions and the method of recruitment. Participants for these pilot interviews were recruited through professional health researcher colleagues. Following the pilot interviews, minor amendments were made to the interview schedule to clarify the questions posed. The method of 'node contact' recruitment also was refined at this stage. Although the method of recruitment of the pilot interviews differed from the main participant sample groups, they were nonetheless included in the data that were subject to analysis.

The data were thematically analysed to generate common themes and provisional hypotheses, and organised into a system of coded patterns and categories. From these coded patterns, provisional hypotheses were proposed. As well as analysing individual interviews, analysis was carried out across the interviews to examine similarities and differences between the sample groups. Ethics approval for this project was granted by the The University of Melbourne Human Research Ethics Committee.
Rigour

Data analysis was undertaken independently by each of the members of the project team, and emerging themes were identified and compared. Given the different disciplinary backgrounds of the researchers it was possible to test assumptions regarding the evidence from a variety of perspectives. To ensure the ethical rigour of the research, appropriate ethical standards were applied at each stage of the research. These included the protection of participants’ privacy through the storage of data in a single locked cabinet, and de-identification of all data. Participants’ quotes in presentations or publications will only be used where participants have given permission.

Feedback and dissemination of findings

The research findings have been or will be made available by the following avenues:

- Written report of findings to all participants.
- Written report of findings to Australian Health Ethics Committee.
- Forum (May 2008) entitled ‘Talking to the Other Side’, at which all participants and other interested people are invited to discuss a specific and important aspect of the research findings, namely, the lack of dialogue between HRECs and health researchers. A panel of HREC members and a panel of health researchers will discuss research ethics and ethical decision-making from their perspective. The aim of the forum is for each group to hear the perspective of the other and to create greater opportunities for improved dialogue and communication.
- Academic conference presentations—local, national and international.
- Academic journal publications.
4. Findings

In this section, we present the project findings. These relate to three major areas:

- The process of ethics review.
- The role of Human Research Ethics Committees.
- Understandings of research ethics and ethical decision-making.

Each aspect is examined from the perspective of both HREC members and researchers.

The Process of Ethics Review

For both HREC members and researchers, the process of ethics review was a major point of discussion in the interviews. Both groups regarded it as a serious endeavour to which they committed significant time and effort.

How the process is working for HRECs

HREC members reported a high level of commitment to their HREC work. It was extremely common during the interviews for members to bring out their papers for a forthcoming meeting or to indicate the impressive height of their pile of HREC papers. Many said they spent their weekends or the early hours of the morning reviewing research ethics proposals.

The workload for a committee member depended on the duration of their committee meeting and the time spent on the preliminary review of papers. HREC meetings on average lasted three hours, with some going over four hours, and some less than two hours. The majority of HREC members we interviewed spent more than four hours per meeting on their committee papers, with a tiny fraction spending less than two hours on this task (see Figure 5).

HREC members’ experiences

With few exceptions HREC members said they enjoyed being on the committee. They looked forward to meetings and saw the work they do as important and worthwhile. Many described being on the committee as a privilege, with some saying it fulfilled a need to give back to the community. There is a strong indication from our findings that members find their work productive. They perceive that they have played their role in making sure that research projects fulfil ethical standards and that participants in projects are protected.

What stood out from many committee members’ accounts of the meetings themselves was their appreciation of the mutual respect between committee members, as well as openness to different opinions and perspectives. They regularly spoke of the stimulation and satisfaction they derived from the opportunity to deliberate over important questions and hear perspectives that differed from their own. Non-institutional members of committees found it interesting to learn about the research and culture of the health sciences. For researchers, too, being exposed to the variety of research in the institution provided an impetus for their HREC work.

This is a way of contributing to the research community, and my natural curiosity about what research is happening. I like to see what’s happening around the place—they’re doing that with [named clinical approach] now, they’re doing that with [named clinical intervention]! I love it. I just feel it’s a privileged place to be…

(H11)
Comments on HREC composition

Some members commented explicitly on the committee structure saying that it works well. The majority of those interviewed talked about the structure implicitly, making comments about the value of different perspectives in the group and the importance of being exposed to a wide range of views on the same research proposal, including ‘the community view’. In several cases, members spoke of feeling that if everyone was at the HREC meeting things were ‘covered.’ At the same time a few pointed to issues in the committee composition, for example, that members often have very long membership terms (see Figure 6), and are generally older, well educated, upper middle class, from a Judaeo–Christian culture, and may have limited insight into the circumstances of many research participants and population groups.

**Figure 5:** Time spent on meeting preparation by HREC members in sample

**Figure 6:** Years of membership on ethics committee by HREC members in sample
HREC members’ perceptions of their committee’s performance

Overall, HREC members reported that their committees were doing a good job. They saw themselves and their committees as diligent and equipped with the necessary expertise to fulfill an ethical review.

