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Ethical expertise and Human Research Ethics Committees (HRECs)

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In setting national standards for the ethical review of human research in Australia, the *National Statement on Ethical Conduct in Human Research* (*NS*) (2007) does not aim to be exhaustively prescriptive, and so requires a degree of ethical reflection when applying the principles of research merit and integrity, justice, beneficence and respect. There are two broad ways in which this need for ethical reflection can be understood. On an objectivist interpretation, an adequate level of ethical expertise is required to ensure the informed application and implementation of these principles. From a subjectivist perspective, recourse to the 'community view' or common-sense morality provides an adequate basis for ethical reflection. The primary purpose of this article is to argue that the *NS* is itself an exercise in objectivist research ethics, but that what we know of the current practices of HRECs is more consistent with a subjectivist approach to ethical reflection, and that this mismatch is best addressed by improving the level of ethical expertise brought to bear in the ethical review of human research. The secondary purpose of this article is to briefly suggest ways of achieving this improvement within the parameters of a de-centralised system of review such as we have in Australia, yet also to hopefully stimulate debate as to whether this need to improve the level of expertise, ethical and otherwise, might best be served by moving towards a more centralised and professionalised system of ethical review.

Subjectivist and objectivist approaches to ethical review

The debate over the appropriate way to structure the system of ethical review in Australia has in the past been sparked in part by researchers' concerns about

burdensome procedures for multi-centre human research projects, as well as inconsistencies in the review of these by different HRECs. These concerns were identified in the 1996 report of a review commissioned in 1994 by the federal minister for Health and Human Services into the role and functioning of what were then known as Institutional Ethics Committees (IECs).[1] Section 4.7 of this report noted that a number of submissions to the review argued for some form of centralised ethical review for multi-centre studies as a way of ensuring timely and consistent ethical review, though these were rejected in favour of maintaining the current system of local committees along with a recommendation for increased communication between IECs and the acceptance of 'a single technical assessment of research' [2] to be conducted at multiple sites. The debate over the respective merits of centralised versus local ethical review of human research has flared a number of times since then, and has given rise to initiatives such as the Streamlined Ethical Review Process (SERP) that started in Victoria but is making its way up the Eastern seaboard, and the Harmonisation of Multi-centre Ethical Review (HoMER) which is currently being rolled out nationally. My interest here is not directly with the merits or otherwise of these schemes, but with what this debate has revealed about differing conceptions of the ethical review of human research and how consistent these are with the requirements of the *NS*.

Below the horizon of these differing conceptions are ongoing philosophical disputes over the basis of moral or ethical judgements *per se*, which are very far from being settled. The philosopher and bioethicist Julian Savulescu provided a useful simplification of these disputes in the context of research ethics in claiming that:

> There are two philosophical views of what ethics review is. On the one view, a subjectivist view, a study is ethical if an appropriately constituted ethics committee follows rules of due process and judges it to be ethical. This leaves open the possibility that committees may legitimately vary in

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1 *Report of the Review of the Role and Functioning of Institutional Ethics Committees: Report to the Minister for Health and Family Services*, Canberra: Commonwealth of Australia, 1996.

2 Ibid., Recommendation 3, Section 4.7.

> their evaluation of research. On the second view, the objective view, … there are substantive principles and criteria for the evaluation of research, and the role of the ethics committee is to examine whether the research is ethical by evaluating the degree to which the research conforms to these objective criteria for ethics review, and that in some cases, where committees disagree whether a project is ethical or not, some committees may be in error by failing to accurately evaluate whether the research conforms to these principles.[3]

Savulescu favours an objectivist approach which is consistent with his support for a centralised and professional system of ethics review,[4] and I suspect that many researchers and pharmaceutical companies would agree if only for reasons of greater consistency and efficiency. And given that the purpose of the *NS* is to provide substantive guidance on the 'ethical aspects of the design, review and conduct of human research,'[5] there is a case to be made that it is itself an exercise in objectivist research ethics.

In contrast, a subjectivist approach to ethics review would be more likely to resist the imposition of ethical guidelines and rely instead on the common sense ethical deliberations of local committees. For example, Millar has argued from what seems to be a communitarian perspective that 'local Committees should represent and share the ethical values of the communities from which they are drawn,'[6] and that 'ethical decisions made under a system of local authority somehow have greater merit than those determined at a national level, or by

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3 As reported in Merle Spriggs, 'Human subjects research: Review of the NH&MRC *National Statement on Ethical Conduct in Research Involving Humans*', *Monash Bioethics Review* 18 (4), Ethics Committee Supplement, 1999, 5–13, 12.

