

Research Exceptionalism – Responses to Open Peer Commentaries

By David Hunter & James Wilson

We would like to thank the commentators for their helpful and useful commentaries on our paper, and the editors for this opportunity to respond to their criticisms and clarify the position we are defending. We do not have the space or scope to respond to the comments in the depth many of them deserve, so we have gathered them into groups of comments which we will respond to as blocks.

Criticisms of the current systems of research regulation

Several commentators such as Schab, McCullough, Moffat, Potter & Bean seem to broadly accept the argument we make justifying some regulation of research but recognising – as we acknowledge in Research Exceptionalism – that a general defence of *regulating research* doesn't equate to a defence of how we *currently regulate research* attack how research is presently regulated – accusing it of being over-regulation or disproportional or an inappropriately one size fits all approach. (Wilson & Hunter, 2010) (Schab, 2010) (McCullough, 2010) (Moffat, 2010) (Potter, 2010) (Bean, 2010) Nothing in our paper speaks to these issues – We weren't defending any particular version of research governance – except perhaps broadly the use of committees to regulate research. Once we have identified a good justification for research to be regulated then the further question to be resolved is how are we best to do this?

However we do want to suggest two notes of caution in regards to these moves to improve present systems of research regulation. The first is a warning about proportionality – which is commonly suggested as the cure for the present woes of researchers facing ethical review systems, and presently being trialled by the National Research Ethics System in England. (Hunter, 2007) The idea of proportionality – that the level of scrutiny ought to be proportional to the level of risk posed by the research is seductive however as one of us has argued elsewhere these seductive characteristics might well be illusory. (Hunter, 2007) This is because of the epistemic difficulties in establishing the level of risk (broadly construed) posed by a research project. We argued given ethical uncertainty and the inherent uncertainty of research, that ethics committees were better placed than researchers to make more accurate all things considered ethical judgements about projects – and it seems likewise they might be better placed to make judgements about the risks posed by research, than researchers or small groups. Hence the epistemic requirements of a good system of proportional review might make it too unwieldy to yield improvements.

The second caution is that there is a lack of proportion in regards to the evidence for over-regulation. It is relatively simple to point to evidence for over-regulation you simply show that an individual project which was low risk and high benefit was significantly delayed by inappropriate regulatory burden – it is much harder to prove that regulation was appropriate since as Bean points out “it is difficult to empirically verify counterfactuals such as the prevention of an adverse event or required amendment to an otherwise scientifically unsound study”. (Bean, 2010) There is a further difficulty with the available evidence which makes it difficult to know how to improve the present system – given the lack of agreement about an over-arching ethical framework there is uncertainty about the correctness of ethical judgements. (Hunter, 2010) This makes it difficult to tell if a change has improved or unimproved the regulatory system.

Neither of these cautions means we oughtn't modify existing systems – they just mean we ought to approach this cautiously with an eye to what evidence there is, and how strong that evidence is.

Treating different research differently

Miller and other commentators such as McCullough suggest that a limitation of the approach taken

in the paper is that it treats research as a whole rather than looking at whether specific types of research is regulated appropriately. (Miller, 2010) (McCullough, 2010) We focused on research as a whole since it seemed to us that first you needed an over-arching justification for research before looking at specific examples. However we have a few comments to make on this subject.

Firstly it doesn't straightforwardly follow from our argument that there are likely to be distinctions between types of research since on our argument research ethics review is derived from the researchers responsibility & researchers in all areas are still researchers. (Wilson & Hunter, 2010) However if such an argument was going to be constructed it would seem likely to be based on the claim that the strongest duty researchers have towards research subjects is to protect them from wrongs - then it would need to be established that these harms are considerably more likely to occur in some research areas than others. This would support in effect the principle of proportionality in review – where the level of scrutiny reflects the level of risk run by the research. We are sceptical about the efficacy of this, without running into the epistemic problems that proportionality in review faces as we outlined above. The two main schemes for doing this which we know of in practice are sorting research either (as in the US) by the institution hosting the research or by topic area (as in the UK). (Hunter, 2008) Neither of these seem likely to directly map onto the level of risk poised – in the US case it is hard to see how specific institutions such as universities are likely to be conducting more risky research than private companies, likewise in the UK while some medical research is highly risky much of it is not and not all non-medical research is innocuous. So while there is scope for exploration here, we are sceptical – especially because exceptions tend to create perverse incentives for the redescription of projects.

