ETHICS CREEP OR GOVERNANCE CREEP?

CHALLENGES FOR AUSTRALIAN HUMAN RESEARCH ETHICS COMMITTEES (HRECS)

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Australian Human Research Ethics Committees (HRECs) have to contend with ever-increasing workloads and responsibilities which go well beyond questions of mere ethics.

In this article, I shall examine how the roles of HRECs have changed, and show how this is reflected in the iterations of the *National Statement on Ethical Conduct in Human Research 2007* (NS). In particular I suggest that the focus of the *National Statement* has shifted to concentrate on matters of research governance at the expense of research ethics, compounded by its linkage to the *Australian Code for the Responsible Conduct of Research (2007)* in its most recent iteration. I shall explore some of the challenges this poses for HRECs and institutions and the risks it poses to ensuring that Australian researchers receive clear ethical guidance and review.

INTRODUCTION

There is a fundamental difference between research governance and research ethics. While I am willing to concede that the two are undeniably linked and even to some extent overlap, their primary focus is different. Research ethics focuses mainly on the rights and interests of research participants, whereas research governance is focused more on the actions of researchers and the interests of the institutions to which researchers belong.

The difference is subtle but important, and it is easy to confuse the two. It is my contention that the *National Statement* has confused both concepts, at times conflating the two areas to their mutual detriment. This has been compounded by the most recent versions of the *National Statement* to the *Australian Code for the Responsible Conduct of Research* (2007) which were conceived and developed as companion documents. This has in turn led to difficulties for ethics committees, researchers and research institutions.

THE NATIONAL STATEMENT

The *National Statement on Ethical Conduct in Human Research* (2007) has been described as the 'primary source of guidance for the conduct of all research that involves human participants' in Australia (Anderson, 2007). In other words it is the underpinning document for Australian ethics committees, institutions, and researchers.

However, the *National Statement* has changed considerably since its first inception, where the main concern was the ethics of medical research. In its most recent iteration the focus has moved beyond medical research and ethics. This is evidenced not only by the prominence given to Research Merit and Integrity as a 'value', but by its coupling with the *Australian Code for the Responsible Conduct of Research* (2007).

THE FOCUS OF THE AUSTRALIAN CODE

The *Australian Code* was created to complement the *National Statement*. It is divided into two sections: Part A consists of 'principles and practices to encourage responsible research conduct', while Part B deals with 'breaches of the Code, research misconduct and the framework for resolving allegations'. This document aims at promoting a higher level of research governance in Australian universities, and goes well beyond ethical considerations in relation to the conduct of research. The *Code* addresses such matters as responsibilities of institutions and researchers, management of data, supervision of research trainees, publication, authorship, peer review, conflicts of interest and collaborative research across institutions. In other words, the *Code* addresses matters of governance, and the *National Statement* matters of ethics.

Although the *Code* and the *National Statement* are referred to as companion documents, the *Code* is the over-arching document because it goes beyond research involving humans to encompass all kinds of research, whether requiring ethics approval or not. Thus it refers to animal research, research requiring biosafety approval, and research requiring no ethical or safety clearance of any kind, such as purely documentary research. In other words, the *National Statement* is now subordinate to the *Australian Code*.

THE FOCUS OF THE NATIONAL STATEMENT

The *National Statement* only refers to research involving humans. In its chapter on 'Values and principles of ethical conduct', the *National Statement* refers to the values of 'Research merit and integrity', 'Justice', 'Beneficence' and 'Respect' (*National Statement* 2007: 12–13), with prominence given to 'Research merit and integrity'. These latter three values, ('Justice', 'Beneficence' and 'Respect') align themselves more readily with matters of research ethics, and the value of respect is recognised as central (*National Statement* 2007: 11). These three values are the lens through which the ethical issues relating to research are viewed by ethics committees, and impact upon such issues as risk, consent, harm, privacy, conflict of interest, etc. 'Research merit and integrity', on the other hand, are more relevant to matters of research governance.