4 See for example Julian Savulescu, 'Is it time to abandon institutional research ethics committees?' *Monash Bioethics Review* 21 (3), Ethics Committee Supplement, 2002, 74–77; Julian Savulescu, 'Harm, ethics committees and the gene therapy death', *Journal of Medical Ethics* 27 (3), 2001, 148–50; and Julian Savulescu, 'Two deaths and two lessons: Is it time to review the structure and function of research ethics committees?' *Journal of Medical Ethics* 28 (2), 2002, 1–2.

5 *NS*, 9.

6 J. A. Millar, 'Is the Australian HREC system unsustainable? *Monash Bioethics Review* 21 (3), Ethics Committee Supplement , 2002, 63–67, 64.

strict observance of national guidelines.'[7] While this is a coherent position in and of itself, it doesn't sit comfortably with the position of the *NS* in ethics review. It is also open to familiar criticisms of communitarian approaches in general, such as how to determine which community's ethical values should hold sway even at the local committee level.[8]

Nonetheless, a recent study of how members of HRECs understand the process of ethical review found that many believed it was important for their committees to consider the 'community view' in their deliberations.[9] In terms of the composition of HRECs,[10] it was commonly seen to be the role of lay members to represent this view, though some 'religious members' also adopted this role.[11] Regardless of how widespread these perceptions of the role of lay members and community values in ethical review are, they need to be set against a number of other significant factors. Firstly, and as alluded to above, in a multi-cultural society such as Australia and particularly in metropolitan areas, there is no single set of community values that cuts across differences in age, ethnicity, class, sexuality, levels of education, health status, and so on. Secondly, the same study also found that members of HRECs '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,'[12] and so are likely to be familiar with only a quite narrow range of community values. Thirdly, even though an HREC considering a research application that impacts on a particular sector of the community is encouraged to take the values of that community into account in their ethical review, committee

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7 Ibid., 65.

8 For an argument against the use of community values in ethics review, see Heta Häyry, 'Should the Decision of Ethics Committees be Based on Community Values?', in *Bioethics: An Anthology*, eds Helga Kuhse and Peter Singer, Malden: Blackwell 2006, 719–24.

9 Marilys Guillemin et al., *Investigating Human Research Ethics in Practice: Project Report*, Melbourne: Centre for Health and Society, The University of Melbourne, 2008, 11, 13.

10 See section 5.1.30 of the *NS* for a list of required membership categories for HRECs.

11 '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', Guillemin et al., *Investigating Human Research Ethics*, 19.

12 Ibid., 11.

members are not appointed as representatives of particular communities but are instead individually 'responsible for deciding whether, in his or her judgement, a proposal submitted to the review body meets the requirements of this National Statement and is ethically acceptable.'[13] And finally, there has been a concern for at least a couple of decades both here in Australian and the USA that non-biomedical graduate members of ethics committees have little influence on the outcomes of ethical reviews. For example, a study conducted by McNeill, Berglund and Webster in the mid-1990s found that:

> Both laymembers and other committee members perceived the lay role as providing a community perspective on proposed research and saw the laymember as especially concerned with the welfare of subjects of research. However, laymembers were usually perceived to be relatively inactive and their views were seen to be relatively unimportant.[14]

The same study found that committee members regarded the role of ministers of religion (a membership category that has since been broadened to include any person who perform a pastoral care role in the community) as being very similar to laypersons both in being primarily concerned with the welfare of research participants and their relative lack of influence. Taken together, these factors bring into question the perception that the deliberations of HRECs do or even could reflect some amorphous set of community values.

Another defence of the local HREC system comes from Paul Komesaroff, who in arguing that '[o]ne of the greatest achievements of ethics committees has been the pioneering of a community-based practice of ethical reflection,'[15] draws on the discourse ethics of the German philosopher and social theorist Jürgen Habermas in preferring:

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13 *NS*, section 5.2.2.

14 Paul M. McNeill, Catherine A. Berglund and Ian W. Webster, 'How much influence do various members have within research ethics committees?' *Monash Bioethics Review* 15 (2), Ethics Committee Supplement, 1996, 16–26, 13.

15 Paul Komesaroff, 'Debate: should Australia move towards a centralized ethics committee system? The case against', *Internal Medicine Journal* 35 (4), 2005, 249–50, 249. See also Paul Komesaroff, 'Ethics committees and ethical decision-making', in *Expanding the Horizons of Bioethics*, ed. Paul Komesaroff, Melbourne: Australian Bioethics Association, 1998, 159–62.

