article

Research, Ethics Committees and Legal Issues

Andrew Moore
Department of Philosophy, University of Otago

Abstract

Who should be publicly authorised to consider legal issues in research? This paper argues that public policy should authorise ethics committees to consider legal issues about their own actions regarding particular research proposals; and that it should not authorise them to consider legal issues regarding the actions of their applicants, or the actions of third parties.

1. Introduction

Professional bodies, employers, and even bills and statutes, increasingly require researchers to submit instances of their professional activity for ethics committee review. A favourable opinion from such review is often now a condition of continued research professional activity. It will be assumed below that this is appropriate. Given that ethics committees have this powerful role, there has been surprisingly little systematic inquiry into which more specific actions policy should authorise them to perform. This paper concerns one aspect of this broad issue, regarding those public bodies ('ethics committees') that conduct ethics committee review of particular instances of human subjects research. In New Zealand, these bodies include regional health and disability ethics committees, the National Ethics Committee on Assisted Human Reproduction, and the Health Research Council Ethics Committee ('HRC Ethics Committee').

Should policy authorise ethics committees to consider *legal* issues, as part of their review of particular research proposals? This paper aims to answer that normative question. It is *not* primarily a question about what ethics committees should do. They should consider all legal issues that current public policy requires them to consider, and only those it currently permits them to consider. Which legal issues are those? That varies from jurisdiction to jurisdiction (for an account of the New Zealand situation, see Dawson and Peart, 2003), and it is ultimately a matter for the courts to determine at judicial review. This paper's central question instead concerns what *public policy* should here permit or require of ethics committees. Nor is this a question of administrative law, about the *current* public authority of ethics committees. What policy is and what policy should be do not necessarily coincide. If they did, policy-makers and their advisors would have no job to do.

Major jurisdictions take opposing approaches to the role of ethics committees regarding legal issues. English policy is that: 'It is not for the REC to provide specific interpretation of regulations or laws …'; and 'It is not the role of the REC to offer a legal opinion …'; though 'it may advise the applicant and the host NHS body whenever it is of the opinion that further expert legal advice might be helpful to them' (COREC, 2001, paragraphs 2.6, 9.11). This makes the legal significance of proposed applicant action irrelevant to ethics committee opinion of that action, but nevertheless authorises separate *comment* to applicants on such matters. Australian policy is clear also, but also clearly the opposite: '… HRECs need to

be satisfied that the conduct of research that they approve is lawful' (NHMRC, 1999, p.5). This makes ethics committee judgment that applicant action is lawful a necessary condition of favourable ethics committee opinion.

Current New Zealand public policy is unclear on the issue. It states, for example, that: 'Committees will also need to ensure that any activities are undertaken in accordance with the New Zealand Bill of Rights Act 1990' (MOH, 2002, paragraph 18). This seems to apply only to the Committee's *own* activities, since no committee can 'ensure' that anyone's activities but its own comply with any Act. It also states that many legal provisions are 'relevant' to ethics committees' operation, but is silent on whether this is relevance only to their own action, or also to action of their *applicants,* or of *third parties*.

This paper proceeds as follows. Section 2: Should public policy require ethics committees to consider the legal significance of *their own* action? Section 3: Should it authorise them to consider the legal significance of their *applicants'* proposed action? Section 4: Should it authorise them to consider the legal significance of *third party responses* to their applicants' action? Throughout the paper, the aim is to give internationally applicable answers to these questions, albeit that New Zealand contexts and examples are prominent.

2. Ethics Committee Action

It is simply assumed below that public policy *should* require each ethics committee to consider the legal significance of its *own* action. For all of us, this is an important part of knowing what we are doing. For ethics committees, however, this is no simple matter. This section explores some of its complexities.

First, public policy should require each ethics committee to consider the *lawfulness* of its own action. This includes taking due care to perform all action it has a public duty to perform, and only action it is publicly authorised to perform; and to do all this in a lawful manner. Second, policy should require each ethics committee to consider the *legal effects* of its own action. This includes effects on the *lawfulness* of others' action. In New Zealand, for example, actions of certain ethics committees can, under s25(1)(c) of the Health Research Council Act 1990, affect the lawfulness of HRC Ethics Committee action. Ethics committee approval can also, under Rule 11(2)(c)(iii) of the Health Information Privacy Code 1994, affect the lawfulness of third party action to disclose information for research use. Ethics committee action can also affect others' *entitlements*. In New Zealand, for example, actions of an ethics committee that is approved by the HRC Ethics Committee or by the Director-General of Health can, under s.32 of the Injury Prevention, Rehabilitation, and Compensation Act 2001, affect research participant entitlement to accident compensation ('ACC') provision. That Act presumptively excludes from ACC entitlement a very broad range of research participants, as a means to the end of making research sponsors carry this liability in a narrow range of clinical trials. This questionable use of research participants also imposes major burdens on ethics committees, to recover or to secure adequate replacement for this presumptive exclusion of citizens from entitlements.

