

The job of 'ethics committees'

Andrew Moore, Andrew Donnelly

Correspondence to

Dr Andrew Moore, Department of Philosophy, University of Otago, PO Box 56, Dunedin 9054, New Zealand; andrew.moore@otago.ac.nz

Received 5 March 2015

Revised 22 September 2015

Accepted 21 October 2015

Published Online First

13 November 2015

ABSTRACT

What should authorities establish as the job of ethics committees and review boards? Two answers are: (1) review of proposals for consistency with the duly established and applicable code and (2) review of proposals for ethical acceptability. The present paper argues that these two jobs come apart in principle and in practice. On grounds of practicality, publicity and separation of powers, it argues that the relevant authorities do better to establish code-consistency review and not ethics-consistency review. It also rebuts bad code and independence arguments for the opposite view. It then argues that authorities at present variously specify both code-consistency and ethics-consistency jobs, but most are also unclear on this issue. The paper then argues that they should reform the job of review boards and ethics committees, by clearly establishing code-consistency review and disestablishing ethics-consistency review, and through related reform of the basic orientation, focus, name, and expertise profile of these bodies and their actions.

INTRODUCTION

Committees or boards in many countries are directed to review, and in light of this to approve or decline, activities such as health research and assisted reproduction. British-influenced countries tend to call these 'ethics committees', and US-influenced countries tend to call them 'Institutional Review Boards'. The present paper calls them 'review boards'. Given that relevant authorities do establish review boards, it asks: "What job is it best that they establish for these boards?" and it responds with comparative assessment of two answers:

1. code-consistency review of proposals for consistency with the applicable code
2. ethics-consistency review of proposals for ethical acceptability.

'Code-consistency review' and 'Ethics-consistency review' describe each potential job in turn. 'Relations between the two sorts of review' argues that the two are distinct in principle and practice. 'Combining code-consistency and ethics-consistency review' identifies different ways in which authorities could establish combinations of code-consistency and ethics-consistency review and argues that each is problematical. 'Arguments for code-consistency review' argues that in respect of practicality, publicity and separation of powers, they would do better to establish code-consistency review and not ethics-consistency review. 'Arguments for ethics-consistency review' rebuts bad code and independence arguments for the opposite conclusion. 'The current job descriptions' examines what currently guidance has established and concludes that it is at best unclear on this

point. 'Risks of ethics-consistency thinking' outlines some risks of code-consistency thinking. 'Reform' argues for reform of committees and boards, to establish code-consistency review and to disestablish ethics-consistency review, and to reform the orientation, name, membership and training of these bodies and the nature of the actions they perform.

CODE-CONSISTENCY REVIEW

The code of a review board includes any applicable statute or case law, and any administrative law that applies directly or indirectly by applying to its parent body. If the relevant legal system is sufficiently developed, the board's code will thereby include applicable due process and other natural justice standards, and principles that apply to any decision it makes in conditions of apparent inconsistency or indeterminacy of code content. Its code also includes any duly issued Terms of Reference, Standard Operating Procedures and other applicable directions and guidance. Such code elements typically also reiterate administrative law standards.

A review board that conducts code-consistency review approves proposals when and because doing so is code-consistent and declines them when and because approving them would be code-inconsistent. In usual cases, the relevant authority establishes a code that specifies which activities are within the board's power to review, which features of those activities it is to consider at review, any features of those activities that are excluded from its review consideration and the process and timing of its review actions. Code-consistency review settles each of these matters as and because the applicable code so directs. If code provisions conflict or leave the matter indeterminate, code-consistency review pursues the best code-based resolution. It also communicates to its applicant both its code-consistency decision and the code considerations that make this decision apt.

Many tribunals, licensing boards and similar bodies deal frequently with apparent conflict among code provisions and with apparent indeterminacy in overall code implications. Any review board that conducts code-consistency review is a relevantly similar body. Administrative law addresses such settings through principles that include 'to resolve code conflicts, let the more specific provision prevail', 'to give effect to the code-centrality of individual freedom, let action be permitted unless the code determinately rules it out' and 'disallow any act that would be repugnant to reasonable people'.¹ Conflict and indeterminacy can also arise among such decision principles. Code-consistency review then exercises overall



- ▶ <http://dx.doi.org/10.1136/medethics-2015-103183>
- ▶ <http://dx.doi.org/10.1136/medethics-2015-103343>
- ▶ <http://dx.doi.org/10.1136/medethics-2015-103345>
- ▶ <http://dx.doi.org/10.1136/medethics-2016-103870>
- ▶ <http://dx.doi.org/10.1136/medethics-2017-104342>



To cite: Moore A, Donnelly A. *J Med Ethics* 2018;**44**:481–487.

judgement, based on the purpose or direction or tendency of the code itself.

