Human research ethics in practice

HUMAN RESEARCH ETHICS IN PRACTICE

DELIBERATIVE STRATEGIES, PROCESSES AND PERCEPTIONS

***Lynn Gillam**, The University of Melbourne*
***Marilys Guillemin**, The University of Melbourne*
***Annie Bolitho**, The University of Melbourne*
***Doreen Rosenthal**, The University of Melbourne*

In theory, HREC members should use the ethical guidelines in the *National Statement on the Ethical Conduct of Research Involving Humans* as the basis for their decisions, and researchers should design their research in accordance with these guidelines However, very little is known about what researchers and HREC members actually do in practice. In this paper, we report some of the key findings of the study "Human Research Ethics in Practice", a qualitative interview-based study of health researchers and HREC members in Victoria. The findings shed light on how researchers and HREC members conceptualise ethics, how they use the National Statement, and what deliberative strategies they employ to assess the ethical appropriateness of research studies. The findings also reveal differences and similarities between health researchers' and HREC members' perceptions of the roles of HRECs, and point to some sources of misunderstanding and tension. We examine the implications of some of these findings for the ways in which HRECs carry out their task, and research institutions support and promote ethical conduct in research amongst their staff and students. The focus of this study is on health research, but we suggest that the findings are highly relevant to all other research areas where human participants are involved.

INTRODUCTION

The importance of having research involving human participants conducted ethically is indisputable. Considerable time and effort is spent by Australian researchers and Human Research Ethics Committees (HRECs) in the process of ethical review to ensure that this goal of high ethical standards in research practice is met. In theory, HREC members should use the ethical guidelines in the *National Statement on the Ethical Conduct of Research Involving Humans*[1] as the basis for their decisions, and researchers should design their research in accordance with these guidelines. Ideally, this would be underpinned by an understanding at least of the ethical principles first formulated in the *Belmont Report*[2] and now standard in research ethics generally. However, very little is known about the actual practice of research ethics. On what basis do researchers in fact

make decisions about how to make their research ethical, and on what basis do HREC members evaluate the researchers' efforts? Their conceptual frameworks and processes of ethical decision-making have not been systematically investigated. In this paper, we report some of the key findings of the study "Human Research Ethics in Practice", which shed considerable light on how researchers and HREC members actually practise research ethics. We examine the implications of some of these findings for the ways in which HRECs carry out their task, and research institutions support and promote ethical conduct in research amongst their staff and students.

The key issues on which we focus in the paper are: how researchers and HREC members think and make decisions about ethics (that is, their deliberative strategies); how these relate to the provisions in the *National Statement*; how each group perceives the role of HRECs; and the processes they use to carry out their role. Our particular interest is how better understanding of these matters, especially the similarities and differences between researchers and HREC members, can assist in both improving the process of ethical review of human research, and promoting the ethical conduct of research. In service of these aims, we will draw attention to some areas of tension, mismatched perceptions and practices which can cause friction or misunderstanding.

The focus of this study is on health research, but we suggest that the findings are highly relevant to all other research areas where human participants are involved.

BACKGROUND

There are no published studies that systematically investigate the reasoning processes or deliberative strategies of either researchers or HRECs in relation to research ethics. A 2004 study by Van Essen et al touches on this area, in that it investigates whether HREC members are aware of and use the principles of natural justice, such as the right to a fair hearing (Van Essen et al. 2004, 63–66). However natural justice issues relate to operational procedures as they affect researchers and committee members. These issues 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 Australian study in 1992 (McNeill et al. 1992, 317–322), 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; and 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 (Paul 2000, 210–214).

There is less published data on HREC members' views and experiences. In 1994, McNeill et al investigated HREC members' perspectives of the ethics committee process (McNeill et al. 1994, 522–32). 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. Fitzgerald and Yule have also provided interesting insights about how committees operate as groups in their account of how open or closed ethics committees are (Fitzgerald and Yule 2004, 35–49). However, they also do not address the question of what ethical principles inform HRECs' decisions.