It can be quite demanding on ethics committees if they are to consider the legal significance of their own action. This is illustrated below in three sorts of case.

Suppose public policy leaves two or more options open for researchers, and is neutral between these. If ethics committees nevertheless develop a *general* preference for one option over the other, do they thereby exceed their public authority? Consider, for example, the New Zealand guidance on privacy and health information, which allows researchers to approach potential participants either directly, or indirectly, in light of prior general practitioner contact, and which expresses no general preference between these two options (HRC, 2002, section 6.7). If ethics committees were to develop a general preference that their researcher applicants take the indirect approach, would this exceed their public authority? Must they instead assess each proposal afresh on its merits, without any standing preference for either approach, unless and until *policy* prefers one approach to the other? The point here is not to *answer* these questions, but is instead to illustrate the fact that an ethics committee that considers the legal significance of its own actions must act on defensible answers to these questions about the scope of its public authority.

In a second sort of case, policy authorisation of ethics committee action is unclear as between two or more interpretations. Consider the following case. Current English policy regarding ethics committee review of multi-national multi-centre clinical trials is that just one committee, typically a multi-centre research ethics committee (MREC), conducts a full review. Its central question is: 'Would this research, if

carried out at a satisfactory locality by a satisfactory researcher, meet established ethical standards?' If the MREC duly answers 'yes', then this opinion is submitted, together with localised papers, to the relevant Local Research Ethics Committees (LRECs). Their central question is much simpler and narrower: 'Given that this proposal does meet established ethical standards, is this particular locality and local researcher satisfactory?' (COREC, 2001, section 8; Terry Stacey, COREC Director, personal communication). If an LREC duly answers 'yes', then its locality comes within the scope of the MREC's favourable opinion. Beyond this, however, current policy is less clear. It is *perhaps* that if the LREC duly answers 'no', then the publicly authoritative ethics committee opinion for its locality is consequently *unfavourable*. In addition, this current policy seems inconsistent with a European Union Directive, legally binding on all member states from May 2004, that there be 'one ethics committee opinion per member state' for each multi-national, multi-centre clinical trial (European Union, 2001). Since the MREC already offers one 'ethics committee opinion', it *seems* that no LREC will after May 2004 be legally permitted to offer any opinion of its own to any applicant for any such study. Its lawful role in such cases might then be confined just to making comment to the relevant MREC. The aim here, however, is not primarily to reach this or any other conclusion on English or European Union administrative law. It is instead to illustrate, in a case where policy is less than crystal clear, the sorts of difficult questions English ethics committees must answer and defensibly act upon regarding the legal significance of their own actions.

Now suppose, to take a third sort of case, that application is made to an ethics committee, but it reasonably believes *no* specific recognised ethical standard, whether in statute or regulation, common law, or in any 'soft law' professional guideline, code, or operational standard, is applicable. Perhaps sale of human organs or tissues is proposed, for example, or stem cell research on tissue from aborted human foetuses, and perhaps policy has not yet addressed either possibility in the particular research setting proposed. Various potential policy approaches to ethics committees' role in such settings are canvassed below.

One option is to give ethics committees a broad authorisation at least to *consider* applicant proposals that policy has not yet specifically addressed. They could do this by applying their *general* substantive standards, such as dignity of the subject, or avoidance of harm to participants. It might even be argued that, since participant protection is the primary job they should be authorised to do, they should consider and *decline* any such proposal, on grounds that absence of such standards is itself a risk to participants.

Suppose application of general substantive standards generates no determinate or univocal response. Policy might then authorise ethics committees to apply their general *procedural* standards. Some of these state that ethics committees' job is to apply recognised ethical standards (eg., COREC, 2001, Section 2). Others require ethics committees to decline, or to decline even to consider, any proposed activity for which no specific formal standards are in place (eg., HART, 2003, Section 16(2)). Alternatively, procedural standards might state that in the absence of specific substantive standards, ethics committees may or should exercise their free ethical judgment. Arguably, however, this approach would constitute either arbitrary action ('we might make the opposite judgment next month'), or *de facto* policy-making that policy-makers should not delegate to operational ethics committees.