I think we do a really good job and I think I’ve appreciated that being on another ethics committee that doesn’t have the experience and the work load, and I see how much hard work they make of it. I think because we have a lot of experience we’ve got very good at picking the eyes out of what it is we need to address. We don’t need to get petty, so we actually address the real stuff and the commitment of the people on the ethics committee I think really makes that work. (H34)

It is apparent that the Chairs of HRECs play a crucial role in the performance of committees, and their importance was referred to by almost all HREC members. They were described by committee members as playing multiple roles: setting an appropriate pace for meetings that could otherwise easily become bogged down; establishing a climate of enquiry that builds consensus; nurturing respect between members of the group; and encouraging laypeople to feel that their contribution is worthwhile.

I think our Chair is a very generous Chair, as in he allows everybody the space and respect, it doesn’t matter how little you are in the scheme of things or whether you’re top dog in your field. I think that certainly allows some of that. And I guess his whole philosophy of how to promote research in science. (H34)

It was very often the Chair who made decisions on whether to seek more information from researchers and, in many instances, the one who had the last word when decisions were contested. It was deemed important that Chairs know the National Statement extremely well. Their strategic insight was considered vital, since ultimately ‘it is up to the Chair’ to make sure the HREC fulfills its role to protect participants and institutions, especially when there is a high level of risk involved.

Our findings also show that administrators had a significant impact on the overall HREC review process. Ethics review generates enormous quantities of paperwork and HREC members spoke highly of administrative efficiency, as did researchers. At the same time, HREC members and Chairs often spoke of the administrator as being an expert on the National Statement. Other qualities of the administrator that rated frequent mention were: experience and qualifications in the field of ethics; ability to deal tactfully with stressed researchers, including people with considerable power and status; and skills at following up with the right questions to Chairs and researchers. We noted that in different instances the administrator was identified as an executive officer, a secretary, an administrator, ‘our ethical lady’ and a CEO, reflecting different perceptions by HREC members and researchers of the role, or of the person’s experience and qualifications.

There were many comments on the way the range of experience of members and the maturity of the committee impacts on HREC performance. Many HREC members wear two hats—as researcher and as HREC member. This gives these members special insight into the ethics approval process and the role of the committee. Some researchers described significant changes in their attitudes to HRECs upon joining an ethics committee. However, new committees and new committee members take time to come to grips with their role and to work effectively towards the HREC’s goals.

I’ve seen on some committees, a new person comes on, and they have a drum to beat, they’re like a dog with a bone—they will not let it go. Whenever a project comes up, they ask the same question, and it can never be answered in a satisfactory way. That really frustrates committees and it really frustrates researchers. That’s where a Chair has to make a decision, whether this repeated raising of a particular issue is in the best interests of the operation of the committee and the ethics of the research. (H1)

On the other hand, there were suggestions that committees with no new blood and long membership terms could develop unquestioned norms that produce ‘groupthink’ with a negative effect on decision-making. A suggestion was made that rotation of experienced committee members between HRECs would be a useful way of dealing with this.

Certain HREC members spoke of feeling constrained by regulation, and saw themselves as part of the ‘machinery’ of drug company trials.

There is some research which is more geared to marketing than actual development of new drugs. So even research ethics committees are drawn into that slightly corrupt world of marketing and commercial competition. We’re part of that machinery if you will. (H3)
Useful processes

A large number of committees whose members we interviewed have systems for expedited review of applications. Those committee members who had previously been on committees that had expedited review, and were now on committees that did not, spoke strongly about the importance of expedited review to an efficient and workable committee process. More than half the committees represented in the study reported 'shepherding', with one member or a pair of members as spokespeople for particular projects through the process. This was seen to provide focus and to greatly assist these committees.

In one interview there was extensive reporting of a large institutional committee's work to separate the governance and ethics review aspects of the process. This institution's response reflects an issue broadly reported in our data, that is, the growing burden of governance requirements on a HREC's workload.

Specific concerns—HREC members

Poorly presented ethics applications

For the HREC members interviewed, applications that attempted to gloss over ethical issues and/or showed a careless approach to presenting an application demonstrated a lack of respect for the ethics review process. This was particularly the case if the same researcher regularly failed to address requirements and provided overly technical lay summaries.

There'll be a couple of researchers who consistently put in below average applications. That doesn't make us trust their research... (H34)

Some HREC members described feeling powerless to deal with researchers who are unwilling to justify the ethics of their research and go through the motions without genuinely anticipating potential issues for participants.

Monitoring

There were many comments about monitoring approved projects, ranging from HREC members having an interest in how things turned out to serious questions on the part of one or two members about how individual committees gauge whether to follow up adverse events in multi-site drug trials. Overall, HREC members were aware that once a project has been approved they have little influence on the research ethics and were uncomfortable about this.

We have some researchers when you see the name on the application you quake because you know it will be a dreadful application with things missing, things left out, going off the rails and so on. That same person in practice could be top rate, I don't know, and we have other researchers who have a reputation for putting in excellent applications but they could be the very devil in the field, again you don't know. So all we can do is look at the paperwork, we're not going out sitting on the shoulder of the researcher when they're conducting the research. (H20)

Lay and other non-institutional HREC members' relationship with technical experts and information

Non-institutional HREC members reported different levels of ease with regard to technical review of ethics applications. Almost without exception they described having to trust the technical experts on their committees, especially when reviewing complex clinical trials. However, they were sometimes concerned about this.