RESEARCH MERIT AND INTEGRITY

The *National Statement* justifies the inclusion of research merit and integrity on the grounds that research should have merit and researchers integrity in order to justify 'the involvement of human participants' (*National Statement* 2007:11). However, my contention is that other mechanisms, such as the peer review system for competitive research grants, are much more suited to deal with research integrity and merit. As mentioned above, the value of 'Research Integrity and Merit' lends itself more closely to matters of research governance than ethics, and should therefore be viewed as subordinate to the other values, but the authors of the *National Statement* have placed it ahead of the values of Justice, Beneficence and Respect.

The value of 'Research merit and integrity' encompasses such issues as the applicability of the methodology and whether it is likely to achieve the stated aims, the ability, qualifications and experience of the researcher, etc. However, paragraph 1.2 of the *National Statement*, says that 'research merit is no longer subject to the judgement' of ethics committees where the research has already been through a peer review process. This immediately creates a conflict for ethics committees who may feel it to be relevant regardless of prior peer review.

PEER REVIEW

Peer review itself is no guarantee of ethical research. There are many instances of unethical research which have been through peer review, which is one of the reasons why ethics committees were deemed necessary in the first place. In addition, there is no guarantee that methodology will not change after peer review. For example, it is rare for researchers to receive all the funding that they apply for and so they may be forced to vary their methodology for pragmatic reasons.[1] Additionally, once in the field researchers might find that circumstances are different to what they expected, and may need to alter their methodology accordingly.

Further conflict is evident by the inclusion of 'gains in skill or expertise for individual researchers, teams or institutions' as an acceptable benefit of research, as this would seem to imply that research merit is not necessarily as important as its placement would suggest. (*National Statement* 2007:17). Certainly this has been interpreted by my own institution's ethics committee as meaning that even if a piece of research is considered by the HREC to be of dubious merit, it is sufficient that it benefit the researcher, for example through the obtaining of a higher degree qualification, as long as there is little or no potential for harm to subjects,[2] and the mechanism for obtaining informed consent

is clear. In other words, it is up to a subject to decide whether or not to participate in the research, provided they are aware of its limitations. In this case, the ethical focus would not be the research merit or lack thereof, but rather that of ensuring consent is free and informed, that the potential for risk/harm to participants is minimal and that the value of the research is not overstated.

The elevation of research merit and integrity to its current prominence represents a significant departure from earlier versions of the *Statement*[3] which focused more heavily on the morality and ethics of research. For example, the first paragraph of the 1992 *NHMRC Statement on Human Experimentation and Supplementary Notes* states:

> ...research must conform to generally accepted moral and scientific principles. To this end institutions in which human experimentation is undertaken should have a committee concerned with ethical aspects and all projects should be submitted for approval by such a committee.

The fact that the same paragraph has a footnote stating that an 'application to the NHMRC for a research grant involving human experimentation is required to be certified by the ethics committee of the applicant's institution...before the application will be considered for funding[4] would seem to indicate that even then ethics committees were viewed as a mechanism of research governance.[5] Nonetheless the primary emphasis was on the moral and ethical conduct of the research itself and its impact on research subjects, which is at the heart of research ethics.

RESEARCH GOVERNANCE

Research governance examines the conduct of the researcher across a broader spectrum than mere ethics. It includes publication, accuracy, financial and academic integrity and accountability, conduct, conflict of interest, legal issues such as contracts and insurance, monitoring, reputational risk, privacy and data legislation. Matters of research design and integrity, I would suggest, are generally more at home in this realm than that of ethics except where they impact directly upon the ethics of the research itself. From a perspective of research governance, negative impact of research on subjects is undesirable more because of attendant adverse consequences for the institution and researcher, such as loss of funding, loss of reputation, issues of misconduct and possible legal consequences. In other words, the focus is on the interests of the research institution and researcher rather than the subjects of research.