Suppose application of their general procedural standards generates no determinate or univocal response. Policy might then authorise ethics committees to apply general standards concerning *citizen-state* relations. For example, the liberty of the citizen is a basic feature of this relation, and of the legal system as a whole. One view worth taking seriously is that this should presumptively carry the day, to generate a *favourable* ethics committee opinion of citizen proposals wherever no specific ethical standard is yet in place.

Where there is no specific standard for ethics committees to apply, it is not easy for them even to identify all the candidate approaches they might reasonably consider. Defensibly settling on one particular approach is more difficult still. Yet it is in the nature of research that it often addresses matters policy has not yet fully contemplated. Ethics committees will consequently face this ongoing difficulty in their practice. Even so, further policy guidance here would certainly assist them.

This section's overall conclusions are as follows. Ethics committees should consider legal issues regarding their own action, mindful that it can be a difficult and subtle matter to assess whether they are acting within or outside their public

authority. There are at least three sorts of difficult case: where policy even-handedly permits more than one option for researchers but ethics committee practice prefers one particular option; where policy is unclear regarding authorised ethics committee action; and where policy does not specifically address this matter at all. Further policy development can make the job of ethics committees easier in all three areas. Committees can also assist policy-makers, by attending to the legal significance of their own actions, and by communicating to policy-makers and their advisors the difficult policy issues that inevitably arise in their practice.

3. Applicant Action

Should public policy authorise ethics committees to treat the legal significance of *applicant* action as relevant to their opinion of that action? This section will first assess arguments for an affirmative answer, then arguments for a negative answer. It will find the latter arguments the more persuasive.

One policy, current in Australia, is that ethics committees should, as a pre-condition of their favourable opinion, duly satisfy themselves that proposed applicant action is lawful; and should form an unfavourable opinion of any applicant action that they are duly satisfied is unlawful. Two arguments for this policy are assessed below.

The first argument is this. Policy should authorise ethics committees to apply established ethical standards to proposed applicant action. This would authorise them to give these standards legal effect, and thus to apply these 'soft' legal standards to proposed *applicant* action.

This is a good argument, as far as it goes. If policy authorises ethics committees to consider proposed applicant action, it authorises them either to apply established ethical standards, to generate standards themselves, or to exercise their own 'standards-free' ethical judgment. It will here be assumed that the first option is appropriate and the second and third options are not. But it does not follow that policy should authorise ethics committees to apply anything other than these established *ethical* standards, even granted the side-effect that these thereby acquire some legal status. The real question is whether policy should authorise ethics committees to consider *wider* legal issues, those that are not merely parasitic on established research ethics standards. The above argument generates no reason to believe it should.

Here is the second argument. Public policy should authorise ethics committees to consider all matters that bear on the ethics of proposed applicant action. The legal significance of proposed applicant action bears on its ethics. Therefore, public policy should authorise ethics committees to consider the legal significance of proposed applicant action.

The claim that the legal significance of applicant action bears on its ethics is related to the much-discussed claim that one has ethical reason to obey the law. Neither claim will be contested here. Critical discussion here will instead focus on the claim that public policy should authorise ethics committees to consider *all* matters that bear on the ethics of proposed applicant action.

Researcher peers and funding body review committees are better placed than ethics committees to judge whether proposed research seeks to answer important questions. Health or disability sector host organisations are better placed to judge whether proposed research would make good use of their resources. Technical committees are better placed to judge whether unlicensed medicines would be safe for study participants in the proposed circumstances of use. All these things bear on the ethics of applicant action, yet public policy should not authorise ethics committees to consider the substance or merits of any of them. It follows that policy should *not* authorise ethics committees to consider the *merits* or *substance* of all matters that bear on the ethics of applicant action. The above argument consequently gives us no reason to believe policy should authorise ethics committees to consider the merits or substance of *legal* issues concerning applicant action.

Consider the following reply. Policy should authorise ethics committees to give at least *purely procedural* consideration to all issues that bear on the ethics of proposed applicant action. The legal significance of proposed applicant action bears on its ethics. Therefore, policy should authorize ethics committees to give at least purely procedural consideration to the legal significance of proposed applicant action. In practical terms, this might involve checking that *other* relevant bodies have considered whether proposed applicant action would meet technical safety requirements, would best utilize the resources of the research host organisation, would be lawful, and so forth.