> A model of moral theory and action based on a view of society as a communication community (or rather, a collection of communities potentially in communication) and of social integration and development as tied to structures of communicative action.[16]

Habermas' notion of communicative action assumes that human interactions have a fundamental orientation towards mutual understanding and rational agreement, and that the normative validity of ethical judgements can only be legitimated by a consensus forged by the force of good reasons and the better argument. This orientation is said to be thwarted by the intrusion of 'instrumental' concerns that treat human interactions as a means to an end, as occurs when individual self-interest, economic efficiency, and bureaucratic administration are prioritised. This seems to be what Komesaroff has mind when he asserts that ethics,

> Does not involve the issuing of peremptory judgements that apply to all people as if they are merely manifestations of some universal principle. Nor is its primary aim accelerated decision making, increasing profits for industry or the convenience of researchers.[17]

In terms of the distinction between objectivist and subjectivist interpretations of ethics review, this approach is more properly described as intersubjective, though is objective insofar as the outcomes of communicative action are said to be universally binding pending the emergence of a better reason for acting otherwise.

Even though the ethical criteria stipulated in the *NS* could be seen as unnecessary strictures on ethical reasoning, they could also be regarded as the outcome of a process of communicative action that has as significant markers key documents such as the *Nuremberg Code, Helsinki Declaration, Belmont Report*, and in Australia the *NS*, and therefore an appropriate starting

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[16] Paul Komesaroff, 'Response to Susan Dodds: Is the Australian HREC system sustainable?', *Monash Bioethics Review* 21 (3), Ethics Committee Supplement, 2002, 68–71, 70.

[17] Komesaroff, 'Debate: Centralized ethics committee system?', 250.

point or framework for the ethical review of specific research applications. In addition, the ethical principles that have been central to research ethics since the publication of the *Belmont Report*:[18] respect for persons, beneficence and justice, and which have been adopted by the *NS*, are commonly regarded as *prima facie* binding; that is, they are binding or obligatory 'other things being equal', which means unless overridden by other principles or duties. As a result, the weight or importance of any one of these principles in relation to the others cannot be settled in advance but must instead be determined in particular contexts.[19] Without claiming that the kind of validity offered by discourse ethics has been operative in the development of research ethics, this interpretation of the *NS* is nonetheless consistent with two qualifications made in its opening pages: firstly, that it 'does not exhaust the ethical discussion of human research;'[20] and secondly, that it allows for 'flexibility in the practice of ethical review, depending on the type and area of research and the degree of risk involved.'[21]

The significance of the preceding discussion for what follows is that a broadly objectivist approach to ethical review is more consistent with the intent and requirements of the *NS* than a subjectivist one. Of the two objectivist approaches discussed above, Savulescu favours a centralised model of ethical reflection as a way of ensuring that the specialist expertise required to further reduce the

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18 The *Belmont Report* was produced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and was issued on 30 September 1978. It was at least in part a response to ethically problematic research studies such as the Tuskegee Syphilis study. Its full title is the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*.

19 There are versions of 'principlism' (as this approach to bioethics has come to be called) that rank principles as a means of reducing the potential conflicts between them in particular cases. The NS attempts to do something like this in stating that '[r]espect for human beings is the common thread through all the discussions of ethical values. Turning to it as the final value is a reminder that it draws together all of the ethical deliberation that has preceded it' (12). However, given that beneficence is a consequentialist principle it is not immediately obvious how it is to be derived from the non-consequentialist principle of respect for persons.

20 *NS*, 2.

21 *NS*, 4.

risk to research participants is available when projects are being reviewed.[22] In contrast, Komesaroff champions a decentralised model to forestall the intrusion of instrumental concerns into the domain of ethical review, yet also recognises the need for the provision of a variety of training programs offered independently of AHEC (the Australian Health Ethics Committee which oversees the operations of HRECs) as a means of stimulating critical debate in ethical review.[23] And as long as we have the kind of HREC system favoured by Komesaroff, and given that there is nothing in the officially sanctioned approaches to the streamlined review of multi-centre health and medical research that challenges it, an objectivist approach to ethical review requires us to pay closer attention to the degree of specialist expertise, including ethical expertise, brought to bear in the deliberations of HRECs.

What we know about the level of ethical expertise in HRECs

There's nothing new in the claim that members of HRECs should be encouraged if not required to undergo regular training in ethics. For example, in an article published in 2002, Susan Dodds shared her concern that increasing demands on HRECs may come at the cost of the quality of ethical review:

> I share the worry that as HRECs are increasingly asked to regulate policy that attention may be given to meeting bureaucratic legal requirements at the cost of overlooking substantive ethical concerns. As a philosopher, I might be thought to be biased, nonetheless I would argue that an appropriate

[22] Savulescu, 'Is it time to abandon institutional research ethics committees?', defends this position as follows: 'If ethics committees are to maximally reduce risk and promote effective communication of risks to participants, they require specialist expertise in pharmacology, systematic review, ethics, communication skills, and the science behind the research. Members should be paid as specialist professionals whose job it is to protect research participants … These comments are not intended to denigrate the important and selfless work many ethics committee members have contributed. But if we want to further reduce the risk to participants, we need to consider the possibility that ethics review is becoming too technical for the people currently asked to perform it, rather than blaming them when avoidable deaths occur' (76). See also Savulescu, 'Harm, ethics committees and the gene therapy death', *Journal of Medical Ethics* 27 (3), 2001, 148–50; and Savulescu, 'Two deaths and two lessons'.