The question of how researchers and HREC members conceptualise and think through issues in research ethics has practical significance, as well as being intrinsically interesting. Our previous work 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 (Gillam et al. 2006, 30–38; see also Jamrozik and Kolybaba 1999, 26–28; Chalmers and Pettit 1998, 79–82). 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 (Pettit 1992, 107). 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 (Chalmers and Pettit 1998, 79–82). Better understanding of how researchers and HREC members think provides the basis for developing strategies to improve communication and understanding between the two groups, and hence work against demoralisation, polarisation and other negative potential outcomes of an ethical review system that is intended to promote the good.

METHODS

The main objectives of the 'Human Research Ethics in Practice' project were to examine HREC members' and researchers' understandings of the ethics review process and the role of the HREC, their approaches to ethical thinking and how this relates to the *National Statement*.

The project was a qualitative study, involving semi-structured individual interviews with HREC members and health researchers in Victoria. Victoria was chosen as the site for logistical reasons, working on the assumption that there is no reason to expect major differences in the individual views and practices of researchers and HREC members between states in Australia, when all are working within a national system with national guidelines. Health researchers were chosen in order to provide a sufficient degree of focus, given that this project was setting out to investigate an issue on which almost no previous work had been done. It was expected that health researchers, who have the longest history in Australia of inclusion in the mandatory national ethics reviews process, would be a population well placed to describe their practices and thought processes. Health research also encompasses a wide range of research methodologies and academic disciplines, so focusing on health researchers is not overly narrow. However, it remains an open question whether health researchers are different from researchers in other disciplines in regard to their understanding of and approaches to research ethics; this would be worthy of further investigation.

The study sample comprised HREC members and health researchers from metropolitan and regional centres, based at hospitals, universities, research institutes and government and non-government organisations across Victoria. It did not include administrators of HRECs. In total, there were eighty-three participants: 34 ethics committee members and 49 health researchers, from metropolitan and regional locations.

The HREC members all had at least two years experience serving on an ethics committee registered with the Australian Health Ethics Committee (AHEC) and came from all categories of membership: researchers, those involved in clinical care, and legal, religious and lay members. Whilst some Chairs of HRECs are included in the sample, they were not recruited specifically in terms of this category. It is worth noting that a number of members were not able to specify which category of membership they belonged to. 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 themselves as belonging to the 'professional care' category. The health researchers came from the fields of biomedicine, epidemiology, clinical and social health research. They 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. Whilst the disciplinary categories we used are distinct and broadly recognised, many of the studies described by participants cut across categories, reflecting the growing importance of large, mixed-methods studies in this research field.

The participants took part in individual semi-structured interviews which involved discussion of the HREC process and how they made decisions about what counts as ethically appropriate practice in research. Interviews were audio-recorded and transcribed. The data were thematically analysed, initially by each member of the project team independently. 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. The data were then organised into a system of coded patterns and categories. Ethics approval for this project was granted by the University of Melbourne Human Research Ethics Committee. In recognition of the potentially identifying nature of some material that participants spoke about, permission was sought from the participants after their interviews for specified quotes to be used in presentations or publications.

FINDINGS AND DISCUSSION

We first provide an overview of the major trends from the project. This gives a context for specific aspects of the findings which we go on to discuss in more detail.

Overall, the interview data paint a relatively positive picture of research ethics and the formal process of ethical review in Australia. They also, however, highlight some aspects that are problematic now, or could be a source of significant problems in the future. Interviews with HREC members showed that the members overwhelmingly believe that they do an important job, and generally feel that they are doing it well. HREC members put in many hours of effort and are committed to the task. The interviews with health researchers showed that, almost without exception, researchers 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. There was considerable commonality between researchers and HREC members in the strategies they described though not total overlap. For each group, the different approaches were potentially complementary rather than competing. Despite this, there

were also signs of underlying tension between researchers and HRECs, in terms of conflicting views of what the proper role of HRECs is, and how HRECs and researchers do and should relate to each other. Some researchers felt personally misunderstood or "judged" by HRECS and many HREC members expressed the belief that researchers see HRECs as an obstacle or a hoop to jump through, with no valuable or worthwhile function.

DELIBERATIVE STRATEGIES USED BY HREC MEMBERS

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 in contradiction. Often a member would describe using a number of different approaches in looking at a single application. The strategies and approaches described by HREC members fall into the following categories.