If a board's code-consistency review appears to generate a repellent decision and this still seems unavoidable on careful re-examination, it takes advice from experienced practitioners and might in the end also pursue code reform with relevant authorities. If such measures still fail to secure any code-consistent pathway to a non-repellent review decision, code-consistency reviewers must either come to think their code-consistency decision is conscionable after all, despite its unpalatable nature in this case, or resign from their review role on grounds that they cannot here conscionably perform it. If they instead make a code-inconsistent decision, they cease to conduct code-consistency review and instead conduct some other sort of review.

ETHICS-CONSISTENCY REVIEW

Ethics concerns what matters, and in the light of this, how best to act and live. The ethical state of things is often not transparently clear to or agreed by all, and human ethical thought and response are always fallible and potentially improvable. These claims about ethics are relied on below. More controversial claims about ethics are not relied on below, such as Benjamin Sachs's realist meta-ethical claim (p. 5) that the point of ethical judgement is that it 'accurately reflects the ethical truth'.²

A review board that conducts ethics-consistency review approves proposals when and because the activities proposed are ethically acceptable, and it declines them when and because they are ethically unacceptable. In usual cases, the relevant authority has established its account of which activities are to be reviewed, which aspects of these are or are not to be considered and which are the grounds on which to approve or decline them. Ethics-consistency review interprets all such code statements as attempts to express the best ethical wisdom so far achieved and thus as presumptive ethical guides. This makes code-consistency and code-inconsistency important first approximations, when considering: Are these proposed activities apt for our review? Which parts of our code apply, and with what implications? Do code provisions conflict here, or leave matters indeterminate? Which resolution of any such matters best expresses the code itself? Yet all such first approximations are only as good as the fallible and always potentially improvable human ethical thought they express and codify. The bottom line is that if the code-consistency standard implies a proposed activity is apt for approval, yet best ethical judgement implies it is instead apt to be declined, ethics-consistency review declines it on ethics-inconsistency grounds. Similarly, if the code-consistency standard implies that a proposed activity is apt to be declined, but best ethical judgement implies it is instead apt for approval, ethics-consistency review approves it on ethics-consistency grounds. Comprehensive application of such review settles every matter in this way, including which activities are to be reviewed, which features of theirs are versus are not to be considered, which review process is apt, and what makes these activities apt to be approved or declined.

RELATIONS BETWEEN THE TWO SORTS OF REVIEW

Code-consistency review and ethics-consistency review are presented in idealised form above. The present section examines relations between them.

It is possible for an act of research or other reviewable activity to be required by the applicable review code, but not be ethically required; to be ethically unacceptable, but allowed by the code; to be ethically acceptable, yet disallowed by the code; or

to be ethically required, but not code-required. The thought that these cases are possible is also presupposed by all parties to debate about whether the relevant code does or does not match the ethics of the case, should or should not be reformed, is or is not ethically appropriate, is or is not an 'ass' in this respect and so forth. The next three paragraphs present cases.

An applicable code for review of research might specify that all personally identifiable data must be destroyed 10 years after research completion, but such destruction might or might not be ethically required. The code might not require that research worth and research risk be considered together, yet doing so might be ethically required because this is the only principled way to avoid the implausible conclusion that all research is unethical because it has greater-than-zero risk. Having non-vicious character might be ethically required of everyone, including researchers, yet not be required by the research review code. The Helsinki Declaration might have ruled out the research use of placebo in certain circumstances, yet the Federal Drug Administration might have rightly judged in 2008 that some placebo uses in such circumstances are ethically acceptable. Each of the above examples is potentially controversial, because ethical judgement in general is fallible and always potentially improvable. In each example above, one reasonable view is expressed on an open ethical question, and that question is distinct from any matter of what any applicable code implies about its issue.

In New Zealand in the early 2000s, the Ministry of Health's code for ethics committees stated at p. 134 that there is to be multicommitee review only for: 'Research conducted simultaneously by several investigators at different centres'.³ Investigators proposed to conduct, from just the one centre in Dunedin, a study involving access to national cervical screening data. Ethics committees insisted that review of this proposal instead be by multiple committees.⁴ This action of theirs was code-inconsistent. But it is possible in principle that multicommitee review might nevertheless have better captured relevant local ethical considerations, and thereby have been the only ethically acceptable review process. If that were so, code-consistency review here would allow only single-committee review process, but ethics-consistency review would allow only multicommitee review. This shows that code-consistency decisions can oppose ethics-consistency decisions.