[23] See Komesaroff, 'Response: Is the Australian HREC system sustainable?', 70.

> training in ethical deliberation as applied to HREC review is consistent with HREC members each bringing their own ethical perspective to bear on the issue before the HREC and will not yield a formulaic approach to HREC review.[24]

In the same edition of the journal this article appeared in, McNeill expressed a similar concern:

> Yet 'ethics' is being used to mean 'following rules' by some Australian research ethics committees. This is most apparent where ethics committees serve the needs of research institutes and universities, by blindly following rules, with little regard to whether or not the outcome is beneficial. The tendency betrays a fundamental misunderstanding of ethics. … It is to be expected that people, with little understanding of ethics, and no training in ethics, will seek the reassurance of guidelines for their decisions. However, when the guidelines are treated as rules, with little thought as their effect, then the word 'ethics' may come to mean its opposite.[25]

Possibly in response to such concerns, the current *NS* – which was issued in 2007 following a process of review which began in 2003 – includes a requirement for HREC members to 'attend continuing education or training programs in research ethics at least every three years'[26] that was not a part of the guidelines it superseded.[27] While any such requirement is welcome, it does not go as far as the *Report of the Review of the Role and Functioning of Institutional Ethics Committees* which recommended in 1996 that 'AHEC should develop a statement of core competencies for IEC members to assist the development of courses for their in-service training.'[28]

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[24] Susan Dodds, 'Susan Dodds' Reply', *Monash Bioethics Review* 21 (3), Ethics Committee Supplement, 2002, 78–80, 79.

[25] Paul M. McNeill, 'Research ethics review and the bureaucracy', *Monash Bioethics Review* 21 (3), Ethics Committee Supplement, 2002, 72–73, 72.

[26] *NS*, section 5.2.3 (c).

[27] The previous set of guidelines was the National Statement on Ethical Conduct in Research Involving Human (1999).

[28] *Report of the Review of the Role and Functioning of Institutional Ethics Committees,* Recommendation 15 in Section 7. Education and Training of EC members.

That such a set of core competences is needed is borne out by the findings of the previously mentioned study undertaken between 2006 and 2008 by Guillemin et al. into the ethical frameworks used by researchers and HREC members,[29] though it should be noted that the researchers did not come this conclusion themselves. The study found that:

> 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. … 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 should be noted that a few HREC members did not use the National Statement at all or were barely aware of it.[30]

Given the timing of the study, this finding cannot be taken as an indication of how effective the abovementioned requirement for HREC members to undergo training in research ethics has been. But when we consider that the ethical criteria set out in the *NS* are expected to form the basis of individual member's decisions, and that it is likely that the *NS* is the only exposure most members have to research ethics, it seems clear that the level of ethical expertise amongst most members does not provide an adequate basis for the rigorous and broad-ranging debate of relevant ethical issues that an objective approach to ethical review requires.

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[29] The findings of this study drew on data collected from individual interviews with 49 researchers and 39 members of HRECs associated with both regional and metropolitan hospitals, universities, research institutions, and government and non-government organisation across Victoria.

[30] Guillemin et al., *Investigating Human Research Ethics*, 22.

Interestingly, the study also found that overall, HREC members believed that they and their committees were 'equipped with the necessary expertise to fulfil an ethical review.'[31] So what do I mean by ethical expertise given my claim that it is a prerequisite for an objective approach to ethical review, yet also something that HREC members seem to believe that either they have already or do not see the need for?

What is ethical expertise?

In an often cited article published in 1972, Peter Singer challenged the orthodoxy among philosophers at the time (and since)[32] that there is no such thing as moral expertise[33] and that, in the words of the distinguished twentieth century English philosopher C. D. Broad, 'Moral philosophers, as such, have no special information not available to the general public, about what is right and what is wrong.'[34] The basis of such claims is the widespread presumption in the English speaking world that moral theory should be grounded in common-sense morality, which Archard has described as 'that set of basic moral precepts which ordinary individuals have command of and use to regulate their own lives.'[35] Within the terms of this presumption, moral philosophers have no special access to, or claim on, common-sense morality, and so it would be presumptuous of them to claim expertise let alone authority on matters of right and wrong.

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31 Ibid., 12.

32 See for example Arthur L. Caplan, 'Moral Experts and Moral Expertise: Do Either Exist?', in *Clinical Ethics: Theory and Practice*, eds Barry Hoffmaster, Benjamin Freedman and Gwen Fraser, Clifton: Humana Press, 1989, 59–87; Christopher Cowley, 'A New Rejection of Moral Expertise', *Medicine Health Care and Philosophy* 8 (3), 2005, 273–79; and Jan Crosthwaite, 'Moral Expertise: A Problem in the Professional Ethics of Professional Ethicists', *Bioethics* 9 (4), 1995, 361–79.