The argument will still not do. Consider: 'Would *this* proposed

research be the best possible use of this researcher's talents?' On most plausible accounts of ethics, answers to such questions *do* bear on the ethics of applicant action. Some perfectionist accounts even take 'yes' answers to be necessary to ethical acceptability (e.g., Hurka, 1993). On most plausible accounts of ethics, one's motive or maxim or character state also bears on the ethics of one's action. Some Kantian (e.g., Kant) and virtue-ethical (e.g., Slote, 2001) accounts even take certain details of this sort to be necessary to ethical acceptability. Yet policy should not authorise ethics committees to consider any of these matters, not even in a purely procedural way. For any ethics committee or other body to do so would be too intrusive; the subject matter too inscrutable; the links between the ethics of applicant action, and character, motive, and talent too controversial; and the overall likelihood too high that they would get the matter plain wrong. In short, then, policy should not authorise ethics committees to bring all ethically relevant matters to bear, even in a purely procedural way, on their opinion of proposed applicant action. The argument for ethics committee authorisation to consider the legal significance of applicant action consequently fails.

Even if the above *argument* for a purely procedural approach fails, however, some might still think it a good idea for ethics committees to be authorised for such a role, to check that *someone* appropriate has given a legal opinion, or a favourable legal opinion, or an authoritatively favourable opinion.

If the ethics committee were to apply any of the above procedures to just some applicants, it would have to make its selections on the basis of its own substantive assessment of each proposal's level of legal risk. This would make its approach substantive, not purely procedural. Applied to *all* applications, however, even the most modest of the above procedures would be very burdensome and expensive for applicants, and typically a waste of their resources. If *favourable* legal opinion were demanded, that would force the ethics committee to make *substantive* legal judgments itself, because legal advice is typically expressed in broadly probabilistic or 'degrees of risk' terms, not in any 'favourable / unfavourable' format. If *authoritatively* favourable legal opinion were demanded, then little or no research would survive ethics committee review, because few applicants could bear the expense and delay of securing the relevant court's declarative judgment. Moreover, law is so nuanced and multi-layered, and so apt for complex multi-participant processes, that it would be extraordinarily difficult to design a policy under which ethics committees could credibly take any purely procedural approach.

We should conclude as follows. First, no ground has yet emerged to believe policy should authorise *substantive* ethics committee consideration of legal issues regarding applicant action. Second, it is impracticable and undesirable for ethics committees instead to give only *purely procedural* consideration to these issues.

Turn now to arguments *against* policy-maker authorisation for ethics committees to consider legal issues regarding applicant action.

Where an ethics committee opinion bears on the lawfulness of applicant action, the committee cannot coherently bring that same legal consideration to bear on formation of its own opinion. For instance, a current policy initiative in New Zealand (HART, 2003, Section 14) would make any assisted human reproduction procedure not listed in its schedule of 'Established Activities' lawful only if favourably reviewed by an ethics committee. Ethics committees cannot in such cases coherently treat lawfulness under that same provision as a pre-condition of their favourable opinion. This argument has force, but narrow applicability. The wider point is that the law sometimes has an interest in the independent ethical assessment of action, and ethical assessment that is itself informed by legal assessment lacks such independence.

There are further and more significant reasons to believe policy should not authorise ethics committees to consider legal issues regarding applicant action. First, their core business should be to apply established ethical standards to proposed application action, and to do so in a lawful manner. If policy were to require them also to apply all relevant *legal* standards to proposed applicant action, this would greatly enlarge their job, at substantial opportunity cost to their core business. Both directly and indirectly, it would also expose ethics committees and their public body parent organisations to increased legal risk. Direct legal risk would increase, through increased potential for them to make procedural or substantive mistakes in these legal processes and judgments concerning applicant actions. Indirect legal risk would increase also, through the increased potential for these more heavily burdened ethics committees to make the corresponding sorts of mistakes in

their application of established *ethical* standards. In addition, there is no clear public interest in this expansive ethics committee role. Applicants will always retain primary professional, ethical, and legal responsibility for their own actions. Even if these actions were to be performed on behalf of a public body, the public interest would still be most effectively and efficiently served by simply making those bodies clearly accountable for their *own* actions. Research sponsors and host organisations might often wish to draw ethics committees into sharing these responsibilities that are clearly their own, but policy should assist committees to resist such invitations.