Now consider code-specified limitation on review actions, a category highlighted by McGuinness at pp. 696–7.⁵ In such cases, a code might direct review boards not to take a view on certain aspects of the activities it reviews. For example, the UK's code⁶ states: "It is not the role of the REC to offer a legal opinion on research proposals" (paragraph 3.2.11). Though any research ethics committee (REC) offer of such an opinion is code-inconsistent, there could in principle nevertheless be circumstances in which its doing so would be ethically permissible and thus ethics-consistent.

One possible case in which code-consistency review and ethics-consistency review would make opposing determinations is enough to show that these are two different jobs. Each of the various cases above delivers this. Even when code-consistency review and ethics-consistency review make identical review determinations, they are rival accounts of what makes proposals apt to be approved or declined at review.

COMBINING CODE-CONSISTENCY AND ETHICS-CONSISTENCY REVIEW

The previous section showed that code-consistency review and ethics-consistency review differ even when they make identical

determinations and that they can also make opposing review determinations. 'Arguments for code-consistency review' and 'Arguments for ethics-consistency review' examine which of these sorts of review authorities would do better to establish. The present section examines whether any combination of the two is better than either 'pure' approach.

Authorities that take a 'both required' approach combine ethics-consistency and code-consistency review by requiring each and by making these jointly sufficient for proposal approval to be apt. This approach has all the troubles of its component parts examined in the next two sections. Further difficulty for it arises from the fact that when code and ethics conflict, no proposal can meet its 'both required' standard. For example, if ethics-consistency requires lawfulness of proposed activities to be considered, but code-consistency requires this not to be considered, no consistent approach at all is possible. Similarly, if ethics consistency requires multicommittee review, but code consistency requires sole-committee review, every review process is ruled out. These things make the 'both required' approach problematical at best.

Authorities that take an 'each is enough' approach combine ethics-consistency and code-consistency review by making each sufficient for proposal approval to be apt and by requiring at least one of these conditions to be met. This approach too has all the troubles of its components. A further trouble of its own arises from the need also to specify what makes proposals apt to be declined. For the 'each is enough' approach, it is natural to make code inconsistency and ethics inconsistency each separately sufficient for this. But that generates inconsistent review decisions about any proposal that is code-consistent yet ethics-inconsistent or that is ethics-consistent yet code-inconsistent. 'Relations between the two sorts of review' showed that such cases are possible. These things make the 'each is enough' approach problematical at best.

Authorities could direct boards to treat code-consistency and ethics-consistency as one and the same. But as 'Relations between the two sorts of review' showed, they are instead distinct and potentially opposed, and this undermines any 'treat them as one' approach. One conventionalist or institutionalist ethical theory claims that being ethically acceptable just is being allowed by duly established code. One natural law theory claims that genuine law or code on any matter just is the ethics of that matter. But these potential rationales for a 'treat them as one' approach are each controversial, and each is inconsistent with credible rival theories. In short, this approach is problematical.

Authorities could direct boards to interpret all code references to ethical acceptability as merely descriptive references to what is widely thought ethically acceptable, and direct them also to treat the code itself as authoritative about what is widely thought ethically acceptable. This in effect establishes code-consistency review, by directing review boards to treat any ethical content as reducible to code content. It has the code prevail whenever proposed activity is either code-consistent, but ethically unacceptable; or code-inconsistent, but ethically acceptable. It is not a distinct approach. It is also a misleading and confusing approach because the fallibility and potential improbability of all human ethical thought means it is always possible that what is widely thought ethically acceptable is actually not ethically acceptable.

Authorities could establish code-consistency review, while also allowing or directing boards to conduct their review and decision processes through ethical thinking. A possible rationale is that the code-consistency target might be better hit through this indirect route than through any direct route. This idea parallels

Bales' thought⁷ that even if right action is utility maximisation, common-sense thought and decision through rules of thumb might hit this utilitarian mark or target better than any utility-focused thought and decision does. This distinction, between what something is and what sort of thought and decision best produces it, is widely applicable. The perfect butterfly swimmer's stroke might be a complex hydro-dynamic matter, for example, but the swimmer's thought process that best produces it might instead focus just on letting 'muscle memory' and relaxed intensity do the job. The present paper is about whether authorities should establish code-consistency review or instead ethics-consistency review. To that question, the approach under present consideration just answers 'code-consistency review', so it is not a distinct option. Different and partly empirical questions that merit examination elsewhere are whether a code-consistency target is actually best hit through ethical thought and decision, and whether an ethics-consistency target is best hit through 'code consistency' thought and decision.

This section has reviewed 'both required' and 'each is enough' ways to combine ethics-consistency and code-consistency review. Both are problematical. It has also canvassed other ideas, but on the core matter in present focus, each reduces to code-consistency review and consequently presents no distinct option.