33 Even though it's not uncommon for the terms 'morality' and 'ethics' to be used interchangeably, in what follows morality will refer to the moral values, rules, or guidelines that are accepted by a given community, while ethics will refer to rational reflection on these.

34 As cited in Peter Singer, 'Moral Experts', *Analysis* 32 (4), 1972, 115–17, 115.

35 David Archard, 'Why Moral Philosophers are Not and Should Not be Moral Experts', *Bioethics* 25(3), 2011, 119–27, 119.

Though not motivated by the same concerns, the common belief amongst HREC members that they should consider the 'community view' in their deliberations, along with the perception that HRECs are 'equipped with the necessary expertise to fulfil an ethical review,' is consistent with the position outlined in the previous paragraph. There is also a case to be made that the four principles or values that inform the guidelines of the *NS* have their source in common-sense morality. Three of these four principles: respect for persons, beneficence, and justice, also appear in the *Belmont Report* which was an early if not the first attempt to codify the basic ethical principles that should underlie the conduct of human research. These ethical principles were described as 'those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions,'[36] which agrees with Archard's definition of common-sense morality. Given the influential role the *Belmont Report* has come to play in the codification of research ethics internationally, and the aspiration of the *NS* to contribute to an ethos in human research underpinned by 'an abiding respect and concern for one's fellow creatures,'[37] it is reasonable to assume that the *NS* is at least implicitly grounded in common-sense morality as well.[38] Just how this is to be reconciled with my earlier claim that the intent and requirements of the *NS* entails an objectivist approach to ethical review, which in turn requires a degree of ethical expertise, will be explained in what follows.

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[36] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (DHEW Publication No. (OS) 78-0012), Washington, DC: US Government Printing Office, 1978, 4.

[37] *NS*, 3.

[38] This aspiration is also consistent with Beauchamp and Childress' claim that the source of the four principles they employ: respect for autonomy, non-maleficence, beneficence, and justice, is the 'common morality' which they define as 'the set of norms shared by all persons committed to the objective of morality' which are in turn defined as 'those of promoting human flourishing by counteracting conditions that cause the quality of people's lives to worsen' (Tom Beauchamp and James Childress, 'Principles of Biomedical Ethics (Selection)', in *Bioethics: An Introduction to the History, Methods, and Practice,* eds Nancy S. Jecker, Albert R. Jonsen and Robert A. Pearlman, Sudbury: Jones and Bartlett Publishers, 2007, 147–152, 156.

Singer's defence of the notion of moral expertise is not surprising coming from a philosopher working in applied ethics. The very existence of applied ethics, which involves at least in part the application of moral theories and the kinds of conceptual clarification and argumentation that philosophers are well versed in, assumes that philosophers have a role to play in debates over practical moral issues such as abortion, euthanasia, genetic research, the fair distribution of health resources, and so on. For Singer, the claim that applied ethics usurps the moral prerogative of the non-philosopher would be reasonable only if common-sense morality had clear and ready answers to the moral dilemmas issues such as these raise.[39]

> Only if the moral code of one's society were perfect and undisputed, both in general principles and in their application to particular cases, would there be no need for the morally good man to be a thinking man. Then he could just live by the code, unreflectively. If, however, there is reason to believe that one's society does not have perfect norms, or if there are no agreed norms on a whole range of issues, the morally good man must try to think out for himself the question of what he ought to do.[40]

To this end, Singer argues that moral philosophers have at least the following three advantages over non-philosophers when it comes to mulling over difficult moral issues: (i) expertise in understanding and producing logical arguments, identifying the logical and practical implications of particular positions, and detecting invalid inferences and possible counter arguments; (ii) expertise in

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[39] For a critique of applied ethics, see for example Cheryl Noble, 'Ethics and Experts' *The Hastings Center Report* 12(3), 1982, 7–9: 'Moral problems are everybody's business. But the past decade has witnessed a surprising challenge to the idea that no discipline has a special competence to resolve matters of right and wrong. Armed with "techniques" of moral reasoning, some academic philosophers have been claiming a form of ethical expertise. This claim arises in connection with a new philosophical subdiscipline, applied ethics. Applied ethics attempts to use ethical theory in the solution of practical, moral, and social problems of all kinds, including the morality of abortion, genetic research, euthanasia, capital punishment, warfare, pacifism, terrorism, and reverse discrimination and racism' (7); and 'Philosophy has not so much broadened to encompass moral reflection as narrowed the field of moral reflection, redefining it as appropriate to a technician's skills' (9).