PRINCIPLE-BASED

This approach involved explicit reference to ethical principles, especially principles named in the *National Statement*. HREC members thought about the projects presented to them in terms of how well they met the basic ethical requirement of scientific merit and benefit. Many defined these aspects as 'worthwhileness'. They also regularly referred to informed consent, justice and privacy, and minimizing of risk to participants.

This approach appears to meet researchers' desire, expressed by many in the interviews, that HRECs provide them with principle-based feedback, preferably using ethical principles from the *National Statement*.

'FLAGS'

Many members also described looking at the projects to see if they contained particular aspects or features which they took to be ethically problematic in general. In essence, they had a pre-formed mental list of these "problem areas", and were on the look-out for any instance of them. The items on the mental list acted as 'flags' to help them identify and focus on aspects of projects that could be expected to raise ethical problems. Members had their own sets of "flags", but many items were common, for example, placebo-controlled trials, use of new or dangerous drugs, inclusion of vulnerable participants, deliberate deception, research on illegal activities, exclusion of certain groups of participants (especially those of culturally and linguistically diverse backgrounds).

A few HREC participants alluded to potential concerns about the use of flags by 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 ethics 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. (HREC 13)

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 HRECs 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

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. (HREC 21)

But interestingly, a number of 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. (HREC 16)

DELIBERATIVE STRATEGIES AND RESOURCES USED BY HEALTH RESEARCHERS

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. In general, researchers stated very clearly that ethics was for them an integral part of research. Consideration of ethics came right at the start of research project planning:

> I don't see ethics and research as two separate things. Because you can't develop a proposal and then think, ok let's look at what the ethical issues are. Because it's right from the beginning, it's how you – so what the question is, what design you choose, how do you recruit participants, how do you get them, what are the privacy issues. (R6)

In discussing their approach to planning research and filling in ethical application forms, researchers pointed to a number of approaches to thinking about ethics of research. The main approaches can be described as follows.

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, 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 something each researcher had come to by 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 which researchers have because they are human beings, rather than something which they acquire because of being a researcher:

> It's really learning through the process of doing it. But some of these things are basic human qualities, you know – respect. I know there's beneficence and the other tenets, but think sometimes the words are hard to say, and so if you think about it as respect. (R22)

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 – either by imaging 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 very useful approach, it could be somewhat problematic.

RESOURCES

Researchers also described a number of resources which they drew on in order to make decisions about ethics, in particular about the research designs and practices that were ethically appropriate. Previous experience was important. Researchers made decisions based partly on aspects of previous research projects that had been approved by, or 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 drew on that to help them understand ethics in research:

> I think that that experience working with clients, with patients and ethics that really guide medical practice really help 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)

There was no explicit recognition that the research and clinical settings are ethically different. In the literature, it is widely accepted that drawing on clinical ethics, where the goal is the best interests of individual patients, might not be appropriate for research ethics, where the goal is not the best interests of individual participants but the search for useful knowledge without comprising participants' rights (Joffe and Miller 2008, 30–42).

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 THE NATIONAL STATEMENT

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 for guidance in the meetings on these matters. One common account from HREC members 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. A few HREC members did not use it at all or were barely aware of it. HREC members in regional settings were less likely to have been able to access training or familiarisation with the *National Statement*.

There was a similar range of knowledge and use of the *National Statement* amongst researchers. Some had never read the *National Statement*, 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. Some explained that the *National Statement* supported their view on what was an ethically appropriate way to do a particular piece of research and was therefore very useful in making their case to the HREC.

Most researchers regarded the *National Statement* and similar guidelines as a good start, 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)

COMMUNICATION, PERCEPTIONS AND RELATIONSHIPS

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 with regard to the role of HRECs, there was variation in views between, and occasionally within, the two groups as to whether HRECs actually fulfilled these goals and how well they did so:

> Well, what I think the role of 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, 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 what, how that actually addressed ethics in the sense of reasoning process where you're actually considering your methods and your why you're doing what you're doing and how you treat the people that are your informants. (R32)

There was also concern about HRECs becoming distracted from their core role and venturing into territory that was not properly their concern:

> 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 about what research is about. So they've forgotten about the research ethics, they're more concerned 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)

Some researchers also made critical comments about how ethics committees go about their task, in terms of their attitudes and perceptions of their role:

> My impression of ethics committees in Australia, at least in Victoria is that they operate in a much more defensive manner. I think that

> reflects society generally, that Australia has a much more defensive bureaucracy which in a sense is good because there's little opportunity loopholes if you like, and little opportunity for people coming back and saying, well I thought it was this way, but in fact it was that way. But it does make the whole ethics approval process considerably more long winded and heavily detailed and raises some of the problems that we've discussed already. With how wording may be interpreted differently in different centres. The main difference, so in New Zealand, at least my dealings – ethics committees have been seen as much more a facilitatory role, saying this is good research, how can we best facilitate it actually being done to achieve the aims that it wants to achieve, rather than how do we test it to see how it does. (R8)

A further point of variation related to 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. Researchers and HREC members both took the strong view that it is unethical to conduct poorly designed research that cannot produce meaningful results. However, there was considerable disquiet on the part of researchers when HRECs attempted to direct researchers as to what 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 [by the HREC] about [the study] – well, is this necessarily the best way to go about asking those questions? (R19)

> We're not going on an ethics committee to redesign the study. Maybe to advise on methodology. I think there's a limited role to an extent that you don't allow the pool to be muddied for other people. You don't allow bad research through. Badly designed I mean. But to tinker with the methodology at the edges I think is outside their remit. (R54)

Many researchers said discussion with HREC administrators and Chairs was useful. However this was not universal, and some reported very frustrating attempts to communicate with committees. Researchers who had experienced notably difficult issues with

an HREC over a particular application, either because of delays or their personal treatment, said that it was very difficult to put these experiences behind them.

CONCLUSION

As noted earlier, one striking feature of the findings is the high degree of similarity between health researchers and HREC members in how they think about ethics and how they understand the role of ethics committees. Despite this, there is also a strong undercurrent of tension and dissatisfaction, especially from the researchers. This suggests that although there is a firm area of agreed ground upon which to base a successful formal ethics review process, there is also considerable room for improving the process. Our findings can be used in a range of ways to make practical contributions to this improvement. In particular, they indicate ways in which HREC and institutional processes could be refined, formalised and extended to increase openness and transparency. The key elements are the active promotion of researchers' understanding of the HREC processes and what the HREC is trying to achieve; and active attempts to send the message that achieving high ethical standards in research is a collaborative process.

In particular, we recommend that institutions 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 the suggestions and guidelines articulated in Section 5.2 in the *National Statement*. In Appendix 1 we provide an example of such a strategy, namely a suggested protocol for managing researcher attendance at HREC meetings. The points in this protocol are derived from the many comments made in interviews by both researchers and HREC members about what goes well and what goes badly when researchers attend HREC meetings, and how these attendances can either enhance or damage co-operative relationships between researchers and HRECs depending on how they are handled. The protocol is premised on the idea that openness and transparency about processes and their purposes will encourage co-operation and collegiality between HRECs and researchers. On the basis of the findings of this study, we believe that such co-operation and collegiality are entirely achievable because there is such strong common ground about the things that matter ethically in research.

APPENDIX 1

SUGGESTED PROTOCOL FOR RESEARCHER ATTENDANCE AT HREC MEETINGS

Derived from the findings of "Investigating Human Research Ethics In Practice", an ARC–funded research project. Investigators: A/Prof Marilys Guillemin, A/Prof Lynn Gillam, Prof Doreen Rosenthal, Dr Annie Bolitho, Melbourne School of Population Health, University of Melbourne.

Full project report available at: http://www.chs.unimelb.edu.au/research/investigating_human_research_ethics_in_practice/finding.

1. **A formal written invitation to attend should be sent to researchers** well prior to the meeting, with the name of a contact person if the researchers have any questions about the process.

    a. The supervisor of student research projects should always be invited, and expected to attend, in addition to the student.
    b. If there is a large research team, attendance by a senior member of the team with good knowledge of the whole project should be requested (the junior RA is not a suitable attendee).
    c. There should be an explanation of what alternatives are possible if the researchers are unable to attend on the date nominated.