ARGUMENTS FOR CODE-CONSISTENCY REVIEW

The arguments of the previous section imply that code-consistency review and ethics-consistency review are the best two options. The present section assumes authorities have the power to establish either of them. It argues that in three respects, authorities do best to establish code-consistency review and disestablish ethics-consistency review. None of these three factors presupposes nor rejects any general ethical theory, such as consequentialism, virtue theory or contractualism. By contrast, Sachs's recent work on related topics² depends on consequentialist appeal just to the effects of policy on the protection and promotion of interests.

Practicality

According to the practicality argument: (1) an authority's establishment of some particular form of review is better in one respect if it is more practical, and (2) code-consistency review is more practical than ethics-consistency review, so (3) an authority's establishment of code-consistency review is better in this respect.

Practicality's 'can know' elements include a board's being readily able to know what the applicable review standards are, to which matters they apply, how to apply them, and which proposals can reasonably be found at review to be consistent or inconsistent with them. Practicality's 'can do' aspects involve a board being able to perform the related review actions.

In support of premise (1) above, if establishment of one review job better enables a board to discern and thereby perform 'approval' and 'decline' actions when and just when each is apt, that is the better policy-making act in the practicality respect.

In support of premise (2) above, some code content can be known for sure, and one's understanding of it is not improvable; but the corresponding content of ethics can rarely be known for sure, and human understanding of every ethical matter is improvable in principle. For example, it can be known for sure that one New Zealand code matter in 2002³ was that multicommittee review was to be only for: 'Research conducted simultaneously by several investigators at different centres'

(p. 134). But it is less clear that this is the only sort of case in which multiple local reviews would be ethically better. Similarly, one can know for sure that one matter of UK code⁶ is that: 'It is not the role of the REC to offer a legal opinion on research proposals' (paragraph 3.2.11), but it is less clear that REC offer of such a legal opinion would never be ethically best. The possibility of such code/ethics mismatches is enough for purposes of the practicality argument. It need not take any position on the larger jurisprudential and philosophical issues, such as whether law or code can 'run out' or be thus indeterminate and thus indiscernible or whether all administrative or judicial thinking must appeal to ethical thinking.

The reasonable conclusion to draw from the practicality argument is that policy makers do better in this respect if they establish code-consistency review and not ethics-consistency review.

Publicity

Here is the publicity argument: (1) policy-maker establishment of a form of review is better in the publicity respect if its review standards can more fully be made accessible in advance, and (2) code-consistency review standards can more fully be made accessible in advance, so (3) policy-maker establishment of code-consistency review is better in this publicity respect.

Premise (1) above is an application of a widely accepted general thesis, articulated by Fuller⁸ at pp. 38–39, about the process and content of law in general, including 'soft law' code matters established under due legal authority. Its core ethical idea is that as far as is reasonably practicable, makers of law and codes should specify its content such that this can be accessible to those potentially subject to it, thereby also letting them know the standards their actions would be judged against.

In support of premise (2) above, more of the content of code-consistency review standards than of ethics-consistency review standards can be made available in advance. On the accessibility of code-consistency standards, see the previous section. By contrast, even if the best ethical thinking to date could be identified and made available in advance, this might still fail to state how things are ethically, because all human ethical thought is fallible and improvable in principle. Any ethics-consistency review board must consequently be empowered to improve the fallible and improvable best current account of ethics-consistency standards and of what they imply about cases. This makes fully reliable prior promulgation of any ethics-consistency review standard infeasible, whereas doing so is feasible for at least some code-consistency review standards.

The reasonable conclusion to draw from the publicity argument is that policy makers do better in this respect if they establish code-consistency review and not ethics-consistency review.

Separation of powers

The separation-of-powers argument states: (1) power in relation to people is exercised better *pro tanto* (ie, 'as far as that goes') if exercised through institutional arrangements that separate code-making powers and decisional powers, and (2) review board review exercises power in relation to people, so (3) such institutional separation is better *pro tanto* in arrangements for such review and (4) this is feasible for code-consistency review but not for ethics-consistency review, so: (5) code-consistency review is better *pro tanto* in this respect.

Premise (1) is a widely accepted design principle for institutions that exercise power in relation to people,⁹ premise (2) is uncontroversial and premise (3) then follows. With the addition of premise (4), the conclusion (5) also follows. Here is a justification of premise (4). If code-consistency review is established,

one institution can make and revise the review standards, and another can review proposals for consistency with these. But if ethics-consistency review is instead established, then no matter who established any prespecified review standards, the review decision maker must be empowered at review to revise those standards when this would make for an ethical improvement. This is because any understanding of ethics-consistency standards themselves and of their implications for any case is fallible and improvable in principle. Authorities' establishment of code-consistency review and not ethics-consistency review is consequently better *pro tanto* in this respect.