[40] Singer, 'Moral Experts', 117.

the clarification and analysis of moral concepts as an aid to producing sound arguments; and (iii) knowledge of moral theories such as utilitarianism, natural law theories, and theories of justice and of rights, their implications for particular moral concerns, and recognised criticisms.[41]

These three advantages are not in and of themselves reason for concluding that moral philosophers are *uniquely* equipped to think their way through difficult moral issues, or more to the point, that their judgements should necessarily be accepted by the uninitiated. Nonetheless, they provide a workable model for what I mean by ethical expertise as a necessary but not sufficient condition for making sound moral judgements in the contexts applied ethics operates within: necessary because the deliberations that applied ethics seeks to inform result in decisions that affect others, and in modern societies where reason and not tradition (of whatever kind) is the basis for assessing the soundness of such decisions, clear and well formed and informed arguments are essential to ensure transparency and accountability; but not sufficient because the details of the practical issues that applied ethics addresses are an indispensible factor in any deliberation over how to think through the ethical dilemmas they provoke.[42]

A number of objections, both conceptual and moral, have been raised against claims of ethical expertise,[43] three of which are relevant to this discussion. The

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41 Singer also argues that moral philosophers have more time to think about moral issues given that most other people have occupations to pursue that leaves little time for such reflection. This fourth advantage was excluded as it doesn't bear in any significant way on the notion of ethical expertise being developed here.

42 Lynn Gillam, 'Expertise in research ethics: Is there any such thing?', *Monash Bioethics Review* 23 (3), Ethics Committee Supplement, 2004, 58–64, 61. Gillam has described her understanding of ethical expertise as including: '… skills in clarification and analysis of concepts, critical analysis and evaluation of arguments (or positions), including identification of possible counter-arguments, and the ability to identify logical and practical implications of positions. These skills depend in part on knowledge of ethical theories and philosophical problems more generally, of recognised criticisms and implications of common ethical positions, and of argumentative strategies and their potential logical pitfalls' (59 –60). To this she adds the following to provide an account of expertise in research ethics more specifically: 'knowledge of research practice, across a range of methodologies; knowledge of issues and debates in research ethics; and knowledge of the legal framework within which research involving humans occurs (such as, for example, privacy legislation)' (61).

43 For recent contributions to the debate over ethical expertise see the following: David Archard, 'Why Moral Philosophers are Not and Should Not be Moral Experts', *Bioethics*

first of these points to the existence of fundamental disagreements between moral philosophies that are thought to be more extensive and radical than in other fields in which expertise can be legitimately claimed. It is not at all clear that this is the case, though, as most fields of enquiry where claims of expertise are not questioned, including physics, biology, medicine, statistics, and jurisprudence, involve disagreements that are at least as fundamental as those found in moral philosophy.

The second objection is that expertise cannot be claimed in matters that are not objective, and that moral propositions are subjective evaluations rather than matters of fact and so cannot claim to be objective. Even if we set aside long-standing criticisms of the distinction between fact and value: that is, between *what is* and *what ought to be*, as well as debates within moral philosophy as to whether or not moral propositions are or could be objective, it still does not follow that expertise is not possible in matters that are purely subjective. As Archard has noted, 'even in matters of subjective taste, as Hume's famous essay argues, there is the possibility of standards whereby some subjective judgments may be thought better than others.'[44]

The third objection brings the discussion back to the relation between ethical expertise and common-sense morality. If moral knowledge is shared by the supposed expert and non-expert alike, as the grounding of moral theory in common-sense morality entails, then there is no basis upon which to claim, as expertise requires, a comprehensive command of a particular kind of knowledge that is not possessed by others. Returning to a claim made by Singer cited earlier

25 (3), 2011, 119–27; Alexander Bogner and Wolfgang Menz, 'How Politics Deals with Expert Dissent: The Case of Ethics Councils', *Science, Technology and Human Values* 35 (6), 2010, 888–914; Bernward Gesang, 'Are Moral Philosophers Moral Experts?', *Bioethics* 24 (4), 2010, 153–59; Giles R. Scofield, 'Speaking of Ethical Expertise…', *Kennedy Institute of Ethics Journal* 18 (4), 2008, 369–84; Norbert L. Steinkamp, Bert Gordijn and Henk A. M. J. ten Have, 'Debating Ethical Expertise', *Kennedy Institute of Ethics Journal*, 18 (2), 2008, 173–92; and Norbert L. Steinkamp, Bert Gordijn and Henk A. M. J. ten Have, 'Ethical Expertise Revisited: Reply to Giles Scofield', *Kennedy Institute of Ethics Journal* 18 (4), 2008, 385–92.