It might be thought problematical for public policy to disallow ethics committee consideration of legal issues regarding applicant action. An ethics committee might then justifiably declare a favourable opinion of a proposal that is unlawful, perhaps even criminal. And so it might. But no ethics committee consideration, nor any legal advice, no matter how much resource it consumes, can ever rule out this possibility. Only the courts can deliver publicly authoritative judgment as to whose action is unlawful. Only a requirement that a declarative judgment be secured in favour of each application could perhaps overcome this problem, but as argued above, this approach is both impracticable and undesirable. Nor is it clear that ethics committee consideration of legal issues about applicant action would even lower the relevant risk. Ethics committees that attend only to their core business of applying established ethical standards thereby apply much that appears also elsewhere in the law. Their close focus on the *ethics* might actually be the way to minimise the likelihood of their forming a favourable opinion of unlawful applicant action.

Policy and practice can make it explicit to all concerned that the legal significance of applicant action is not relevant to ethics committee opinion. Its practical expression could be this: 'Ethics committee opinion of your proposal XYZ is favourable. This does not imply any legal assessment of your proposal. That is your responsibility.'

In sum, policy should not authorise ethics committees to treat the legal significance of proposed applicant action as relevant to their opinion of that action. It should only authorise them to determine whether, in terms of a narrower range of ethically relevant matters and established ethical standards, their opinion is favourable or unfavourable. Which narrower matters? That depends on what the public interest is in this area, and on whether ethics committees are the best public bodies to serve it. Pursuit of this issue beyond its application to legal issues will have to await another occasion.

Why is it tempting to think policy should authorise ethics committees to treat legal issues about applicant action as relevant to their opinion of that action? Perhaps this response is based on the mistaken thought the ethics committees alone conduct ethical review. In fact ethical review is conducted also in the course of self-review, peer-review, technical review, and funding body review. In addition, primary responsibility for research ethics must always rest with research professionals rather than ethics committees. Relatedly, some might think any *ethics* committee must consider *all* ethical issues. Instead, however, they should consider only those they are publicly authorised to consider. Which should these be? That again depends on what public interests are at stake, and on whether ethics committees are the best public bodies to serve those interests. There are also international norms in this area, of course, but they generally leave wide scope for interpretation and for discretion. If the title 'ethics committee' were to prove persistently misleading in the ways discussed above, then policy-makers might consider less misleading titles. One candidate might be 'independent review committee'.

If policy should not authorise ethics committees to treat legal issues regarding applicant action as relevant to their opinion, should it nevertheless authorise them to make separate *comment* to applicants on such matters? This would permit potentially helpful advice to applicants, without complicating formation of their *opinion* of applicant action. But would ethics committees be able to sustain the long-term practice of both commenting on these matters, and always also treating them as irrelevant to formation of their overall opinion? This issue will here be left open.

4. Third Party Action

The main parties to ethics committee review are researcher applicants and ethics committees. Should public policy authorise ethics committees to consider legal issues regarding the actions of *third parties*, such as research participants, research sponsors, and public registries of health information? Consider this argument that it *should*. It is unethical for any researcher to invite any third party to perform an unlawful act. Therefore, ethics committees *should* be authorised to

assess this matter, and this would indirectly require them to consider the lawfulness of any third party response to such an invitation.

The above argument depends on the implicit claim that ethics committees should be authorised to consider *all* matters that bear on the ethics of proposals before them. As was argued in the previous section, however, this key claim is mistaken. The argument that depends on it consequently fails.

Consider now the case against ethics committee authorisation to concern itself with third party legal issues. Several points can be made here.

Where an ethics committee opinion itself bears on the lawfulness of third party action, the committee cannot coherently bring that same legal consideration to bear on formation of its own opinion. A New Zealand example is that 'if required', ethics committee approval is a pre-condition, under Health Information Privacy Code (HIPC) Rule 11(2)(c)(iii), of *lawful* third party release of health information to researchers. Ethics committees cannot coherently bring that same legal provision to bear on their approval or otherwise of such information release.