The reasonable conclusion to draw from the present section is that in practicability, publicity and separation-of-powers respects, authorities do best if they establish code-consistency review and disestablish any ethics-consistency review, including disestablishing any code that itself allows conduct of ethics-consistency review.

ARGUMENTS FOR ETHICS-CONSISTENCY REVIEW

This section rebuts the two best arguments known to the present authors for the thesis that authorities would do best to establish ethics-consistency review and not code-consistency review.

Bad code

Here is the bad-code argument: (1) it is better *pro tanto* that authorities establish a form of review that does not approve unethical activities and do not establish any form of review that approves unethical activities, (2) if code content is sufficiently bad, code-consistency review approves unethical activities, but ethics-consistency review does not, so (3) if code content is sufficiently bad, it is better *pro tanto* that authorities establish ethics-consistency review and not code-consistency review.

Clarke¹⁰ makes roughly the bad-code argument at his p. 46 and illustrates it with a code that does not require subjects' consent to research but does allow harm to them.

As its name and content admit, the bad-code argument only applies when code content is sufficiently bad. This very substantially limits its scope. If recast as an argument with universal scope, it would then face 'hard cases make bad policy' and 'bad jurisdictions make poor international policy' replies. The bad-code argument also appears to 'prove' too much by generalising to the conclusion that all licensing boards, administrative tribunals and their kin are best established to conduct ethics-consistency review and not code-consistency review. These issues are not pursued further here.

Premise (2) above mistakenly claims that code-consistency review is to be conducted even when it would generate unconscionable review decisions. This mistake makes the bad-code argument unsound. As is outlined in 'Code-consistency review' above, the matter is instead as follows. If a board's code-consistency review appears to generate a repellent decision, it should carefully re-examine this. If a repellent decision still seems unavoidable, it should take advice from experienced practitioners and other wise informants. If this too fails to secure any code-consistent and non-repellent path, the board should alert the relevant authorities and pursue code reform with them. If even this fails to secure any code-consistent and non-repellent pathway, code-consistency reviewers have two options. They can come to think their code-consistency decision is conscionable after all, despite its unpalatable nature in this case, or they can resign from their review role on grounds that they cannot here conscionably perform it. Code-consistency review disallows approval of any proposal that is code-inconsistent and

disallows a 'decline' decision on any proposal that is code-consistent; but these fundamentals leave open the option of refusal to reach any review decision in such cases, ultimately at the cost of resignation.

In summary, 'bad code' considerations do not support establishment of ethics-consistency review over code-consistency review.

Independence

Consider Sayers¹¹ at p. 41, 'If ethics committees were told how to think, their opinions would no longer be independent—they would be implementing a state-driven agenda'. We need instead their 'independent opinion on whether a research proposal is ethical, that opinion needs to be independent of ... the state'.

Here is a more formal presentation of the independence argument: (1) reviewer independence is better than its lack, (2) ethics-consistency review is independent, because here ethics content is reviewer judged and (3) code-consistency review lacks independence because here code content is judged by policy-makers and not reviewers, so: (4) ethics-consistency review is better in this respect.

The independence argument is ambiguous, and when clarified in either of the two obvious ways, it is also unsound. On one interpretation, its premises (1) to (3) refer just to review's independence from the study's applicant, sponsor and funder. Such independence does desirably reduce potential for conflict between the needs of disinterested review, and applicant and sponsor and funder interest in the activity's proceeding as proposed. Thus interpreted, however, the argument is unsound because its premise (3) is false. This is because independence from the study's applicant, sponsor and funder can also be specified in a review code and implemented in code-consistency review. On the obvious alternative interpretation, premises (1) to (3) refer also to review's independence from any duly established code. Thus interpreted, the first premise of the argument simply asserts the superiority of ethics-consistency review, but that simply begs the central question at issue, which concerns the merit or otherwise of exactly this sort of independence. The independence argument thus fails to identify any respect in which authorities would do better to establish ethics-consistency review rather than code-consistency review.

The present section has rebutted the best two arguments known to the present authors for the claim that authorities should establish ethics-consistency review and not code-consistency review.

THE CURRENT JOB DESCRIPTIONS

'Arguments for code-consistency review' concludes that authorities do better in three respects if they establish code-consistency review and disestablish any ethics-consistency review. 'Arguments for ethics-consistency review' concludes that neither of the best arguments for the opposite conclusion succeeds. The present section examines the implications of current guidance and commentary.

Current WHO guidance¹² states the following, respectively, in its preamble to Chapter III and its Standard 7.