I don't like working with things I don't understand basically. And I know I wasn't meant to understand the science particularly, and the participants don't, but that's not my comfort zone. (H34)

At the same time various non-institutional HREC members described needing to be patient in their interactions with lay members on the committee. Some said that they had to bear in mind the important point that lay members' views often reflected the community's view.

Training and compensation of lay members

A significant number of lay HREC members contrasted the high level of commitment required of them with the low level of compensation they receive as volunteers in terms of training and simple benefits like parking vouchers and refreshments.

Specific concerns—regional HRECs

Almost all regional HREC members interviewed noted that it was important to consider the small population base in which regional researchers operate, and from which participants are drawn. Comments highlighted the sensitivity required of researchers in relation to participant confidentiality, and also of HREC members in respect to fairness to researchers in the ethics review process, since they were likely to be well known to committee members.
Multi-site process and regional research

A number of HREC members expressed uncertainty about multi-site streamlining. They stated that centralised, metro-based committees were likely to overlook issues specific to regional researchers, communities and participants.

Training and networking

From the regional perspective it was particularly difficult to access training because of distance and resourcing issues. Regional HREC members expressed the desire to network with other HRECs and find out how other HRECs operate.

How the processes of ethics review are working for researchers

The researchers interviewed recognised the necessity for HREC review and its role in ensuring that participants’ rights are protected. They regarded preparing ethics applications as another step in getting research underway, and one which entailed considerable work (see Figure 7 below).

There was some variation, but a large number of researchers discussed the value of ethics review. Firstly, ethics review demands that researchers clearly articulate their research and look realistically at the benefits and risks of their research.

I actually think doing an ethics application helps clarify in your own mind what your research is about, and makes it easier to articulate that to other people when you're talking about your work. It does make you think about what will the next step be too. (R12)

Secondly, researchers commented on the benefits of their proposals receiving vetting from an independent body. Many researchers saw the process of ethics review as a safety net that offers protection to researchers.

Researchers ascribed particular importance to HREC Chairs, taking the view that it is they who establish the tone of particular committees. A number of researchers said that they could be confident that chairs would know the National Statement very well. Our findings show that approachable administrators are highly influential in informing researchers’ thinking about ethics. Administrators are often the first port of call with enquiries and act as intermediaries between committees and the research community. Many researchers claimed that when it occurred, discussion with HREC administrators and Chairs was useful. However, this was not the rule, and some researchers reported very frustrating attempts to communicate with committees. Researchers who had experienced notably difficult issues with an HREC over a particular application, either in terms of delay or their personal treatment, said that it was difficult to put these experiences behind them.

Many researchers reported frustrations with the time taken to submit ethics applications, and delays before receiving approval. However, they described how they became progressively more efficient at doing so, often using material from existing applications.

I start filling my application and then I remember ‘in this case with this population I think the reason that we gave in the last project that we worked with them was…’ We’ll be able to look at the past applications as well and look at the comments from the committee to our response. So past applications really help me to develop the new application because the issues are quite similar. It is becoming easier to field these and to justify and to negotiate with the ethics committee in terms of the reasons for doing that. And that's in the case of the verbal consent, it's in the case of compensation to participants. So basically the previous applications really help me to work on the current one. (R31)
Specific concerns of researchers

The two predominant concerns of researchers were reviews of multi-site trials and the lack of recognition of ethics in the field by HRECs. An additional concern of some researchers was that HRECs lack capacity to follow up what actually goes on in practice, once a research project is approved.

Multi-site applications

Researchers reported their concern that committees responded quite differently to the same proposed project. The differences were hard or impossible to predict and resulted in considerable time spent on minor word changes. There were mutually inconsistent changes to project protocols at different sites. This regularly caused inefficiencies and time delays. This issue was particularly problematic for multi-site epidemiological studies.

Ethics in the field

Some researchers spoke of many sensitive yet everyday interactions that go on as part of developing relationships and trust with research participants, which involve the researcher having to judge what is right in the moment. Examples given included: how to conduct research practice in such a way as to allay participants’ anxieties; how to respond to participants’ requests for assistance; and how to deal with an unexpected instance when the role between researcher and clinician becomes blurred. Various researchers spoke about the difficulties of getting truly informed consent from participants in certain population groups, weighing this up against the importance of research actually being conducted in these areas.

I mean [it’s] important research data to be able to gather … my gut reaction in terms of the ethics committee and the work that I do, it’s a little bit hands off, it’s a bit too detached from … the true reality of doing work with this population. (R19)

Some researchers felt that HREC members were not aware of the complexity of these matters, or the thought and effort that researchers put into dealing with them appropriately.

Fees for HREC review

A small number of researchers in the clinical category expressed the strong view that researcher-initiated projects that do not have commercial funding should not be subject to fees for HREC review. They believe that HREC fees threaten to stifle non-commercially funded research.

