*Note: This is the author’s post-print version of an article published in the Journal of Medical Ethics (Online First in 2016). The final publication is available via BMJ at* [*http://dx.doi.org/10.1136/medethics-2015-103345*](http://dx.doi.org/10.1136/medethics-2015-103345) *. It is one of a series of commentaries on Moore and Donnelly, “The job of ethics committees”, also currently Online First at JME.*

Code-consistent ethics review: Defence of a hybrid account

G. Owen Schaefer

Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore

 It is generally unquestioned that human subjects research review boards should assess the ethical acceptability of protocols. It says so right on the tin, after all: they are explicitly called research *ethics* committees in the UK. But it is precisely those sorts of unchallenged assumptions that should, from time to time, be assessed and critiqued, in case they are in fact unfounded. John Stuart Mill’s objection to suppressers of dissent is instructive here: “If the opinion is right, they are deprived of the opportunity of exchanging error for truth: if wrong, they lose, what is almost as great a benefit, the clearer perception and livelier impression of truth, produced by its collision with error.”[[1]](#endnote-1)

Andrew Moore and Andrew Donnelly’s compelling article, “The job of ‘ethics committees’”, is just this sort of challenge to conventional wisdom, a rejection of the notion that review boards should be considering ethical matters at all.[[2]](#endnote-2) If true, we should be substantially reforming our research ethics policies. And if false, rebuttals would help strengthen and ground the otherwise-unquestioned assumption of the role of ethics committees. As it happens, I will argue that their critiques fall into the second category. While mistaken, they present a valuable opportunity to clarify the role of ethics committees and their relationship to relevant codes. In particular, I will defend a hybrid account where codes (those with regulatory force, in particular) have strict primacy, but leave significant room for review boards to make ethical judgments concerning a protocol’s acceptability.

**A hybrid account**

Moore and Donnelly argue that review boards should be solely focused on ‘code-consistency’, rejecting both purely ‘ethics-consistency’ approaches and mixed approaches where review committees assess both ethical acceptability and consistency with codes. However, I propose an alternative sort of hybrid account that does not fall prey to their critiques, and offers significant advantages over the code-consistency approach. This proposal will focus on research ethics review. Moore and Donnelly’s article is broader in scope, but I believe the arguments will apply mutatis mutandis to other forms of ethics review.

I would submit that research ethics review boards should treat relevant codes as hard side-constraints on the ethical acceptability of protocols. This means that, when they conflict, codes should take primacy over committees’ ethical judgments. But codes are (and should be) typically designed to delineate when a protocol must be rejected, not when it must be approved.

As a result, this approach avoids Moore and Donnelly’s objection that hybrid approaches lead to irresolvable conflicts. Conflicts will only emerge when the code requires rejection (or emendation) of a protocol, but in the ethical judgment of a committee member it should be approved. This approach resolves the conflict by taking codes as ‘trumping’ the variable ethical judgments of committee members and requiring that the protocol be rejected accordingly. However, in a case where the code does not require rejection, but committee members believe it to be unethical, there is no actual conflict – since codes do not generally require approval, ethics boards can consistently reject the protocol. Similar things can be said when there are ethics and code conflicts concerning appropriate review procedures – codified procedures should be implemented, but when the codes do not prohibit or require certain procedures, ethical considerations may be determinative.

**Avoiding objections**

Moore and Donnelly object to hybrid approaches based on both the general flaws of ‘ethics-consistency’ approaches and the particular problem of inconsistencies between codes and ethics that, they claim, make hybrid approaches untenable. I have already noted how the above approach does not actually generate inconsistencies, and will now turn to how it mitigates the further flaws of pure ethical approaches while providing further advantages of its own.

By requiring subservience to the content of codes, the hybrid approach can maintain practicality, publicity, and separation of powers that Moore and Donnelly find lacking in ‘ethics-consistency’ approaches. A solid backbone of ethical requirements for research gives committees clear requirements and standards for how to review. The approach is public insofar as the codified requirements are explicitly delineated, and ethical discretion is itself codified by explicit delegation of judgment in particular areas; this gives researchers an adequate guide on how to design their protocols for ethical acceptability. And it maintains separation of powers by disallowing ethics committees from overriding codified requirements.

 Moore and Donnelly are further concerned that ‘ethics-consistency’ approaches make ethics committees unanswerable to the state, encourages authoritarian deference to committee decisions and lead to confusions over scope. Again, the hybrid approach maintains subservience to the state’s required codes. It also involves no greater deference to authority than a pure ‘code-consistency’ approach: ‘code-consistency’ approaches risk researchers mixing up consistency with the code and ethical acceptability, just as one might mix up an ethics committee’s decision and ethical acceptability. As for scope questions – the dangers of inconsistent interpretations of what is within the scope of ethics committees’ purview can be met by stricter guidance on how ethics committees should structure their ethical judgment. A clear way to avoid appeal to controversial moral theories is to require appeal to overlapping consensus, as promoted by the Belmont Report.[[3]](#endnote-3)

**Further advantages of the hybrid approach**

Beyond meeting these objections, the hybrid approach has particular advantages over a ‘code-consistency’ approach that strongly militate in its favour.

The most pressing reason to adopt the hybrid approach is that blanket rules are too insensitive to contextual considerations to make for reliable guidance without the intervention of ethical judgments. Assessing whether a risk-benefit ratio is favourable, a payment arrangement is exploitative, a waiver of consent would adversely affect the rights of a participant, what information is germane to consent – these all require ethical assessment of features particular to the protocol and subject population that will vary from case to case. Codes should delineate particular requirements in such domains, but it is impossible for them to account for each and every contingency. Review committee discretion is necessary to account for these nuances and contextual variations.

The hybrid approach is also safer than a purely code-based approach. Because the hybrid approach requires both code-consistency and ethical acceptability, it holds researchers to a higher ethical standard than code-consistency alone. This higher standard should mean that fewer unethical research practices will take place.

Finally, the hybrid approach is conservative – it does not require major revisions to Moore and Donnelly propose, as it is more or less a defence of current practice. Reforms are costly to design and implement, as committees need to become retrained and reconstituted and researchers adapt to a new framework. In addition, Moore and Donnelly overlook the extent to which changes will need to be made to codes themselves to adapt to their reforms - the significant discretion given to ethics committees at various points in codes would have to be stamped out, and likely all relevant codes substantially rewritten.

Taken together, these considerations give us strong reason to prefer a hybrid approach to either the ‘code-consistency’ or ‘ethics-consistency’ approaches. We should leave room for review boards to make ethical judgments, as the whole point of research ethics codes in the first place is to ensure that research is conducted ethically. But those judgments should be strictly subservient to the thoroughgoing requirements of duly-constituted codes, to ensure clarity of standards and consistency of review.

1. Mill J. S. On liberty. (E. Alexander, Ed.). Peterborough, Ont.: Broadview Press. 1869/1999. [↑](#endnote-ref-1)
2. Moore A, Donnelly A J, The job of ‘ethics committees’. J Med Ethics, Online First. 2015. [↑](#endnote-ref-2)
3. The Belmont Report: Ethical Guidelines for the Protection of Human Subjects. Washington, DC: Department of Health, Education and Welfare. 1979. [↑](#endnote-ref-3)