44 Archard, 'Why Moral Philosophers are Not and Should Not be Moral Experts', 123. The essay referred to is: David Hume, 'Of the Standard of Taste', in *Essays: Moral, Political and Literary*, ed. E. F. Miller, Indianapolis: Liberty Classics, 1985 [1757], 226–49.

in this section, this objection would be convincing only if common-sense morality had clear and ready answers to all the moral dilemmas we are confronted with. The augmentation of common-sense morality by applied ethics, which involves the command of a means of clarifying, refining, and possibly modifying common-sense morality in response to such dilemmas, implies at the very least a limited kind of expertise insofar as the non-expert, who is not in command of such means, is not in a position to endorse or reject the moral judgements of the expert in an informed way. But given a commitment to common-sense morality, which in liberal democracies includes an expectation that competent individuals have a right if not an expectation to decide for themselves what they ought or ought not to do, it is clear that we should not conflate ethical expertise with moral authority and expect the moral judgements informed by ethical expertise to be accepted by others. What this leaves is the presentation of clear and systematically argued reasons in support of particular moral judgements that can act as a spur to critical reflection on the moral dilemmas that confront us, but on which competent individuals must ultimately decide for themselves. None of this is to say that ethical expertise is or should be the sole preserve of moral philosophers, even though they are in a position to develop a higher degree of ethical expertise than most, as one of the aims of applied ethics should be to spark and inform debate as a means of raising the level of ethical expertise throughout the community.

The *NS* is itself an example of the refinement, clarification and modification of common-sense morality, and as such the result of the application of ethical expertise to the social practice of human research. However, and this is a crucial point, its role in the regulation of human research gives it an objective status and so a moral authority that ethical expertise is not otherwise entitled to. As such, the *NS* acts a guide for an ethical review process that makes limited decisions on behalf of research participants as HRECs negotiate the tension between, on the one hand, the value of respect for persons which involves an obligation to allow research participants to decide for themselves how much risk they are willing to accept,[45] and on the other, an obligation to ensure that research is

[45] See section 1.12 of the *NS*: 'Respect for human beings involves giving due scope, throughout the research process, to the capacity of human beings to make their own decisions.'

designed and conducted in such a way as to minimise harm to participants.[46] For these decisions to be made in accordance with the *NS*, mere familiarity with its guidelines or a recourse to 'community values' or common-sense morality is not enough, as without an understanding of what Gillam has referred to as 'the complexities of what [the guidelines] actually *mean*, and the implications of these meanings,'[47] there is a real risk that ethical review becomes an exercise in following rules that are poorly understood and so poorly applied. If we place this concern in the context of the previously mentioned finding that it is not uncommon for HREC members to review research applications without explicit reference to the *NS*,[48] then there is reason to suspect that the moral authority of the *NS* is being undermined in practice by a lack of ethical expertise.

Enhancing ethical expertise in HRECs

Within the constraints of the current de-centralised system of ethical review, there are at least two ways this concern can be addressed. The first is to include as one of the membership categories of an HREC a person with ethical expertise, however that be defined. This has been proposed more than once during the periodic reviews of the various guidelines that preceded the current *NS*, which without actually doing so has gone so far as to stipulate that: 'Wherever possible one or more of the members listed in 5.1.30 [which lists the various membership categories] should be experienced in reflecting on and analysing ethical decision-making.' While this is welcome, I am not aware of any data on how many HRECs include a person who fits this description, or why it has never been included as one of the required categories of membership. Still, the inclusion of such a person would go some way towards enhancing the ethical expertise of HRECs.

The second way of addressing this concern is to raise the level of ethical expertise of all HREC members. This would address both the requirement for

[46] See section 1.6 of the *NS*: 'The likely benefit of the research must justify any risks of harm or discomfort to participants. The likely benefit may be to the participants, to the wider community, or to both.'

[47] Gillam, 'Expertise in research ethics: Is there any such thing', 61.

[48] See the study conducted by Guillemin et al. discussed earlier in the paper.

each member of an HREC to evaluate research proposals with reference to the relevant sections of the *NS*, and the claim that at least some degree of ethical expertise is required for the informed application of these guidelines. To this end, I endorse the recommendation from the 1996 review of IECs mentioned earlier that 'AHEC should develop a statement of core competencies for IEC members to assist the development of courses for their in-service training,' along with the associated recommendation that: 'Institutions should make available sufficient (ongoing) funding to enable its IEC members to avail themselves of opportunities for relevant in-service training and development.'[49] The usefulness of a statement of core competencies in this context would obviously depend on what it contained. Most existing training programs designed for HREC members that I have seen tend to focus on technical aspects of ethical review, and so touch only briefly if at all on the ethical complexities and implications of the guidelines in the *NS*.[50] There are a limited number of university–based programs that do a much better job of this,[51] though more flexible and less expensive options could easily be developed in response to a statement of core competencies. With regard to the associated recommendation, I know that at least some HRECs are supported financially by their institutions to enable committee members to undertake such training, though it would be useful to know how widespread this is, as well as the extent of the support made available.