When they want to charge you as a researcher to put things through ethics, I find that hard because I don’t have great budgets, I’m not in a real sexy area, I struggle to win grants. So for me to suddenly pay $500 or whatever it is, maybe I’ve got it, maybe I haven’t. I think that our institutions have to recognise that you want to attract the best people, those people want to be doing research, you need an infrastructure that’s going to support that, and the ethics committee should be part of it. That’s why I volunteer my time to be on my subcommittee. That’s often been mooted that we will move towards a charge for ethics, and I would argue against that, because I think, you know if you’ve got a drug company sponsored trial and they’re sinking $1,000,000 into the trial well fine, charge them $5000 who cares. But when you’ve got in-house studies with your investigators scratching around to get the money to do the assays, I just think you want to do everything to help them rather than put a barrier in place. (R17)

Shared concerns—HREC members and researchers

Student projects

For all but a few HREC members interviewed, student projects and quality of supervision were a cause of concern. Members were often concerned about whether supervisors had exercised sufficient oversight in preparation of ethics applications and had realistic expectations of the students and project timeframes.

I think it’s generally held by the committee that a lot of the graduate research proposals, the standard is very often poor, and it’s really the supervisor’s responsibility. So where a Masters student or a PhD student’s project or proposal is inadequate in various ways, they should never have come through. It really speaks to poor quality supervision. (H12)

Some HREC members spoke of their own awareness of the timeframes for Honours’ and Masters’ projects, in relation both to the time needed for ethical review and the time to actually carry out the project. Their view was that the committee should try to be helpful in their comments to students so as not to discourage them from undertaking research.

The review of student projects was a concern for many researchers interviewed, the majority of whom supervised higher degree research students. Researchers spoke of delays in approving students’ ethics applications having a detrimental and sometimes damaging effect on projects with
Role of Human Research Ethics Committees

What are the roles of the HREC?

There was considerable overlap between HREC members’ and health researchers’ views on the role of HRECs, and widespread agreement from both groups that the role of HRECs was to:

- protect participants;
- ensure that the benefits of research outweighed the risks;
- assist and guide researchers in the ethical conduct of research;
- ensure the merit and value of research under review; and
- ensure the methodological rigour of the research.

Despite this agreement between HRECs and health researchers there was variation in views between, and occasionally within, the two groups in terms of:

- whether HRECs actually fulfilled these goals;
- the extent to which these roles were carried out; and
- whether HRECs attempted to operate beyond these roles.

I think ethics committees have become so bound up in the procedure part of it and the legal ramifications of not doing their jobs that they’ve actually forgotten what research is about… I don’t think they’re sort of really concerned about the ethics, I think they’re concerned about the legal constraints or the legal implications of what research might mean. You know, the possibility of being sued or whatever, rather than their responsibilities to researchers and participants and the ethics of both. (R22)

Well, I think the role of the ethics committee is that it ought to be a bit more than ticking boxes as to whether you’ve met certain technical requirements. And that’s what’s worrying me now about the kind of ethics form they’ve got. It’s so technically driven, like have you put these things into your Plain Language Statement or have you tick, tick, tick the box? Or have you mentioned the exclusion criteria or something like that? Which are all technical aspects of research, which I haven’t got a problem with, but I can’t really see how that actually addresses ethics, in the sense of
the reasoning process where you’re actually considering your methods and why you’re doing what you’re doing and how you treat the people that are your informants. (R32)

Both groups agreed that HRECs should be an advisory body and serve as a resource for researchers in the ethical conduct of research. Although many researchers spoke in positive terms of the assistance they had received from HRECs, this was not a uniform response. A number of researchers stated that HRECs were ‘actually a bureaucratic hurdle’ serving as ‘gatekeepers’ in blocking research, for example, by being overly protective of participants rather than leaving them to make their own decisions.

So there’s a lot of gate keeping by ethics committees. And I sometimes think that they think that participants must be stupid [laughs] or not able to make their own decisions, you know. If as long as a person can read and they can ask questions, be fully informed, then it’s as an adult they have a right to be in a study or not be in a study, as long as they’re safe guarded so they can drop, opt out and they can take the data with them. (R22)

Some researchers questioned the ability of HRECs they had encountered to fulfil their role of ensuring that benefits outweighed risk due to lack of methodological expertise or comprehensive knowledge of the research context, in particular when dealing with vulnerable populations.

I don’t have an expectation that a full committee will have a lot of methodological expertise amongst them, even with the clinicians that are there, they’ll have some idea but not necessarily a lot. I think that’s why having a technical panel committee review specifically for that is a good idea. I guess sometimes it’s a struggle to get them to understand why it’s important that the research be done. (R12)

HRECs and methodology

A further point of variation was whether HRECs should give methodological advice or direction. There was widespread agreement from both HRECs and health researchers that HRECs should take into account the appropriateness of the proposed research methodology when conducting ethical review, both in terms of methodological rigour and ethical integrity. Researchers and HREC members took the strong view that it is unethical to conduct research if it is poorly designed and cannot produce meaningful results. However, there was considerable disquiet on the part of researchers when HRECs attempted to direct researchers as to what research methods to use. This was perceived to exceed the remit of the HREC’s role.