The primary task of an REC [i.e. research ethics committee] is the ethical review of research proposals ... based on the *ethical acceptability* of the research [italics in original]

The REC bases its decision about research that it reviews on a coherent and consistent application of the ethical principles articulated in international guidance documents and human

rights instruments, as well as any national laws or policies consistent with those principles.

The first WHO quotation endorses ethics-consistency review for ethical acceptability. The second quotation is less clear. On one interpretation, it endorses code-consistency review for consistency with itself and certain other international guidance documents and human rights instruments and law. A rival interpretation is that it instead again endorses the 'both needed' combination of code-consistency and ethics-consistency review, for consistency with itself only when its provisions actually do capture the ethics of the matter at review. This second interpretation is perhaps less plausible because it attributes to the WHO document a modesty that is at odds with the fact that it also purports to give itself priority over national law or policy whenever they conflict with it.

In its paragraph 1.1.1, UK guidance⁶ states:

A research ethics committee is ... to assess formally if the research is ethical

A research ethics committee is ... to review research proposals ... the research must conform to recognised ethical standards.

The first UK quotation endorses ethics-consistency review. The second is less clear. One interpretation is that it endorses code-consistency review; another is that it instead endorses the 'both needed' form of combined review.

At paragraphs 5.2.21 and 5.2.29, respectively, Australia's national guidance¹³ about the nature of review states:

A review body may approve, request amendment of, or reject a research proposal on ethical grounds.

Decisions by an HREC about whether a research proposal meets the requirements of this National Statement...

The first Australian quotation endorses ethics-consistency review, and the second instead endorses code-consistency review. The overall document does not give any clear direction as to how these two matters are related.

Further guidance statements are quoted below. The first endorses code-consistency review, the second seems ambiguous between code-consistency review and the 'both needed' combination view, the next three endorse ethics-consistency review and Singapore's statement endorses the 'both needed' combination.

This committee must ... not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration (paragraph 23)¹⁴

HDECs check that proposed health and disability research meets established ethical standards that aim to protect participants. These ethical standards are set out in guidelines authored by the National Ethics Advisory Committee (p. 6)¹⁵

All proposals ... must be submitted for review of their scientific merit and ethical acceptability to one or more scientific review and ethical review committees. (Guideline 2)¹⁶

ethics committees should ... assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings (Article 19)¹⁷

Institutions shall establish or appoint REB(s) to review the ethical acceptability of all research involving humans (Article 6.1)¹⁸

An IRB has a duty to ensure that all Human Biomedical Research carried out under the auspices of its appointing institution are ethically acceptable, and to comply with the principles outlined in Section IV (paragraph 5.20)¹⁹

The following published commentaries all endorse ethics-consistency review.

One role of research ethics committees (RECs) is to assess the ethics of proposed health research (p. 732)²⁰

Research ethics committees (RECs) are charged with providing an opinion on whether research proposals are ethical (p. 39)¹¹

the moral restraints ... upon clinical research ... RECs [are] to make sure that these restraints are understood and observed (pp. 4–5) Ethical review of research is inherently and by definition a moral concern” (p. 159)²¹

judgement over what research is considered ethical (p. 410)²²

Independent ethical review ... can assure potential research participants that the study they are considering is ethical ... [and] of a study’s compliance with ethical requirements (p. 130)²³

Let us sum up. Several guidance statements and published commentaries endorse just ethics-consistency review. A few endorse code-consistency review. Others appear to endorse the ‘both needed’ combination of code-consistency and ethics-consistency review, but they are not clear about this. ‘Relations between the two sorts of review’ above also shows that there are at least two significantly different ‘combination’ positions. On the whole, the guidance documents scanned above lack the desirable feature of clarity on this core issue. Those responsible would make these documents better if they were to make them clearer on this central point.

RISKS OF ETHICS-CONSISTENCY THINKING

This section identifies three significant risks of ethics-consistency thinking and contrasts these with those of code-consistency thinking.

One risk of ethics-consistency thinking is that it invites the idea that ethics-consistency reviewers are answerable only to higher masters than, or at least to factors independent of, democratically elected governments. This self-exceptionalist orientation is problematical if taken by or on behalf of any board that is empowered through democratic modes of authority. Sayers¹¹ expresses this orientation at p. 41: ‘If ethics committees were told how to think, their opinions would no longer be independent—they would be implementing a state-driven agenda’. The Declaration of Helsinki¹⁴ at paragraph 10 is an influential expression of similar ethos: ‘No national or international ethical, regulatory or legal requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration’. Similarly, WHO states¹² in its Standard 7: ‘The REC bases its decision about research that it reviews on ... the ethical principles in international guidance documents and human rights instruments, as well as any national laws or policies consistent with those principles’. The World Medical Association and WHO statements each assert their own independent force or priority over the government laws and policies that would otherwise have priority. Each is also difficult to justify if review is best understood just as code-consistency review. A further expression of self-exceptionalist orientation on behalf of review boards is the extensive published literature on issues of the form ‘What should ethics committees do about X?’ that proceeds without any reference to what these bodies have been duly directed to do by the authorities that establish them. The risks here outlined are distinctive of ethics-consistency thinking and of the related self-exceptionalist orientation to or on behalf of review boards.