Here is an argument with wider scope. Policy should authorise ethics committees to apply established *ethical* standards to their *applicants'* proposed actions. Assessment of *third party* action, by research participants, research sponsors, public registries, or others, is not directly relevant to this core business. Furthermore, if it is inappropriate for policy to authorise ethics committees to consider legal issues regarding applicant action, and it is, then one might reasonably conclude that such authorisation regarding third parties is inappropriate too. This is especially clear where the third party is a *public body*, such as a public registry that is asked by observational researchers to release personal health information. These bodies are publicly accountable for the lawfulness of their own actions in response to such requests. If a second set of public bodies, the ethics committees, were *also* publicly authorised to consider the matter, that would generate potential for confusion, controversy, and inefficient use of public resources.

The general reasons against ethics committee consideration of legal issues in applicant action apply also to third party action. Such an authorisation would come at major opportunity cost to ethics committees' core business, it would place them and their parent public bodies at increased legal risk, and none of this would serve any clear public interest.

One complexity should nevertheless be noted. Policy should authorise ethics committees to protect research participants against harm, and to give some priority to this. Since any researcher invitation to a participant to perform an unlawful act risks significant harm to that participant, this authorisation will also include protection of participants against 'legal harm'. No *separate* authorisation is needed, however, for ethics committees to consider legal issues regarding participant actions.

This section has examined whether policy should authorise ethics committees to consider legal issues regarding *third party* responses to its applicants' actions. It has argued that the answer is 'no', though their 'participant protection' authorisation will include protection against the 'legal harm' of unlawful research participation.

5. Conclusion

This paper has argued that policy should authorise ethics committees to consider legal issues regarding their own actions, but should not authorise them to consider legal issues regarding the actions of their applicants or of third parties.

More generally, policy should clarify what is within, and what is beyond, authorised ethics committee powers with regard to legal issues. Current New Zealand policy is especially deficient in this respect. It has been the responsibility of the Ministry of Health to develop policy a little further in this area, by informing ethics committees that 'the interpretation of legislation relating to personal privacy is for the agency holding the patient's data to decide' (Duffy *et al*, 2001, p.259). Even if fully implemented, however, this policy does not address matters other than privacy, or aspects of the law other than legislation. It also does not tell ethics committees whether or not they may make such an agency's 'favourable legal opinion' a condition of their own favourable opinion. Further improvements to policy here will be of much assistance to researchers and ethics committees. One possible vehicle for this would be the development of a wider 'research governance' framework, broadly along the lines of the one recently developed for the National Health Service in the United Kingdom (Department of Health, 2001).

Acknowledgement

I am grateful to Janet McLean, Tim Mulgan, Charlotte Paul, Martin Wilkinson, two referees for this journal, and the members of NEAC; and to participants in the Philosophy Department Seminar at the University of Otago, the Australasian Bioethics Association Conference in Queenstown in July 2003, and the National Health and Medical Research Council Conference on Research Ethics in Canberra in April 2003, for their helpful comments on earlier drafts of this paper.

Disclaimer

Andrew Moore is Chair of the National Ethics Advisory Committee (NEAC) and a member of the Data and Safety Monitoring Board (DSMB), a committee appointed by the Health Research Council of New Zealand to monitor conduct of clinical trials. The views expressed in this paper are not necessarily those of either NEAC or the DSMB.

References

COREC (Central Office for Research Ethics Committees) (2001). *Governance Arrangements for NHS Research Ethics Committees*, London, July 2001.

Dawson, J. and Peart, N. (2003). *The Law of Research: a guide*. Dunedin: Otago University Press.

Department of Health (2001). *Research Governance Framework for Health and Social Care*, London, March 2001. Available at: www.doh.govt.uk/research

Duffy, A., Barrett, D. and Duggan, M. (2001). *Report of the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region*. Wellington, New Zealand.

European Union (2001). *Directive 2001/20/EC of the European Parliament and of the Council (2001) on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*.

HART (2003). New Zealand House of Representatives, *Human Assisted Reproductive Technology Supplementary Order Paper*, Wellington, New Zealand.

HRC (Health Research Council of New Zealand) (2002). Health research and privacy – guidance notes for health researchers and ethics committees, reprinted in *Guidelines on Ethics in Health Research*. Auckland, New Zealand.

Hurka, T. (1993). *Perfectionism*. Oxford: Oxford University Press.

Kant, I. *Groundwork of the Metaphysic of Morals*.

MOH (Ministry of Health) (2002). *Operational Standard for Ethics Committees*. Wellington, New Zealand.

NHMRC (National Health and Medical Research Council) (1999). *National Statement on Ethical Conduct in Research Involving Humans*. Canberra, Australia.

Slote, M. (2001). *Morals from Motives*, New York: Oxford University Press.