I think they can make a useful contribution to the methods without telling people how to do their studies, but I think there can be some things raised about, well is this necessarily the best way to go about asking those questions? So I would feel it wouldn’t be too much of a thing to justify why you’re doing something in a way. If you’ve got research money to do it, then you’re clear about why you’re asking that thing, and convincing an ethics committee I think that’s part of the role. (R19)

I still argue whether certain things are actually ethical or not when ethics committees are sort of making rulings, telling me recently, basically trying to alter my methodology… I actually regarded that it was not an ethical issue—but I answered. (R24)

HRECs and protection of the institution

Another point of concern was voiced by some researchers who believed that HRECs were protecting the institution rather than protecting participants or researchers. It was felt that the reputation of the institution sometimes took precedence over the rights of the participants or the researchers involved.

I was once told by the Chairperson of an ethics committee that he saw it as making sure that the university didn’t get sued. And I guess my experience of various ethics committees is that for some of them that seems like that’s how they operated. It’s been more a concern about ensuring the university’s reputation than actually about ensuring good research. And I had no problems with ensuring the university’s reputation, but I think when that becomes the only rationale and everything else is secondary that becomes problematic. (R24)

Monitoring

Finally, regarding the monitoring of research once approved, many HRECs and researchers believed that this is an appropriate HREC role. However, most felt monitoring was rarely done in anything other than a cursory manner.

On whose behalf do HRECs act?

When HREC members were asked on whose behalf they made decisions, there was often pause for thought. Generally, irrespective of category of membership, they agreed that as HREC members they made decisions on behalf of participants and the community at large. However, those members who were also researchers were more likely to add that they also had a responsibility to support researchers and to ensure the safety of researchers.
in the conduct of research. Of note was that members from the religious category did not see their role on the committee as representative of that particular category; they were there as individuals who were on the committee to represent the interests of participants. Members in the legal category also saw themselves in this way, but emphasised their capacity to bring a principle-based view to thinking about protecting participants and, in particular, their privacy.

**Understandings of Research Ethics and Ethical Decision-Making**

**HREC members’ individual approaches to research ethics and ethical decision-making**

HREC members described a range of different understandings of research ethics and different approaches to ethical decision-making. Their various approaches to ethical evaluation were largely complementary rather than contradictory. Often a HREC member would describe using a number of different approaches in looking at a single application. In terms of ethical evaluation and decision-making they spoke about both their own thought processes when reading and assessing ethics applications and the nature of group discussions during the HREC meetings.

HREC members described the following individual strategies and approaches to considering and evaluating project applications prior to an HREC meeting:

**Principle-based**

This approach involved explicit reference to ethical principles, especially those named in the National Statement. Many HREC members readily named two or three ethical principles that they regarded as being of central importance. HREC members stated that they thought about the projects presented to them in terms of how well they met the basic ethical requirement of scientific merit and the general ethical requirements of benefit. Many defined these aspects as ‘worthwhileness’. At the same time, they regularly referred to informed consent, justice and privacy, and minimising of risk to participants. In relation to informed consent, almost all participants said they put their initial focus on the Plain Language Statements and Consent Forms. Many checked to see that the information given to participants matched what was said in the project description in the body of the application, especially bearing in mind potential risks to participants.

The principle-based approach when used by HREC members met researchers’ expressed desire that HRECs provide them with principle-based feedback, preferably using ethical principles from National Statement. At the same time, numerous HREC members spoke of principle-based reflections from other members providing a common language that could assist with communication within the HREC.

I’ve noticed that it seems that when the correspondence goes out to the researchers in response to any changes or any comments, whatever the comment is, if it can be backed up by some section from the National Statement, it seems to carry more weight. (H21)

**‘Flags’**

Many HREC members also described looking at the applications to see if there were particular aspects or features which they took to be ethically problematic. In essence, they had a pre-formed mental list of these ‘problem areas’. The items on this mental list acted as ‘flags’ to help them identify and focus on aspects of projects that would be particularly ethically problematic. Members had their own sets of ‘flags’, but many items were common. These included placebo-controlled trials, use of new or dangerous drugs, inclusion of vulnerable participants, deliberate deception, research on illegal activities, and exclusion of certain groups of participants (especially people of NESB).

A few HREC members alluded to issues with using flags through the use of references to individual members ‘getting a bee in their bonnet’ or having ‘pet’ issues, resulting in too much attention being given to things that were not particularly ethically problematic.

**Imaginative identification**

One strikingly common approach to ethical evaluation emerged in our data. We have called this ‘imaginative identification’. Many HREC members explained how they imagine either themselves or a close family member as a participant in the project, and ask whether they would be prepared to participate themselves or would be comfortable for the family member to participate.

One gets used to being in the person’s shoes as it were—obviously you haven’t experienced everything, but just looking at things from their point of view. I can put myself in the position of them and feel a lot of empathy for what they might be going through. (H13)
Imaginative identification appeared to focus the attention of the HREC member on what it would be like for a participant to actually be involved in a project, and allowed a particularly vivid and non-abstract way of considering the potential risks and disadvantages to participants, as well as possible benefits they may derive from participation. This strategy is well matched to the overall purpose of the HREC as stated in the National Statement, namely ‘to protect the rights and welfare of participants’. A small number of participants pointed to possible pitfalls in this approach. They were aware that those using it might tend to bring along their own values, preferences and experiences when imagining what it would be like for the other person.