A further risk of ethics-consistency thinking arises from the fact that all human ethical thought is fallible and potentially improvable. This makes reliable and stable ethics-consistency thinking difficult to perform in practice and difficult for reviewers and others to assess in terms of performance quality. Due to the relative inscrutability of ethical considerations, ethics-consistency review would tend in practice to drift into the fundamentally different but epistemically easier practice of treating the say-so of boards as being what makes reviewed activities ethically acceptable or unacceptable. Instead of treating boards as answerable to ethical standards, this treats ethical standards as answerable to boards. If framed as ethics-consistency review, such practice in effect treats review as a ‘Simon says’ matter, and ‘ethics committees’ as the all-powerful ‘Simon’ figures, whose say-so makes it so. This would both aggrandise ‘ethics committees’ and diminish ethics. By contrast, on a code-consistency orientation, it is hard to escape the more sober thought that boards are answerable to their codes and the codes are not answerable to the boards.

Ethics-consistency thinking will tend to run together the matter of which factors are apt to be considered at review with the matter of which issues are ‘ethical issues’. On related topics, see also McGuinness⁵ at p. 695 and Hunter.²⁴ Focus will tend to accrue to such questions as: Is the lawfulness of a proposed activity an ethical issue? Is the scientific quality of a proposal an ethical issue? Principled answers to such questions are difficult to give, unless one appeals to some controversial and reasonably rejectable conception of ethics while also rejecting other such conceptions. It is undesirable for policy about review boards to put itself about in such controversial territory. One conception associated with Aristotle and Mill is that the moral or ethical sphere includes all normative and reason-giving factors in the practical domain. A rival conception that some associate with Kant is that the moral sphere is instead a special but incomplete subset of the much larger practical domain. If one instead adopts a code-consistency orientation, one simply considers which issues need to be addressed and what administrative arrangements would do this best, with no need for any ethically controversial reference to which are the ‘ethical’ issues and which are not.

REFORM

The present paper argues that there are practicality, publicity and separation-of-powers respects in which authorities would do best to establish code-consistency review and to disestablish any ethics-consistency review, and it argues that the best two arguments for the opposite view each fail. If these arguments withstand peer scrutiny, then they also identify some good reasons for authorities to make the reforms that the next paragraph sketches. The last paragraph scouts out wider issues.

If authorities should establish code-consistency review and should disestablish any ethics-consistency review, then they also have some good reason to name or to re-name the relevant bodies ‘review boards’ and not ‘ethics committees’. In addition, it would be useful for this name to refer to the activity at review, for example, ‘research review board’. Authorities also have some good reason to name: the core activity here ‘research review’ or the like and not ‘ethical review of research’, the guidance about the activity that is at review ‘research guidelines’ and not ‘ethical guidelines for research’ and the provisions in such guidance ‘research conduct principles’ and not ‘ethical principles for research’. The point here is to name matters for the nature that they are best given, and consequently to drop all ethics-centred names. Review of boards’ expertise profile would

also be apt. Any code-consistency reviewer needs expertise in the applicable code. Insofar as it depends on the mistaken claim that authorities should establish ethics-consistency review, the idea that specialist ethical expertise is a core board need is mistaken. Still, such expertise might have other good purposes, such as to alert reviewers to their impending mistake whenever they are tempted to make an ethics-consistency review decision, and perhaps to provide one perspective on which code-consistency review decisions would be unconscionable.

One reply to the above is that review boards and their actions merit the 'ethics' brand, because ethical considerations informed the genesis of these boards and express their aspirations. But ethics is present also in the genesis and aspirations of many and diverse institutions, without giving its misleading name to them: the United Nations, free and compulsory public education, social welfare provision, host responsibility in the serving of alcohol, environmental protection bodies, rules of war and so on.

Central themes in the present paper extend further. Can decisions reached at code-consistency review be correct or incorrect, due to there being facts of this matter? Should authorities make provision for appeal from review decisions, as is generally appropriate for kindred entities, such as administrative tribunals and licensing boards? Could code-consistency review allow that two or more divergent, but reasonable decisions are possible in some cases? Even if code-consistency review is the best job to give boards, should they be given any job? Wider still: can the present paper's arguments convincingly generalise to the conclusion that professions worldwide act with hubris whenever their statements purport to determine ethical standards for their members rather than to determine merely professional code and practice standards? All these good questions must await another day.