HISTORY OF RESEARCH GOVERNANCE IN AUSTRALIA

Research governance has only recently come into prominence in research administration in Australia.[6] Even outside of the research environment, the term was so little understood that only than a decade ago the Australian Parliament felt it necessary to publish a research note explaining the term. (Verspaandonk, R, 2001). That document is obviously concerned with governance in a much wider sense than just research, but generally governance is understood as accountable, transparent and responsible management of public resources or public administration. In relation to research, '[G]ood governance also seeks to ensure that research is carried out with the highest scientific and ethical standards, appropriate use of finances and robust monitoring, review and evaluation processes.' (Poustie et al. 2006: 623)

HRECS AND RESEARCH GOVERNANCE

Proper research governance is undoubtedly important for the credibility of research and research institutions. However, expecting HRECs to be responsible for such matters is cause for concern when they lack the necessary capacity, expertise and resources. Of equal concern is the fact that not all research passes under HREC scrutiny. In addition, making ethics committees responsible for governance as well as ethics may negatively impact upon their ability to do what they were primarily established for, which is the protection of human subjects of research. It distorts the role of HRECs to make them responsible for research governance matters in addition to research ethics and creates a risk that neither will be done properly.

This in itself would in my view be sufficient to explain why the *National Statement* and the system of HRECs are inadequate to address matters of research governance, but because committees exist so widely it is tempting for institutions to use them for governance purposes. Whilst the term 'ethics creep' is used pejoratively in relation to ethics committees, I believe that the term 'governance creep' is in fact more accurate.

Not all research involves humans as subjects or participants. This means that while all research may be said to be subject to the *Code*, it may not necessarily be subject to the *National Statement,* and hence review by an HREC. Other matters of concern from a governance viewpoint, such as fair attribution, data management, financial accountability, authorship etc, cannot be effectively or realistically reviewed by ethics and safety committees.[7] The authors of the *National Statement* appear to recognise this, writing on page 9 that research ethics 'is only part of an institution's responsibilities for research governance'. However, at the same time the *National Statement* (Section 1.1) describes

research merit and integrity as encompassing methodology, aims, experience, competence and qualifications of the researchers, adequate supervision, appropriate facilities and resources, honest conduct and dissemination of results, whether favourable or not. This highlights the confusion which exists, and this is reflected in some of the questions asked in the NEAF (National Ethics Application Form) which would appear to be more akin to research governance than research ethics.[8]

It is, I believe, unreasonable to expect ethics committees to assume responsibility for matters that are so clearly beyond their control, and which are more about governance and compliance than ethics, particularly when members tend to be unpaid and voluntary (particularly if they are external to the institution).

Compliance by its nature is satisfied with meeting minimum standards. It requires adherence and obedience rather than critical thought, and certainly does not reward going 'above and beyond' the minimal requirement. As such, it can be an invitation to mediocrity and a lost opportunity for committees to develop more positive relationships with researchers, to enter into dialogue and to mutually explore challenges and issues, such as how to cope with new methodologies or different types of research. Further, there is a danger that it will promote an adversarial relationship, because the ethics committee is no longer just the advisor, but also policeman, taxman and auditor. This may lead researchers to develop an attitude of 'ethics avoidance', like 'tax avoidance', where they strive to expend minimal ethical thought and effort. My concern is that it would also foster a mentality on the part of both ethics committees and researchers of only addressing those matters which are most easily dealt with, such as matters of compliance, particularly given the ever increasing workload of ethics committees, and this would be at the expense of meeting the more subtle and difficult ethical challenges.

HISTORY OF ETHICS COMMITTEES

Ethics committees first emerged in the United States in the 1960s. As they spread to other countries, including Australia, they rapidly became 'the standard means throughout the world for resolving the conflict between the scientific need to conduct research on human subjects and the humanitarian need to protect those subjects.' (McNeill, 1993: 53) In other words, their original focus was on the ethics of the research itself.

Ethics committees were created in response to examples of unethical research which shocked the public. Most of the examples related to medical research, and it is fair to say that many members of the medical profession were also shocked. McNeill cited instances of unethical research stretching back millennia, including Hippocrates, the

Ptolemies in Egypt, second century Persia, and nineteenth century Europe and America (McNeill, 1993: 17–19). He also described early concerns raised from within the ranks of the medical profession which resulted in codes of behaviour relating to medical research. The earliest medical ethics guidelines might rightly be said to be the Hippocratic Oath, originating some two and a half millennia ago, which famously exhorts medical practitioners to 'do no harm'.