Personal values, experiences and intuition

A number of HREC members indicated that they drew on their own values and experiences to assist them in evaluating applications. The experiences they mentioned included their own experiences of being a patient or research participant, or having a family member or a friend who had had this experience. Drawing on this experience enabled them to have a better understanding of what it might be like to be a participant in the project they were reviewing and what concerns there might be for participants.

In relation to their personal values, many HREC members spoke about being guided by ‘intuition’ or ‘intuitive feelings’. Some pointed out that values they drew on in this process were the ones they had developed during their life, rather than those set out in the National Statement, or any other formal code or set of guidelines.

I know when I’m reading protocols I don’t sit down and think: now what are the autonomy issues? What are the beneficence issues? And all that. But if somebody said: what does that come under? You could say ‘well yes, that comes under that and that’. But I don’t know that it’s useful looking at it in those terms. For some people it might be useful to do it that way, but it’s more as I read through something I sense that there’s something wrong here.

But interestingly, a number of committee members made quite explicit statements that they consciously did not use their own values but rather tried to take a more generic, community perspective. This was the case for some laypeople and for some religious members.

Now that’s what ethics is all about isn’t it, it’s deciding whether something is proper. Now ethics is applying not our own values, but proper values to things, and considering all issues.

Researchers’ abilities and attitudes

Another approach to decision-making in ethics review was to seek to make an evaluation of the researcher, as well as of the proposed project. Some HREC members described how they tried to work out from the way the application was presented whether the researchers really understood ethical considerations or were just going through the motions of filling in the form.

What I’m really looking for is something that says to me they understand the principles of ethics. So they understand issues around what informed consent actually means, and they understand what privacy means. They understand about voluntariness and that there’s been a genuine attempt to address those issues. So it’s really looking for what would seem to be an understanding as opposed to, I’m just filling out a form, I’m just going through the motions. If I get the sense that [they are] just going through the form, then my alarm bells go off.

Others were looking to get a sense of the researchers’ values or their attitude towards research participants.

So I suppose it’s the way the thing is presented, the consideration for the people who are involved, the fact that their privacy is being safeguarded, that they’re considered to be partners in the exercise rather than just guinea pigs.

These approaches may reflect the emphasis given in the first few pages of the National Statement to the need for researchers to have integrity, but it is not possible to tell from our data whether this is the actual reason that these HREC members looked for evidence of researchers’ attitudes. Members wanted to feel confident that they could trust the researcher. They worked at getting clues from the written application but found meeting the researcher in person much more helpful. When researchers attended meetings they described being ‘reassured’ by the way the researchers presented themselves.

And it also brings to the members of the committee an opportunity to see the quality of the researchers, to see that they are human, and that they’ve got the best interests of their participants and the reasons why they want the research done. So, it builds a trust between both parties.
There was, however, some recognition that making personal judgement about researchers could be problematic.

I think it is [problematic] — and that can mean getting involved in making decisions about people that you shouldn’t make, or things that have happened a long time ago that people still carry the history of. So I was thinking look, I’d really like to know a bit more about them and then, why do I want to know? And then that becomes a really subjective judgement. (H27)

Strategies for reading agenda papers

A number of members described strategies that they used when reading the many applications in their agenda papers for each meeting. These strategies were related to the approaches to ethics or to decision-making described above. Rather than read straight through each application from start to finish, some members explained how they focused on particular parts, or read particular parts first, in order to focus on what they regarded as the most ethically significant aspects of the applications.

This is the process I use. I start with Module 1 and I look at the lay description to satisfy myself that it is something worthwhile, that it is legitimate research. I then look at the people who are involved in the research and whether I think their description of the work they have done… now this is perhaps a wrong word… whether they are competent to do it. Now it might be said I have no idea whether they’re competent, but whether their discipline and what they’ve done say, ‘Yes they should be involved.’ (H6)

A number of HREC members explained that they looked first at the Lay Summary and the Plain Language Statement to check that they matched, before going to check matches between the Plain Language Statement and what was said in the application form about risks and benefits.

HREC group decision-making processes

Many of the individual strategies for ethical deliberation noted above were also referred to by HREC members when they were talking about group discussions at HREC meetings. Above and beyond these, though, virtually all committee members emphasised that decisions made at the HREC meeting were the result of a genuine group process. They described how, as other members of the committee spoke, more points, ideas and issues were raised which they had not personally recognised. They did not see this as negative in any way or as an indication of disagreement. Indeed, the vast majority of HREC members reported that they did not have significant disagreements on their committee and reached their decisions by consensus. The range of different issues raised by different members at a meeting was interpreted as a clear indication of the value of the group process.

Somebody raises an issue and others talk about it, and as people talk about it, it’ll be decided as a group that something needs to be said about this or done about it, or something needs to be clarified or justified. (H21)

Some members explained how they relied on the whole committee rather than on particular individuals to make good decisions and felt more confident of the committee’s decision-making when all members were present.