Acknowledgements Our thanks to Angela Ballantyne, John Dawson, Paul Formosa, Grant Gillett, Mike King, Mianna Lotz, Catriona Mackenzie, John McMillan, Tim Mulgan, Charlotte Paul, Nicola Peart, Peter Skegg, Kandy White and Martin Wilkinson, for their comments; and audiences at the University of Otago (in various settings), Victoria University of Wellington, University of Tokyo, and Macquarie University, for their questions and challenges.

Contributors The large majority of writing work on the present paper is by AJM, including all of the 'revise and re-submit' work. Six or so years ago, AD drafted an ancestor of the present paper, which briefly discussed the basis of ethics committee review but heavily focused instead on whether appeal from the findings of such review should be established. AD also commented on multiple previous drafts of the present paper, and identified various references for it too. AJM has since comprehensively re-written the paper, and has then done so again to 'revise and re-submit'.

Competing interests AJM was previously a member of ethics committees at university, regional and national levels. The present paper discusses committees of

this sort. AJM was also previously Chair of New Zealand's National Ethics Advisory Committee (NEAC). Some NEAC work is discussed in the present paper.

Provenance and peer review Commissioned; externally peer reviewed.

REFERENCES

- 1 Wade W, Forsyth C. *Administrative law*. 11th edn. Oxford: Oxford University Press, 2011.
- 2 Sachs B. The case for evidence-based rulemaking in human subjects research. *Am J Bioeth* 2010;10(6):3–13.
- 3 Ministry of Health. *Operational standard for ethics committees*. Wellington, 2002.
- 4 Davidson J, Dawson J, Moore A. Law, Ethics and Epidemiology: The Case of the Cervical Screening Audit. *NZ Bioeth J* 2001;2:8–26.
- 5 McGuinness S. Research ethics committees: the role of ethics in a regulatory authority. *J Med Ethics* 2008;34:695–700.
- 6 Department of Health. *Governance arrangements for NHS research ethics committees: a harmonised edition*. London, 2011.
- 7 Bales R. Act-utilitarianism: account of right-making characteristic or decision-making procedure? *Am Philos Q* 1971;8:257–65.
- 8 Fuller L. *The morality of law*. New Haven, CT: Yale University Press, 1964.
- 9 Vile M. *Constitutionalism and the separation of powers*. New York: Oxford University Press, 1967.
- 10 Clarke S. Two models of ethics committees. *J Bioeth Inq* 2005;2(1):41–7.
- 11 Sayers G. Should research ethics committees be told how to think? *J Med Ethics* 2007;33:39–42.
- 12 World Health Organisation. *Standards and operational guidance for ethics review of health-related research with human participants*. Geneva, 2011.
- 13 National Health and Medical Research Council, Australian Research Council, Universities Australia. Australian Government, Canberra: National Statement on Ethical Conduct in Human Research, 2007.
- 14 World Medical Association. *Declaration of Helsinki: ethical principles for medical research involving human subjects*. 1964/2013.
- 15 Ministry of Health. *Standard operating procedures for health and disability ethics committees*. Wellington, 2012.
- 16 Council for International Organisations of Medical Sciences. *International ethical guidelines for biomedical research involving human subjects*. Geneva, 2002.
- 17 United Nations Educational, Social and Cultural Organization. *Universal declaration on bioethics and human rights*. Geneva, 2005.
- 18 Canadian Institutes of Health Research. *Natural sciences and engineering council of Canada, social sciences and humanities research council of Canada*. Ottawa: Ethical Conduct for Research Involving Humans, 2010.
- 19 Bioethics Advisory Committee. *Research involving human subjects: guidelines for IRBs*. Singapore, 2004.
- 20 Douglas T. Ethics committees and the legality of research. *J Med Ethics* 2007;33:732–6.
- 21 Evans D, Evans M. *A decent proposal: ethical review of clinical research*. John Wiley and Sons, 1996.
- 22 Edwards S, Ashcroft R, Kirchin S. Research ethics committees: difference and moral judgement. *Bioethics* 2004;18(5):408–27.
- 23 Emanuel E, Wendler D, Grady C. An ethical framework for biomedical research. In: Emanuel E, Grady C, Crouch R, et al., eds. *The Oxford textbook of clinical research ethics*. New York: Oxford University Press, 2008:123–35.
- 24 Hunter D. Proportional ethical review and the identification of ethical issues. *J Med Ethics* 2007;33:214–45.