Strict guidelines were specifically developed to address medical research. The *Nuremburg Code* arose in response to Nazi experiments in World War 2. It was followed by the *Helsinki Declaration*, first adopted by the World Medical Association in 1964, and revised six times since, most recently in 2008. The *Helsinki Declaration* made it clear that research should be approved by an independent committee (Basic Principle 1), a requirement absent from the *Nuremberg Code.*

In addition to the Nazi experiments during the Second World War, there was the Tuskegee Syphilis Study and closer to home, the 'unfortunate experiment' in New Zealand. The Tuskegee Syphilis Study involved over 200 poor black men in rural Alabama who were monitored but not treated for syphilis over a 40 year period, from 1932 to 1972 (Brandt, 1978; McNeill, 1993: 61–2). The 'unfortunate experiment', which took place from 1966–1981, partially overlapped the Tuskegee Study, and involved women who were monitored but not treated for cervical cancer (Coney, S.1993). These and other examples (see Beecher, 1966) hugely impacted on public consciousness, and led to strong social, political and professional pressure which culminated in the development and proliferation of ethics committees because, as McNeill (1993: 50) pointed out, codes alone were obviously insufficient 'to safeguard research subjects and ensure ethical experimentation'. Codes had, after all, existed in Germany before the Second World War, but clearly had not stopped unethical research from occurring. Ethics committees, therefore, were seen as a necessary adjunct to codes, to ensure that they were actually adhered to by researchers.

ROLE OF ETHICS COMMITTEES

Ethics committees exist to review the ethics of research applications, to protect the interests of subjects, and as Poustie et al (2006:623) point out, they are 'poorly equipped to exert governance beyond their primary role of the ethical review of research proposals'. Ethical review by an HREC does not and cannot guarantee ethical behaviour by a researcher. When one adds to the mix the additional matters referred to above as part of the responsibility of a research governance framework, (i.e. finances, monitoring, authorship, sci-

entific standards etc,) it is clear that these are well beyond the scope and ability of ethics committees.

MEDICAL FOCUS OF ETHICS GUIDELINES

That the system of ethical review of research initially arose in relation to medical research is reflected in the name of the first major Australian research ethics document, the NHMRC *Statement on Human 'Experimentation'* (as opposed to the to the current term 'research'). However, non-health research disciplines are also subject to the strictures of the *National Statement*, and ethics committees must constantly interpret the *Statement* in a way that is helpful to researchers. If they do not, they risk alienating researchers and driving them underground, or encouraging them to be less than forthcoming in their dealings with ethics committees.

Further, even a rudimentary exploration of the history of research shows that ethical sensibilities do not stay still. Ethical principles themselves do not change so much as our understanding and application of the principles to particular circumstances. In the past, for example, it is clear that many medical practitioners did not feel the need to obtain consent from their patients before enrolling them in clinical research, in spite of the existence of codes of behaviour that required such consent. The earlier examples of Nazi experiments, the Tuskegee Syphilis study and the cervical cancer research at the Women's Hospital in New Zealand are evidence of this. It should be noted that in these latter two cases, the research was publicly funded, and articles about the research were published in medical journals. This means that both pieces of research must have undergone multiple peer review processes which had failed to recognise and address the ethical issues inherent in the research.

Beecher's landmark 1966 article listed numerous examples of unethical medical research. Beecher pointed out the dangers of the combination of pressure on researchers to produce outcomes with huge and increasing expenditure on medical research, which could 'lead to unfortunate separation between the interests of science and the interests of the patient' (Beecher 1996: 368). Whilst Beecher clearly identified ethical concerns it was apparent, again, that others in the medical profession had not. The examples he gave were of published research papers, so once again multiple levels of peer review which are arguably a part of research governance procedures had failed to recognise and prevent unethical research from occurring.[9] The Tuskegee Study and cervical cancer research at the Women's Hospital in New Zealand were but two examples of unethical research which continued to be funded and published after the publication of Beecher's

article.[10] The conclusion to be drawn from this is that research governance and research ethics are not the same, and that research governance, while important, is no substitute for research ethics.