2. Information should be provided to researchers before their attendance at meeting, including:

    a. Reason/s that their attendance is being requested
    b. List of questions or issues which the committee wishes to discuss with them
    c. Who will be present at the meeting – a list of members of the committee and their categories of membership, plus names of any others who will be in attendance
    d. What to expect – what the process will be, approximately how long they will stay, how the discussion will be conducted, whether a decision will made while they are present or after they leave.
    e. Any documents that they should bring with them.

3. There should be **a standard procedure** for the way in which the researchers' attendance is managed, which **aims to make the event respectful, collegial and useful to all parties**. This should include:

    a. Having a timeline and sticking to it: Ask researchers to arrive at a specific time and ensure that they are not left waiting outside for more than a few minutes.
    b. Chair introduces researchers to all committee members by name when they come into the room.
    c. Have name plates for committee members, so that researchers are able to identify them and address them by name during the discussion
    d. Chair explains the process by which questions will be asked of researchers – eg by members through the chair, or by the chair only, or by nominated members of the committee. This process is then adhered to.
    e. Researchers are given an opportunity to ask questions or make comments, in addition to answering questions.
    f. When it is time for researchers to leave, chair explains to researchers what will happen next, and when they can expect to hear from the committee.

4. After the meeting**, a follow-up letter** should be sent to researchers thanking them for their attendance, setting out any decision which the committee has made, or explaining what will happen next, and reminding them of any information they had agreed to provide to the committee.

5. **This protocol should be placed on the HREC's website,** so that any researcher can find out about what is involved in attending a meeting.

6. The HREC/institution should **consider whether researchers can initiate a request to attend a meeting** to explain or discuss their project, in addition to having provision for the committee to ask them to attend.

    a. If the HREC/institution decides this should be an available option, researchers should made aware of this.
    b. A list of criteria which the HREC will use to decide whether to agree to a researcher's request to attend should be drawn up.
    c. These criteria should be made known to researchers, for example by putting the list on the HREC's website.

ENDNOTES

1 National Health and Medical Research Council. 1999. National Statement on the Ethical Conduct of Research Involving Humans. Canberra: Commonwealth of Australia.

2 Office of the Secretary, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 1979. The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. US Department of Health Education and Welfare.

REFERENCES

Chalmers, D; Pettit, P. 1998. 'Towards a consensual culture in the ethical review of research'. *Medical Journal of Australia* 169: 79–82.

Fitzgerald, M; Yule, E. 2004. 'Open and closed committees'. *Monash Bioethics Review* 23 (2): 35–49.

Gillam, Lynn; Guillemin, Marilys; Rosenthal, Doreen. 2006. "Obstructive and power-hungry'?: The Australian research ethics review process'. *Monash Bioethics Review* 25 (2): 30–38.

Jamrozik, K; Kolybaba, M. 1999. 'Are ethics committees retarding the improvement of health services in Australia?'. *MJA* 170: 26–28.

Joffe, S; Miller, F.G. 2008. 'Bench to bedside: Mapping the moral terrain of clinical research'. *Hastings Center Report* 38 (2): 30–42.

McNeill, P. et al. 1992. 'Do Australian researchers accept committee review and conduct ethical research?' *Social Science and Medicine* 35: 317–322.

McNeill, P. et al. 1994. 'How much influence do various members have within research ethics committees?' *Cambridge Quarterly of Health Ethics* 3 (4): 522–532.

Paul, C. 2000. 'Health researchers' views of ethics committee functioning in New Zealand'. *New Zealand Medical Journal* 113 (1111): 210–214.

Pettit, P. 1992. 'Instituting a research ethic: Chilling and cautionary tales'. *Bioethics* 6 (2): 107.

Van Essen, G; Story, D; Poustie, S. et al. 2004. 'Natural justice and human research ethics committees: an Australia-wide survey'. *Medical Journal of Australia* 180: 63–66.

Cite this article as: Gillam, Lynn; Guillemin, Marilys; Bolitho, Annie; Rosenthal, Doreen. 'Human research ethics in practice'. *Monash Bioethics Review* 28 (1): pp. 7.1 to 7.17. DOI: 10.2104/mber0907.