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## “More what you’d call guidelines”

In a notorious scene from *Pirates of the Caribbean: The Curse of the Black Pearl*, Captain Barbarossa refers to the Pirate’s Code cynically as ‘what you’d call guidelines’ suggesting that conformity is merely a matter of choice:

*Elizabeth: Wait! You have to take me to shore. According to the Code of the Order of the Brethren...*

*Captain Barbarossa: First, your return to shore was not part of our negotiations nor our agreement so I must do nothing. And secondly, you must be a pirate for the Pirate's Code to apply and you're not. And thirdly, the Code is more what you'd call 'guidelines' than actual rules. Welcome aboard the Black Pearl, Miss Turner.*



Recently, some evidence has emerged that the same observation could be made about another set of guidelines, namely, those relating to the ethics review and conduct of human research in Australia: the National Statement on Ethical Conduct in Human Research issued by the National Health and Medical Research Council, the Australian Research Council and Universities Australia in 2007 and modified to the current version of May 2015. These guidelines set out the principles and processes for ethics review by human research ethics committees (HRECs) and conduct of research in which people are participants. The guidelines also set out requirements for the establishment, membership and operation of HRECs and assign obligations to institutions to see that these are followed. Since 2001, the NHMRC has established and maintained a register on which institutions list their HRECs and agree to operate them according to the National Statement.

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## Hints for Using Worked Examples in Training Sessions

Training sessions for new ethics committee members and new researchers frequently use a completed application as a fully-

First of all a frank acknowledgement by the AHRECS team – In the past we've merrily used invented applications/vignettes,

worked example of how to practically implement legislation, codes, and administrative processes. There is now a solid body of scientific findings that can guide the effective use of worked examples in promoting learning and its generalisation to new situations.<sup>1</sup> Based on these findings, here are three evidence-based hints:

(1) Walk trainees through at least two completed ethics applications for related projects.

According to the available research, a single example will

most likely cause new committee members to see it as an ideal exemplar that all applications must conform to. Similarly, new researchers will tend to see a single example as an ideal template. They may try to squeeze all their information into that template even if it metaphorically means pounding square pegs into round holes. Enabling trainees to study, compare, and contrast two or worked examples dramatically increases understanding of the underlying principles and, more importantly, the ability to see analogies between the examples and new applications.<sup>2</sup>

(2) The initial worked examples should be correct, particularly for new members and researchers who are not yet familiar with the legislation, codes, and administrative processes. As familiarity increases, test cases with deficiencies can then be introduced for study and facilitated discussion.

(3) The projects described in initial examples should be relatively simple while still being authentic. Then, as understanding and skill increases, more complex worked examples and test cases can be introduced.<sup>4</sup>

sometimes with deliberately inserted defects, and de-identified real proposals (with permission) in the professional development activities we've facilitated. We did so as a way to help research ethics reviewers and researchers (but reviewers made up the overwhelming majority of these workshops) to spot mistakes and in doing so demonstrating they understood an ethical principle or a specific provision of a statement/code/policy. At the time we might even have congratulated ourselves on providing a real world practical activity rather than merely telling attendees what they should do...

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## **NHMRC – Invitation to provide feedback to inform a review of Section 4 of the National Statement on Ethical Conduct in Human**

## Research

The **National Statement on Ethical Conduct in Human Research** (2007, updated May 2015) (National Statement) consists of a series of guidelines made in accordance with the National Health and Medical Research Council Act 1992. It promotes ethical human research and is intended for use by researchers, ethics review bodies, research administrators and potential research participants. The National Statement is developed jointly by the National Health and Medical Research Council, the Australian Research Council and Universities Australia.

The National Statement is revised according to a 'rolling review' approach. This means that sections of the National Statement are revised as needed, rather than revising the document all at once. Section 3 has recently been revised and its release is anticipated in mid-2018. Section 4 of the National Statement: Ethical considerations specific to participants is the next section to be reviewed.

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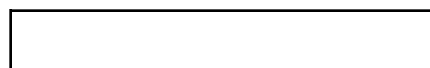
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