CHALLENGES FOR NON-HEALTH RESEARCH

Most of the above discussion has focused upon medical and health research, and the problems that medical researchers have experienced with HRECs are well documented (Gillam et al 2009). However, as institutions increasingly require all research involving humans to be subject to HREC review, non-health researchers are facing the kinds of dilemmas encountered by the medical profession as well as problems resulting from the translation of their professional practice to an academic research environment. (Richards 2010).

Research by its nature is about breaking boundaries and seeking new knowledge. Fostering a compliance mentality in researchers runs the risk of undermining their ability to conduct groundbreaking research. It is already clear that some researchers feel that having to go before an ethics committee is an unnecessary impediment; however in my experience[11] a robust engagement with the ethics committee can lead to improvement in the research and a relationship of mutual respect. There is a vast difference between an ethics committee that merely concerns itself with split infinitives and grammar, and whether or not the form has been filled in correctly, and the committee that engages in genuine dialogue with the researcher about the ethics of the research itself. Again, speaking from experience, it is actually easier for an ethics committee to concern itself with negative aspects of the research, and HRECs must consciously strive to be positive and supportive rather than negative in their interactions with researchers. If ethics committees are mainly viewed as compliance hurdles, then researchers will be tempted to exercise tactics to avoid scrutiny and will rightly hold them in contempt.

As more discipline areas come into the realm of research ethics, ethics committees are also wrestling with how best to deal with them. The model of consent, for example, is a vexed one, and journalistic researchers complain about the inappropriateness of the consent form for their type of research (Richards 2010). If ethics committees adopt a compliance mentality, then it will be sufficient for them to assure themselves that a consent form has been included in the application, regardless of whether it is appropriate or not. In fact, in some instances, a consent form could be unethical, such as when dealing with mainly oral cultures, with someone who is illiterate, or when a written record of research subjects might put them at risk. For example, a researcher who wanted to

investigate the use of state sanctioned torture would place respondents at risk if they used a signed consent form or any other identifying mechanism. In such cases, a truly ethical researcher might actually have to go against the wishes of the ethics committee. After all, including a sample consent form in the application does not mean that a researcher will actually use it.

Then there are the types of consent forms, for example, where the language is inappropriate (Buccini et al 2010). Ethics committees must go beyond mere compliance, which is sufficient from a governance mentality, to considering that which is most ethical. At times they must be willing to be guided by the researcher, who may well have more relevant and actual experience than they do.[12]

All this is even before researchers are face to face with research subjects. A researcher might tick all the right boxes and tell ethics committees what they want to hear, but unless they have properly grappled with the ethical issues inherent in the research, then the best ethics application (in terms of compliance) will be less than helpful to researchers facing real ethical dilemmas. Worse, it might instill a false sense of confidence in researchers and discourage them from being alert to ethical problems that arise in the context of their work.

Where researchers have genuinely tried to address potential risks and ethical dilemmas in their application, they will be more alert to problems that may arise, even if unanticipated. Researchers in the field must be ready to deal with situations far from the aegis of the ethics committee. If their ethical stance has been distorted into one of mere compliance, then they will be ill-equipped to confront the complexities of real life ethical interaction.

The success of much research, particularly research of a qualitative nature, depends upon the quality of the relationships that are developed. A longitudinal study, or one delving into personal matters, will only succeed where the researcher and subject have developed and maintained a relationship of mutual trust. An ethics committee cannot measure or quantify such a relationship, particularly beforehand. A committee can only ask questions about how the researcher *intends* to manage their research.

