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CASE STUDIES

Managing Conflicts of Interest Should Begin with Dialogue and Education, Not Punitive Measures

Comment on "Toward a Sociology of Conflict of Interest in Medical Research" by Sarah Winch and Michael Sinnott

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The case study presented by Winch and Sinnott (2011) shows not only how difficult it is for clinicians and researchers to identify conflicts of interest (COI), but also how damaging it can be when there are uninformed and uncoordinated policy responses by senior administrators. The final decision by the Chief Probity Officer (CPO) proves that he lacked experience in ethical decision making, as he incorrectly weighed the harms associated with a real and apparent COI on the part of Dr. B and his technology company against the benefits of the technology for improving clinician safety and medical practice. Further, the CPO was clearly working on the assumption that the only means of managing COI was recusal; no other means of reducing the potential harm—that is, bias and lack of objectivity in the clinical studies and a subsequent loss of patient or public confidence in Dr. B and/or his technology—were envisaged. Finally, an apparent unwillingness to engage in dialogue with the Research Ethics Committee (REC) or the clinician-researcher shows an authoritarian approach on the part of the CPO that gives the message that Dr. B is engaging in misconduct because "COI is simply bad, by definition"! This approach should make one wonder whether the actual goal of the CPO's report was not the appropriate management of COI, but instead the avoidance of potential scandal and so preservation of institutional reputation (Williams-Jones 2011).

This case also highlights the problems that arise when there is a widespread lack of understanding by institutional entities—namely the Research Governance Officer (RGO), the CPO, and the REC—and clinician-researchers of what constitutes COI and how these should be managed effectively. Dr. B and the REC were most likely operating in good faith, but with an incomplete understanding of the nature and scope of the COI—which was both real and apparent—and the risks posed for trust and confidence. By deciding there was no actual COI and by not checking with other relevant institutional agents for advice (i.e., the RGO), the REC missed an important opportunity to learn about the U.S. Institute of Medicine's (Lo and Field 2009) recently revised definition of COI and so improve its review of Dr. B's project. To make matters worse, the RGO, after communicating with Dr. B, did not confer with the REC

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and instead passed the matter on directly to the CPO. By doing an "end-run" around the REC, the RGO undermined the autonomy of the REC and made it less likely there could be a moderate and nuanced response that would deal appropriately with the associated risks. The result is a potentially damaging loss of trust by all parties involved, namely the REC, the RGO/CPO, and Dr. B. The CPO and the RGO clearly do not trust the REC to determine whether the COI is one that could be managed, nor that Dr. B could monitor his own behaviour in dealing with the COI. The REC would be quite reasonable in feeling that its autonomy as a review body was being undermined, that there was a COI with the CPO, and so lose interest, even trust, in its institution's governance. Finally, Dr. B would have reinforced the all-too-prevalent view that research ethics is just a bureaucratic process that impedes research; and so any knowledge transfer or technology innovation would have to be done elsewhere, at another institution.

This case points, above all, to a general problem at the institutional level. That is, if Dr. B is unable to detect that he is in a COI, the REC does not see the problem, and the CPO sees only one solution, it is likely due to the fact that the institution has not put into place appropriate educational tools and oversight policies to help its staff recognise and identify COI so COIs can be avoided where possible and otherwise managed appropriately. Is there an institutional COI policy or institutional COI guidelines that would have helped Dr. B and the REC (1) better analyse the possibility of COI resulting from Dr. B owning a spin-off company and (2) plan appropriate mechanisms to mitigate associated risks? Had such a policy been associated with regular institution-wide awareness development activities and the promotion of relevant educational tools, it is much more likely the REC would have been able to work with Dr. B to better understand the nature of the COI and so arrive at a productive means of managing the situation, without the heavy-handed intervention of the CPO. Instead, Dr. B is left with a punitive judgment that does not help him move forward with his innovation in a manner that is both ethically appropriate and helpful for improving clinical practice … a loss for Dr. B, his colleagues, and the institution.

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