These two ways of addressing this concern are complementary and would ideally be implemented together. As mentioned above, the *NS* has addressed without going so far as to implement these recommendations. I am not aware of the reasons for this, though resourcing could be a factor: there are more than 200 HRECs in Australia and so there may not be enough people experienced in

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[49] *Report of the Review of the Role and Functioning of Institutional Ethics Committees*, Recommendation 16 in Section 7. Education and Training of EC members.

[50] See, for example, the web-based courses available at the following sites: http://www.mq.edu.au/ethics_training/; http://www.cems.monash.org/online-ethics-training-course.html; http://researchethics.od.nih.gov/

[51] For example, The Centre for Human Bioethics at Monash University offers both a Graduate Certificate in Research Ethics and a residential Bioethics Intensive course once a year.

ethical reflection who are willing to serve on HRECs to go around; there may not be sufficient funds to cover the costs of adequately training HREC members in research ethics; and the voluntary nature of the work undertaken by HREC members could make it unreasonable to expect a further commitment of time to undergo such training. If resourcing is an issue for reasons such as these, then given that less than a fifth of all HRECs are currently certified under the HoMER scheme for the single ethical review of multi-centre research studies,[52] that these committees tend to be associated with large institutions which are more likely to be able to provide the resources required, and that there is an expectation that the ethical judgements of these HRECs will be accepted by other committees, this subset of the HREC system would be the most appropriate place to trial the implementation of these recommendations.

The final point I would like to briefly make is that even if these recommendations were implemented and proved both workable and worthwhile, the cause of improving the level of expertise, ethical and otherwise, of HREC members might still be better served by a centralised and professionalised system of ethical review. [53] In this context it is worth noting that a report commission by the UK Department of Health which was released in 2005 found that 'the totally voluntary systems of RECs [Research Ethics Committees] may not be sustainable and, indeed, may no longer be appropriate,'[54] recommending that 'It is timely to rationalise further the number of RECs, with more intense operation for the smaller number resulting.'[55] None of this would soothe the concerns of critics of a more centralised system such as Komesaroff. Nonetheless, such a change would sit comfortably with the argument presented here that an objectivist approach to ethical review

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52 At the time of writing, a document dated 21 December 2011, listing the institutions that are currently certified to conduct the single ethical review of multi-centre research studies under the HoMER scheme included 43 committees: Retrieved from http://hrep.nhmrc.gov.au/_uploads/files/certified_institutes.pdf

53 My thanks to the anonymous reviewer of this article for suggesting this.

54 UK Department of Health (DH), 268110/*Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees,* 2005, 14. Retrieved from http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4112417.pdf

55 Ibid.

requires a higher level of ethical expertise than is currently the case amongst members of HRECs in Australia.

Conclusion

The two recommendations proposed in the previous section aim to enhance the ethical expertise of HRECs as a means of strengthening the objectivist approach to ethical review of human research entailed by the *NS*. What I have referred to as the mismatch between the requirements of the *NS* and what we know of the current practices of HRECs has its basis in the disjunction between this approach and the assumption that community values or common-sense morality is an appropriate basis for, or at least a valid adjunct to, ethical review. Given that the *NS* is the result of the application of ethical expertise to the social practice of human research, that ethical expertise is a response to the limitations of common-sense morality in particular contexts such as human research, and that the notion of community values is hopelessly underdetermined in liberal pluralist societies such as Australia, I can see no benefit in appealing explicitly to something that all members of HRECs carry with them implicitly anyway. And even though lay members of HRECs are commonly thought to represent the 'community view' in ethical deliberations, it is more consistent with an objectivist approach for lay members to perform a function like that of non-executive directors on the board of directors of a company: that is, to act as a counter-balance to potential biases from committee members involved in research themselves and/or associated with the institution that hosts the committee.

Further, because appeals to community values or the community view are more consistent with a subjectivist than an objectivist approach to ethical review, and variations in ethical judgements between committees are more likely to be tolerated under the former rather than the latter, the enhancement of ethical expertise on HRECs would strengthen the latter by providing a more informed basis for the ethical judgements of reviewing committees. In theory this should also reduce the variability in ethical judgements, though even if it does not it would make it more likely that well reasoned justifications for the ethical judgements made by reviewing committees would be given.

It is expected that the cumulative effect of the implementation of these recommendations would be to, firstly, entrench in the social practice of ethical review an explicit recognition of the moral authority of the *NS*, and secondly, acknowledge the role that ethical expertise should play in the application of the *NS* as a basis for the ethical deliberations of HRECs. However, it must also be acknowledged that a move towards a more centralised and professionalised system of ethical review could well be a more appropriate means of advancing these aims. Whether or not the attendant drawbacks of such an approach are sufficient to counter the benefits is a matter for broader debate.