The issue of risk poses different challenges depending upon the type of research. It is easier to measure risk in relation to medical research because such risk is more likely to be quantifiable, whereas risk for participants in qualitative and non-health research may vary from individual to individual according to circumstance. A clinical trial might involve quantifiable risk, such as a 1 in 5 chance of adverse reaction to a drug or a 50 per cent survival rate for a surgical procedure. But how would an ethics committee measure the potential risk of an academic researcher wanting to interview survivors of incest or workplace bullying? Such risk will be difficult to measure because it will vary

from individual to individual depending upon their resilience and other factors that may come into play. These will include the skill of the researcher, the method of recruitment and gathering of data, as well as the value of the research itself. In such cases as these, where the material is clearly sensitive and the potential (as opposed to likelihood) of risk is high, it would not be ethically acceptable, as in the type of case alluded to earlier, to argue that the mere obtaining of qualifications or experience was sufficient reason for the research to be undertaken. These types of calculations are beyond the scope of mere compliance, and require delicate interaction and negotiation between the researcher and the committee. Just because a risk is difficult to quantify does not make it any less real or any less deserving of ethical review and consideration.

Workloads are already a problem for ethics committees. I am unaware of the national figures for the number of ethics applications considered by HRECs on a yearly basis, but speaking from my own university's view point (and from communication with many of my colleagues I have no reason to believe that this does not reflect the experience of other ethics committees) the number of applications has continued to rise steadily.[13] I can also attest that the types of applications have increased in scope and complexity as well, which means that the demands upon ethics committees are ever greater. It is hard for ethics committees to monitor research effectively, and most satisfy themselves with a written annual report as being the only practical means available to them. Yet in addition to reviewing the ethics of the research and protecting subjects, committees are expected to be able to review reports, ensure adequate insurance coverage, review budgets, participant material, methodologies, data gathering and analysis tools, and consider relevant legal aspects, which are surely to a greater or lesser extent matters of governance rather than ethics.

There are many guidelines and legislation that ethics committees need to be aware of and take into consideration in relation to research. When I assumed responsibility for my institution's HREC in 1992, there was little, other than the NHMRC *Statement on Human Experimentation*, available as a guide. Today the relevant documents include state and federal privacy legislation, child protection legislation, data legislation, the *Australian Code for the Responsible Conduct of Research*, Therapeutic Goods Administration, Clinical Trial Register, as well as various professional codes and guidelines, some of which may conflict with the *National Statement*.[14]

The tendency to push research governance onto ethics committees can lead to their becoming a de facto risk assessment mechanism for an institution. Some governance matters may be unavoidable, such as ensuring that Child Protection legislation is adhered

to. Other areas, such as data management, are less clear. Data management is generally considered an ethical issue, because of privacy and confidentiality concerns. However, it is also a legal/governance issue, and the need for verifiability of data conflicts with privacy and confidentiality concerns. An institution that depends upon the ethics committee to address such governance matters is courting danger, as ethics committees are neither trained nor equipped to assess other than ethical risks, particularly, as previously stated, not all research comes under the purview of an HREC.

In these days of multi-tasking, there is a temptation for institutions to use ethics committees for multiple purposes, and to assume that they are ensuring proper governance through the assessing of research merit and integrity in addition to research ethics. However, it is important for institutions to resist this approach, as the only risk in relation to research that ethics committees are suited to assessing is ethical risk.

LARGER RESPONSIBILITIES OF HRECS

Ethics committees may 'belong' to an institution, but they are not just answerable to that institution. They are also answerable to the Australian Health Ethics Committee, the public, and sundry others, such as state and federal privacy commissioners, to whom they must report, and this is one of the reasons why they are required to have significant external membership. It is the responsibility of the institution to support the needs of ethics committees, as outlined in the *Code* and *National Statement*. If the focus of ethics committees is distracted by other institutional needs, such as research governance requirements, then their independence is undermined and their attention switches from risk for the research subject to risk for the institution. This in turn may tempt ethics committees to refuse to approve research on non-ethical grounds, such as researchers who wish to undertake dangerous research, for example in a war zone, or undertaking research that might show the institution in a less than favourable light.

As already stated, relationships between ethics committees and researchers can be problematical. By increasing the responsibility of ethics committees to cover research governance as well as research ethics, institutions fail in their responsibilities to researchers, research subjects, and society. We all have a vested interest in the continued health of research because it is important for the health of our society. We should rightly be wary of anything which undermines the ability of ethics committees to concentrate upon the ethics of the research and the potential risk for participants.