I think what I really enjoy and what always surprises me, is when we’ve had that first discussion, and we go around the table and it’s like people pick up stuff that I have never seen, or I go [x] and they go I hadn’t even thought about that. So what I get a sense of is a real confidence that we’ve got the things covered. Because we have an ethicist, we have a clinician, we have the two laypeople—they are really thinking laypeople. They’ve got no background in research but they really think about stuff, and they bring that. (H14)

When this range of ideas and issues was discussed, members characterised this as ‘bouncing off each other’, a process in which concerns were considered, evaluated and refined. Many of the members indicated that the Chair played a crucial role in making this process work effectively. ‘Good’ Chairs were described as ensuring all voices on the committee were heard, helping the committee to evaluate the relative significance of the points raised, and guiding the committee in reaching consensus.

Researchers’ understanding of research ethics and ethical decision-making

A number of researchers found it difficult at first to articulate how they knew or decided what counts as ethical or unethical research. Their ethical values and principles appeared to be deeply implicit in their practice so that there were some things that they would not even consider doing, and others that were seen as absolutely standard practices not requiring any ethical consideration as such. Others articulated their thinking about ethical practice in research very readily and specifically. Researchers stated clearly that ethics was, for them, an integral
part of research. Consideration of ethics came right at the start of research project planning.

In discussing their approach to planning research and filling in ethics application forms, researchers pointed to a number of approaches to thinking about ethics of research:

**Formal Principles**

Some researchers used formal ethical principles in explaining how they thought about the ethics of their research. In particular, they named beneficence, non-harm, autonomy, informed consent, and privacy/confidentiality, which are the key principles named in the *National Statement*.

> Ethics, I think, involves that there is no right or wrong answer one hundred percent. It’s just that you need to balance that and probably if you think of the principles of ethics in terms of respect to people and beneficence and justice as well and integrity, and as long as you have that clear, I think you can never shed that. (R31)

**Informal principles or values**

More commonly, researchers referred to informal principles to convey their thinking about ethics, especially when they tried to pin down the crucial issue or fundamental idea. These principles were informal in the sense that they appeared to have been derived by each researcher through their own process of reflection rather than adopted from some formal external source. Some researchers seemed to suggest that understanding of the right way to treat people is a basic human quality that researchers have because they are human beings, rather than something that they acquire because of being a researcher.

**Imaginative identification**

Researchers gave accounts of thinking about the ethics of their research by trying to imagine what it would be like for the participants—or either by imagining themselves or a close family member as a participant. This is the same strategy described by HREC members.

> I figure most of my medical decisions in terms of... would I want me to be doing this to me or to my mother? Now I don't think that's probably the best marker in terms of ethics but I can’t find a better one. [In research], it’s the reasonable man kind of thing, I always think. If it was me, what do I think is reasonable to expect of me? (R30)

As this quote shows, there was some degree of recognition that while this was a useful approach it could be somewhat problematic. One researcher even went so far as to recommend that researchers actually become a research participant, in order to do this well.

> I tell any students that I have, that it's very important if you're serious about research, jump the fence and be a participant. Compare what actually happens to you, to the information you read in the information sheet. (R11)

**Resources**

Researchers also described a number of resources that they drew upon in order to make decisions about ethics, in particular about the types of research design and practices that were ethically appropriate. Previous experience was important; researchers made decisions based partly on aspects of prior research projects that had been approved by, or had raised concern for, ethics committees. They took note of what other researchers, especially senior researchers, were doing and learned about research ethics by role modelling rather than by either explicit instruction or by introspection.

Those with clinical training and experience claimed that they drew on this to help them understand ethics in research.

> I think that that experience working with clients, with patients and ethics that really guides medical practice really helps me to understand some of the issues, especially in the issues of illness, the issue of privacy as well and autonomy and confidentiality, and integrity in the research and integrity in my work and my treatment of my colleagues. (R31)

Researchers also consulted with their colleagues about ethics in a number of ways. In the process of formulating an ethics application, members of a research team often communicated at length about the details of the research design and how to explain it in the ethics application form. Researchers also talked with their colleagues outside their own research teams to get a feel for what was generally accepted as appropriate practice in their particular area of research.

Researchers made many comments which indicated that their own sense of integrity, personal and/or professional, was important to them. In some ways, their integrity was a way of thinking about ethics but it also functioned as a motivating force. The drive to act ethically in the conduct of research for many researchers came from within, as a strong personal need to do the right thing rather than as a response to externally imposed processes and standards.
Use of National Statement and Other Guidelines by Both Researchers and HREC Members

There was considerable variation in the extent of knowledge and use of the National Statement among both researchers and HREC members.

Most HREC members had ‘some’ to ‘good’ awareness of the contents of the National Statement. Interestingly, members tended to see the Chair of the HREC and/or the administrator as the repositories of knowledge on the National Statement and would look to them in meetings for guidance on these matters. HREC members used the National Statement in a variety of ways.

One common account was that they had read the National Statement at some stage in the past, had internalised the basic principles, and now did not refer to it directly. Others did refer frequently and directly to the National Statement, either during meetings or in preparation for meetings, as a way of checking or giving a basis for their intuitive concerns about a project. It was also used during meetings or in correspondence with researchers.