The Arguments

Both Wilkinson & Hansson address the overall argument of the paper suggesting that we do not in the end argue for research exceptionalism – Hansson in particular makes a useful distinction between substantive and procedural exceptionalism which he characterises in this way:

- (1) *The substantial issue*: Should the demands on potentially harmful activities, such as risk limitation and informed consent, be higher if these activities are part of research than what they would otherwise have been?
- (2) *The procedural issue*: Should decisions on potentially harmful activities be made in more intrusive and/or more formal ways in research than in non-research settings?

Claiming that we argue for procedural but not substantive exceptionalism – which on the whole we agree with, the argument we offered to defend the regulation of research is primarily procedural in nature. (Hansson, 2010) (Wilkinson, 2010) Hansson makes the further point, which we agree with as well that we might want to look at some non-research activities to see if they ought to be regulated in a similar fashion.

The argument from aims

John points out that the existence of indirect benefits weakens the argument for the aims of the research. (John, 2010) We don't disagree (one reason we described this as a weak – though still positive – argument for research exceptionalism) however we would like to point out we were primarily pointing towards the motivations and perceptions of the researcher in this section – in a sense making a version of the shall not judge in your own case principle that Wilkinson alludes to. (Wilkinson, 2010)

Wilkinson likewise critiques this argument pointing out that it is only compelling when the research imposes risk – again we concur, however as with the argument for proportionality the means of

determining whether research is risky are uncertain and arguably without full committee review we are unlikely to have a reliable indicator of the risks. (Wilkinson, 2010) (Hunter, 2007)

The argument from trust

Both Wilkinson & John point out that many activities are dependent on public trust and, as we argued, that the evidence connecting research ethics committees to the protection of public trust in research is scanty. (Wilkinson, 2010) (John, 2010) Again we tend to agree – although we think there is some merit in this argument, without further research and evidence it is difficult to support it. (Wilson & Hunter, 2010) The existence of other activities requiring public trust doesn't necessarily undermine the public trust argument for regulation however – since it may well be the case that these activities either are regulated or ought to be regulated. What would be needed to wield the public trust argument effectively for the present sorts of regulation in research would be a combination of evidence for the effectiveness & necessity of regulation for maintaining public trust – and some support for this particular system in terms of creating, repairing or maintaining public trust.

The argument from uncertainty

John raises an ingenious objection to the third argument we offer – namely that of an analogy between the recruitment techniques of organised religion & research. (John, 2010) We don't have the scope to deal with this objection in full however broadly we think there are sufficient disanalogies to enable us to resist the illiberal conclusion that John sets out.

Firstly the recruitment activities, practices & aims of particular religions don't vary nearly as much as those of researchers – this diversity in practices (and thus potential outcomes) in part underwrites the argument from uncertainty in the case of research. Secondly while we support independent oversight we think that a useful distinction can be drawn here, between independence from the practitioner and independence from the institution. We doubt any church would want to have no oversight mechanisms for regulating how their priests recruit parishioners – even if they would strongly resist institutionally independent oversight. Given the more limited range of activities this might well be all the regulation that is required.

Wilkinson argues that we neglect the strongest argument for regulation “the shall not judge ones own case principle”. (Wilkinson, 2010) We agree this is important (it underwrites the argument from aims & blocks the notion of self regulation) however it presupposes that there is a case to be judged – in most cases even where activities potentially pose significant harms to other (such as driving) we generally decide for ourselves. At best this is a supplementary reason for supporting research exceptionalism – given that it supports the notion that researchers will do a bad job of deciding for themselves.

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