CONCLUSION

It is important for ethics committees, researchers and research institutions to be aware of the differences between research governance and research ethics. Whilst research governance and research ethics do overlap to some extent, they are also fundamentally different. Governance focuses more on the needs and interests of the institution, and in ensuring that the researcher has met their obligations to the institution and funding body. Consideration of the ethics of the research is only one small part of that equation, but also covers different ground than governance because it is focused externally on the needs of research subjects, rather than internally on the interests and obligations of the institution. Governance is undeniably important for the credibility and transparency of institutions and researchers, but HRECs are ill-equipped and resourced to deal with governance issues outside of a framework of research ethics, particularly as not all research undergoes review by an HREC. The fact that the *Australian Code* and the *National Statement* were conceived of as companion documents has contributed to the confusion.[15] I believe that future versions of both documents should clarify the distinction between governance and ethics, and ensure that the institutions establish appropriate mechanisms to manage governance requirements so as to preserve the ethical focus of HRECs.

History has demonstrated the dangers of allowing the aims of science and interests of organisations to overshadow the rights and interests of individuals. By conflating governance and ethics, there is a real danger that the interests of research subjects will be submerged and the independence of ethics committees diluted. This is to the detriment not just of research subjects, but ultimately to the interests of researchers, institutions and research itself.

ACKNOWLEDGEMENTS

This paper was developed as a result of my participation in the inaugural Graduate Certificate in Research Ethics run through Monash University's Centre for Human Bioethics. I would like to acknowledge my debt not only to Associate Professor Justin Oakley, but also to my fellow students, and the many others who contributed to the course, which helped me to crystallise the ideas in this paper resulting from nearly two decades of managing human research ethics at UTS.

ENDNOTES

1 I am indebted to Justin Oakley for this observation.

2 I have used the terms 'subject' and 'participant' interchangeably.

3 See NHMRC *Statement on Human Experimentation and Supplementary Notes* 1992.

4 There is a further footnote stating that those who do not belong to such an institution should obtain comments on their protocol from an established ethics committee at, for example, a university or hospital.

5 The NHMRC and ARC eventually limited this requirement to successful applications for funding after representations from institutions that it was a waste of time and effort for researchers and HRECs to have to consider applications which might not be funded.

6 The previous iteration of the Code, the NHMRC / AVCC *Joint Statement and Guidelines on Research Practice* (1997) does not use the term 'governance', but rather 'good research practice'.

7 I mention animal ethics and biosafety committees merely to illustrate a point about the limitation of such committees in relation to matters of research governance. Unless otherwise specified, references to ethics committees relate to human research ethics committees.

8 For example, some of the questions relate to financial issues, peer review, data, insurance, legislative obligations, etc.

9 The recent case of Dr Patel in Australia shows that this failure to recognise unethical behaviour is not limited to research, but encompasses medical practice as well (Bentley 2010).

10 Not all ethically problematical research belongs to the areas of medicine and health. Famous examples include the Milgram obedience and Stanford Prison experiments, but there are many others as well (Zimbardo 2007).

11 I have been involved in the area of medical and research ethics for over three decades.

12 An example of this relates to an experience I had while managing my institution's Animal Care and Ethics Committee (ACEC). The ACEC received an application relating to a species they had no experience with, so I contacted the Animal Research Review Panel (ARRP), the NSW government body responsible for ACECs, to ask their advice on behalf of the committee. ARRP referred me to the researcher in question as the foremost Australian expert with that particular species.

13 For example, at my own university, the number of active protocols has risen from 45 at the end of 1993 to 385 at the end of 2009, an increase of 853 per cent.

14 For example, see the MEAA *Code of Ethics* governing the conduct of journalists.

15 It is beyond the scope of this paper to do more than mention that the earlier documents relating to research conduct, which were the precursors to the current Code, were developed separately by the Australian Vice-Chancellors' Committee and the NHMRC until the development of the NHMRC / AVCC *Joint Statement and Guidelines on Research Practice* (1997). The Joint Statement replaced the NH&MRC *Statement on Scientific Practice* (1990) and the AVCC *Guidelines for Responsible Practice in Research and Problems of Research Misconduct* (1990).