Researchers who knew and used the National Statement did so for a variety of reasons. These included feeling that the National Statement supported their view on what was an ethically appropriate way to do a particular piece of research and was, therefore, useful in making their case to the HREC.

It should be noted that a few HREC members did not use the National Statement at all or were barely aware of it.

There was a similar range among researchers. Some had never read it, some had skimmed through it and felt they had a good grasp of the general ideas, and some referred to it frequently and directly as a source of guidance about how to design their projects. This was particularly so for researchers whose field of research is ethically contentious and is covered by a specific section of the National Statement. Examples include epidemiology, genetic research, research on illegal activities and research with children. Most researchers regarded the National Statement and similar guidelines as a good starting point but by no means the whole story in deciding what constitutes ethical practice.

You certainly, you’re aware of them, they form a basis I think that’s probably the best you can say, they’re a beginning, a beginning, they’re something. (R13)
5. Recommendations

On the basis of these research findings, we propose that HRECs and research institutions in Australia act on the following recommendations. We note that these recommendations have some similarities with recommendations made in a number of publications on ethics committees in the last decade, such as Chuppli and Fraser,15 Chalmers and Pettit,16 Savulescu, Chalmers and Blunt,17 and Jamrozik.18 These similarities indicate that it is timely to act on them.

1. Develop and implement systematic mechanisms and strategies to open communication and improve dialogue between HRECs and researchers

These strategies should focus on the actual implementation of suggestions and guidelines articulated in Section 5.2 of the National Statement. They should aim to encourage cooperation and collegiality between HRECs and researchers rather than an adversarial approach. Systematic mechanisms at an institutional level would serve to break down the notion of the ‘faceless’ ethics committee. Specific recommendations are to:

a) Develop formal mechanisms to encourage researchers to consult with the HREC before submitting an application and set guidelines to ensure common understanding of expectations and boundaries in these consultations.

b) Develop guidelines for processes to be followed when researchers attend HREC meetings. These would serve to enhance researchers’ respect for the role of HRECs as a facilitative and cooperative research resource and support. It would ensure best value is gained from the attendance and indicate respect for researchers.

c) Develop a process that enables researchers to attend HREC meetings as observers and provide anonymous feedback to HRECs through the administrator.

2. Expand training for researchers in research ethics

The training of researchers in research ethics tends to be ad hoc and may over-emphasise procedural matters of research ethics, such as how to apply for ethics approval. It is recommended that the training of researchers be expanded in the following ways:

a) The content of training for researchers should specifically promote understanding of what HRECs seek when reviewing applications. This would include, for example, making clear that HRECs want researchers to openly acknowledge ethical issues in their ethics applications and the ways that they will address these, rather than ignore or gloss over them.

b) Specific research ethics training for Higher Degree Research supervisors should be mandated by institutions. This should address their obligations to train and support students in acquiring ethical knowledge and skills and to take appropriate responsibility for the ethics application.

c) Training for researchers should make systematic use of the experience of researchers who have sat on HRECs and who are able to understand the ethics review process from the perspective of both researchers and committee members.

d) Provision of opportunities for HREC members to be exposed to research in the field, particularly in sensitive and clinical research contexts. This could be achieved, for example, by short-term placement or meeting of HREC members with research teams. This would be consonant with many HREC members’ commitment to the research endeavour and would enhance understanding of ethical research practice from the researchers’ perspective. Guidelines should be developed to ensure mutual understanding of the purposes and boundaries of such placements and to emphasise that it has nothing to do with monitoring of particular projects but is for purposes of education and training.

e) Ready access to training for HREC members in regional and rural areas should be ensured.

3. Expand training of HREC members

There is considerable training provided through the Australian Health Ethics Committee for HREC members. We recommend that the scope of this training be significantly expanded to include the following:

a) Training in different strategies that might be employed in evaluating ethics applications, including a workable approach to dealing with the paperwork, as well as training in the processes of making decisions both as individuals and as a committee. This would include training in reflecting on the personal and professional values each HREC member brings to the decision-making process and the influence this bears.

b) Training in how to communicate the committee’s decisions and requests for changes or further information to ensure that their rationale is clear to researchers and is linked to the National Statement.

c) Training in the processes of making decisions as individuals and as a committee. This would include training in reflecting on the personal and professional values each HREC member brings to the decision-making process and the influence this bears.

d) Specific training for rural and regional HRECs that would include providing assistance in how to manage the multiple roles of many rural and regional HREC members.

e) Ready access to training for HREC members in regional and rural areas should be ensured.

4. Implement membership processes for HREC members

a) Ensure regular turnover of HREC membership. This could be achieved by defined terms of membership, for example, an expectation that members only serve for three years to maximise opportunity for participation.

b) Develop systems to spread expertise of members between HRECs. Rotation of experienced members between committees could be considered so that expertise is not lost to the system as a whole.

5. Form a working party to deal with Plain Language Statements and Consent Forms

The excessive length of the Plain Language Statement and Consent Forms is a well-recognised problem that was commented upon by almost all of our participants. It is recommended that AHEC form a working party to address this. The working party should involve key stakeholders including insurers and pharmaceutical companies and should aim to produce agreement on acceptable shortened and simplified Plain Language Statements and Consent Forms.