REFERENCES

Anderson, W. 2007. *Letter of introduction to National Statement on ethical conduct in human research.*

Beecher, H. 1966. 'Ethics and clinical research' in *New England Journal of Medicine*. 274 (24): 367–372.

Bentley, A. 2010. 'Broke Patel applies for aid to fund appeal' in *Brisbane Times*. Accessed 22 October 2010. Available at: http://www.brisbanetimes.com.au/queensland/broke-patel-applies-for-aid-to-fund-appeal-20101015-16mjt.html?from=smh_ft&autostart=1.

Brandt, A. 1978. 'Racism and Research: The Case of the Tuskegee Syphilis Study' in *The Hastings Center Report*, 8 (6): 21–29.

Buccini, L; Iverson, D; Caputi, P; Jones, C. 2010. 'An Australian based study on the readability of HIV/AIDS and Type 2 Diabetes clinical trial informed consent documents' in *Bioethical Enquiry*, 2010 7: 313–319.

Gillam, L; Guillemin, M; Bolitho, A; Rosenthal, D. 2009. 'Human research ethics in practice: deliberative strategies, processes and perceptions' in *Monash Bioethics Review*, 28 (1).

Coney, S. (ed). 1993. *Unfinished business: what happened to the Cartwright Report?* New Zealand: Women's Health Action.

McNeill, P. 1993. *The ethics and politics of human experimentation*. Cambridge: Cambridge University Press.

MEAACE. 2010. *Media and Entertainment Arts Alliance Code of Ethics*. Accessed 7 October 2010. Available at: http://www.australian-news.com.au/codethics.htm.

NHMRC. 2010. *NEAF* (National Ethics Application Form). Accessed 30 October 2010. Available at: http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/ahec/neaf/neaf-proforma-application-clinical_trials.pdf.

NHMRC. 1992. *Statement on Human Experimentation and Supplementary Notes*. Australian Government.

NHMRC/AVCC. 1997. *Joint NHMRC / AVCC Statement and Guidelines on Research Practice*. Accessed 30 October 2010.Available at: http://www.nhmrc.gov.au/grants/policy/research prac.htm.

NHMRC; ARC; AVCC. 2007a. *Australian code for the responsible conduct of research*. Australian Government.

NHMRC; ARC; AVCC. 2007b. *National statement on ethical conduct in human research*. Australian Government.

Nuremberg Code. Accessed 23 October 2010. Available at: http://www.cirp.org/library/ethics/nuremberg/.

Poustie, S; Taylor, D; Forbes, A; Skiba, M; Nelson, R; McNeil, J. 2006. 'Implementing a research governance framework for clinical and public health research' in *Medical Journal of Australia*, 185 (11/12): 623–626.

Richards, I. 2010. 'Uneasy bedfellows: ethics committees and journalism research' in *Australian Journalism Review*, 31(2) 35.

Verspaandonk, R. 2001. Politics and Public Administration Group, Parliament of Australia. Research Note11 2001–02. 'Good Governance in Australia'.Accessed 22 October 2010. Available at: http://www.aph.gov.au/library/pubs/rn/2001-02/02RN11.htm.

World Medical Association Declaration of Helsinki. 1964. http://www.cirp.org/library/ethics/helsinki/ (accessed 23 October 2010).

World Medical Association Declaration of Helsinki. 2008. http://www.wma.net/en/20activities/10ethics/10helsinki/index.html (accessed 23 October 2010).

Zimbardo, P. 2007. *The Lucifer Effect: How good people turn evil*. Great Britain: Ebury Publishing (Random House Group).

Cite this article as: Gorman, Susanna M. 2011. 'Ethics creep or governance creep? Challenges for Australian Human Research Ethics Committees (HRECs)'. *Monash Bioethics Review* 29 (4): pp. 14.1 to 14.16.